VACCINES AGAINST VICE

A CONSTRUCTIVE TECHNOLOGY ASSESSMENT OF IMMUNOTHERAPIES FOR ADDICTION

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ABSTRACT

This thesis examines the development of active immunotherapies or 'vaccines' for drug addiction, within the framework of constructive technology assessment. Drawing on post-structuralist and Foucauldian critiques of medicine and constructivism derived from Science and Technology Studies it explores how addiction has come to be understood and regulated in the twenty first century in the different socio-political contexts of the UK and the US. It argues that vaccines for addiction can be seen to combine 'old' and 'new' modes of biopolitics in a flexible way, representing neither the abdication of sovereign power nor a simple continuation of the well-known biopolitical strategies of advanced liberal democracies. Part I of the thesis assesses the role of the technology as a form of anatomo-politics aimed at disciplining and normalising the individual addicted body through voluntary and coerced treatment. Part II looks at the role of prophylactic vaccination as a form of biopolitics of the population and the ways in which technologies of domination are internalised and reproduced by individuals in the context of their parental role as guardians of their children's future health and happiness.

The study is a comparative UK/ US qualitative research design, focusing on two case studies of an illegal drug (cocaine) and a legal drug (nicotine). 31 interviews were conducted in the UK and the US with key actor groups involved in the development, and potential regulation and deployment of the vaccines, and 8 focus groups with potential users in the UK. The data analysis examines the discursive construction of addiction by these groups in order to guide empirically grounded interpretations of the potential benefits and drawbacks of the use of the technology in different settings. It also considers how lay participants in the UK respond to, or challenge, the dominant clinical gaze both as active participants in the medicalisation of addiction and as sites of potential resistance. This thesis challenges the notion of the neo-liberal individual which underpins the dominant discourses of biomedicine and bioethics. It is argued that the dualism of autonomy and subjugation marginalises the subjective experiences of the patient. Specifically, it suggests that the construction of the vaccines as life-long and 100% effective directs political attention away from the benefits of harm reduction whilst also excluding alternate technologies of the self from consideration. It concludes that there is a need to widen debate in order to develop a more integrated approach to drug use and addiction.

Keywords: STS, social construction of technology; sociology of knowledge; medicalisation of addiction; biopolitics; sociology of bioethics; comparative policy; immunotherapy.

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AUTHOR'S DECLARATION

This thesis has been submitted to the University of York, UK, to fulfil the requirements for a PhD Degree in Sociology. The candidate confirms that the work presented is entirely the author's own original work and that appropriate credit has been given where reference has been made to the work of others. The data has been collected by the author and has not been published or presented elsewhere.

1. FACTS ARE NOT BROUGHT BY STORKS: CONSTRUCTING THE SOCIAL PROBLEM OF ADDICTION

'Almost every psychoactive drug known to humanity, from alcohol to opium, has been regarded by some government and society as a dire threat to public order and moral standards, and by another government and another society as a source of harmless pleasure. Further, nations and governments sometimes change their views completely.'

British Medical Association, 'Living with Risk' (1987, p58).

1.1. INTRODUCTION: THE PATHOLOGY OF 'L.M.F.'

I am an addict. As I sit at my desk pouring over this thesis I want a cigarette, but since my partner would shift uncomfortably if any smoke wisped his way in order to satiate my desire I now have to go downstairs, outside, alone. I am on the back foot and can't challenge my partner to justify why his preference should usurp mine, in the way I might with other household affairs, since my choice is no longer regarded as a mere social nuisance. Rather, on the basis of mounting scientific evidence that passive smoking increases the risk of lung cancer in non-smokers (cf. Taylor, Najafi and Dobson, 2007) the debate has taken on the form of rights and duties. It has become incumbent upon me to bow to his legally constituted 'right' as a non-smoker to be protected from the involuntary inhalation of my smoke. This evidence has extended beyond our private sphere to become enshrined in UK law, where since the 1st July 2007 smoking has been banned in all enclosed and substantially enclosed public spaces (DH, 2006).

In sharing this anecdote I realise that statistically I am not likely to invoke compassion from the reader, but rather a nod of approval at my own, and other smokers', exile. But this is not a story of my personal struggles; rather, within it is a telling account of how the social acceptability of smoking has changed over the years and the construction of passive smoking as a scientific fact (Jackson, 1995). At the end of WWII smoking was not only acceptable to the dominant ideology, but desirable, perhaps even necessary in some subcultures (Cottrell, 2004). That is probably well understood, but less commonplace may be that the 'cancer sticks' of the twentieth century were the 'coffin nails' of the nineteenth (Engs, 2003, p71) and that the turn of that century saw a complete ban on cigarette smoking in 14 American states (Nuehring and Markle, 1974). Indeed since the arrival of tobacco into Europe with the return of Christopher Columbus from his first voyage to the New World in 1492, smoking has persistently caused controversy (Pollard, 2004). In 1604 James I of England published his *Counterblaste to Tobacco,* declaring smoking 'a custom loathsome to the eye, hateful to the nose, harmful to the brain, dangerous to the lungs, and in the black, stinking fume thereof nearest resembling the horrible Stygian smoke of the pit that is

bottomless' (in Hilton, 2000, p24). But his contemporary, Robert Burton's 'tobacco, divine, rare, superexcellent tobacco, which goes far beyond all panaceas, potable gold and philosopher's stone, a sovereign remedy to all diseases' (in Hilton, 2000, p32) would continue to gain popularity in both the US and Britain until the late-twentieth century.

The legitimated story continues that in the early 1950s scientists discovered the causative link between smoking and a litany of diseases, and that with the landmark release of the 1964 US Surgeon General's report, '*Smoking and Health'*, the reality of the harmful effects of smoking has led to its gradual demise in an arguably rational-calculating public. Those of us who continue to smoke against the ever growing body of research that announces it is detrimental to our health are now said to be suffering from addiction, characterised as a chronic relapsing brain disease with neurobiological changes that lead to compulsion to take a drug with loss of control over intake (Kosten, 1998; Koob, 2000; Leshner, 1997, 2001; Nutt, 1997). This loss of control, which is the hallmark of the medical model of addiction, demands that my opening admonition be treated not with disdain but rather that I should be helped to overcome my 'illness' (Gusfield, 1967). This shift from a predominantly moral to a medical construction of addiction is evident in an article titled '*Federal Approach to Drug Addicts Represents a Change of Emphasis: Rehabilitation and Research Added to Law Enforcement'* which ran in the Ohio newspaper *The Toledo Blade* on the 11th July, 1971 (Woods, 1971). Juxtaposing approaches to drug addiction in the visual form of two photos symbolising 'Punishment' and 'Psychiatric Social Work', the article discussed the possibility of a new approach to drug rehabilitation through the creation of methadone maintenance clinics in the context of the problems faced by the estimated 40,000 military personnel who had become addicted to heroin while in Vietnam. The article also proposed the need for vaccines for heroin addiction, 'in much the same fashion as the public is now immunized against German measles, diphtheria and other infectious diseases' (p2). Dr Bertram of the US National Institutes for Mental Health, NIMH, was reported as saying a 'far-out' possibility was to link heroin, or another opiate, with a protein to develop a vaccine against heroin addiction, and called for more funding to be directed towards federal drug abuse research.

Four decades later there has been much progress with the technicalities of the vaccines, but the underlying tension as to questions of voluntarism and free will in differing constructions of addiction is still very much in the picture. Although the shorthand *L.M.F.* may no longer appear in the private notes of psychiatrists, the belief that an addict is somewhat 'Lacking in Moral Fibre', a term originally introduced by the RAF in the 1940s to deter aircrew from reporting sick or refusing to fly, continues to colour public and political perception (Jones, 2006). Indeed, it has been argued that the attempt to separate 'Will' from 'Desire' has never been entirely successful (Hickman, 2004; May, 2001; Valverde, 1998). The view remains that if I desired to cease my

pursuit enough, my volition could assert itself, affirmed by the recently enacted coercive legislation aimed at decreasing rates of smoking alongside limiting the detrimental effects of passive smoking. Consequently, the idiopathic status of the modern addict still hovers between that of sick and sinning, and I take my pathology and retreat outdoors.

1.2. THE SOCIO-POLITICAL CONTEXT AND VISIONS OF THE FUTURE

Now in the late stages of clinical development, a nicotine vaccine is set to hit the market within two years, likely closely followed by one for cocaine addiction. Their arrival will come at a time of interesting political and economic pressures, when national budget deficits in the UK and the US are placing increasing demands on the public purse and the need to make savings wherever possible are an accepted, if controversial, reality.

In the UK, the coalition government's first official drug strategy (HO, 2010) has marked a shift away from the language of 'harm reduction' and places more responsibility on individuals to seek help and overcome their dependency. However, the new government shelved plans for an abstinence-based drugs strategy, which would have placed strict time limits on drug substitute treatments, such as the heroin substitute methadone, which had been called for by the National Treatment Agency, NTA, a National Health Service, NHS, special health authority set up in 2001 to improve the availability, capacity and effectiveness of drug treatment services. The coalition has also opposed the implementation of the Welfare Reform Drug Recovery Pilot schemes proposed by the previous Labour government under the Welfare Reform Bill 2009 (DWP, 2009). This would have seen some welfare benefits dependent on the claimant undergoing drug treatment, and allowed Jobcentre Plus advisers to refer claimants to mandatory Substance Related Assessments, SRAs, and impose mandatory rehabilitation plans.

But other changes are afoot. Following on from the public health White Paper *Healthy Lives, Healthy People* (DH, 2010a) and the Department of Health's *Arms Length Bodies Review* (DH, 2010b) the NTA will be abolished, with its key functions transferred to a newly created Public Health England, in 2012, which will also bear responsibility for reducing smoking. Funding services primarily aimed at prevention rather than treatment, the PHS will transfer responsibility from Primary Care Trust's to local authorities, who will receive 'health premium' incentive payments for progress based on a public health outcomes framework. The core elements of the proposed system are set out in the controversial *Health and Social Care Bill 2011* (DH, 2011) currently before parliament. Reflective perhaps of the Conservative ideology of rolling back the state in

favour of the 'Big Society', combined with funding constraints, the NHS is in for a major overhaul said to be second only to its creation in 1948. Although the public health White Paper emphasises the importance of addressing the wider determinants of ill health, the effects of these changes to public health policy have yet to be seen.

In the context of the war on drugs in the US, since the 1990s the Office of National Drug Control Policy, ONDCP, has reflected the shift to a medical construction of addiction, recasting drug users not so much as 'the enemy' but rather as victims suffering from the 'disease' of drug use who desperately need treatment (ONDCP, 2003). However, with no universal system of healthcare coverage, and more than 50 million people uninsured in 2009 out of a total population of 300 million and millions more under-insured, there are vast discrepancies between states in terms of access to treatment (USCB, 2010). Where treatment is available, critics have argued that the influence of the Alcoholics Anonymous, AA, lobby and the ascendency of the associated 12-step model of recovery has led to predominantly abstinence-oriented treatment approaches, which have fettered innovation, precluded early intervention and limited treatment (Tournier, 1979). Further, the rise in the number of referrals to drug treatment through the criminal justice system has prompted questions as to the ability of the US system to meet the complex demands of patients and the agencies that refer to it (McLellan, Carise and Kleber, 2003).

With the inauguration of Barack Obama on January 20, 2009, reform of the American healthcare system rose to the top of the domestic agenda. Although there are some government funded programmes, such as the federally operated Medicare and the jointly federal-state funded Medicaid, which extend some level of provision to the over-65s and those on low incomes respectively, the escalating costs of supporting these schemes is one of the biggest contributing factors to the spiralling US budget deficit. The inadequacy of the overall system can be argued to be reflected in the 62% of all bankruptcies of which illness and medical bills are contributing factors, where three quarters of the medically bankrupt held insurance (Himmelstein and Woolhandler, 2010). Amidst deep objections from the political right, Congress passed the *Affordable Care Act* in March 2010, which put in place comprehensive health insurance reforms that would hold insurance companies more accountable (HR, 111-1, 2010). It sought to extend coverage to more than 32 million uninsured people and make it illegal for insurance companies to deny coverage to customers with pre-existing conditions or drop beneficiaries if they became sick. However, spurred on by November 2010's mid-term congressional elections, which saw a Republican majority in the House of Representatives, objections to the health care reforms from both Republicans and the American public have deepened. In January 2011, the House of Representatives passed the '*Repealing the Job-Killing Health Care Law Act*' (HR, 2-EH, 2011) introduced by Republican members. Although at this point, in early 2011, the Democrats hold a

Senate majority and can block a move to overturn health care reform, the future of health care reforms in America have become deeply uncertain before they are even fully implemented.

This then is a brief overview of the socio-political context in the UK and the US into which the vaccine technology will arrive in the coming years. Although developed in clinical trials with currently addicted adult populations for relapse prevention, the script contained within their materiality directs the answers to normative questions around their deployment (Verbeek, 2006). As the moniker suggests, media reports of so-called 'vaccines against vice' (cf. Boyce, 2003) builds public and political expectations that their use can, and should, be directed to large-scale cohorts of children by analogy to other childhood immunisations. As Brown, Rappert and Webster (2000) have argued, such expectations present particular framings of the future and help shape this future by enrolling actors and mobilising resources, impacting on the likely success or failure of the technology. Indeed, the development of vaccines, or immunotherapies, for addiction has already initiated substantial political interest and was the subject of the previous round of the UK Government's Office for Science and Technology national-level Foresight program, created in response to the 1993 White Paper, *Realising our Potential* (CO, 1993) with the aim of increasing the UK's exploitation of science. With the broad aim of identifying potential opportunities for the economy or society from new science and technologies, and how future science and technologies could address key future challenges for society, the Brain Science, Addiction and Drugs Project, BSAD, was launched on the 13th July 2005 to explore how scientific and technological advancement may impact on the understanding of addiction and drug use over the next 20 years. Including a report on the ethical aspects of developments in neuroscience and drug addiction by Ashcroft, Campbell and Capps (2005), the project also conducted a public consultation exercise, carried out in order to inform the question set by the BSAD: 'How can we manage the use of psychoactive substances in the future to best advantage for the individual, the community and society?'. The consultation was carried out as a series of focus groups, workshops and a one-day forum exploring trade-offs and preferences with a total of 87 participants taken from the general public, those with or caring for children with Attention Deficit Hyperactivity Disorder, ADHD, young people from school years 9-13, and 3 users of illicit psychoactive substances (Beddoes and Rudat, 2005).

Alongside other developments in neuroscience and pharmacology, such as the use of mental health drugs, mood-altering drugs and cognition enhancers, participants were asked to consider the potential use of vaccines for addiction, using 'scenarios of the future' set in 2025. In the first, '*Getting the Results',* smoking is illegal, and parents are asked to get their 18 month old child vaccinated against nicotine after he tests positive for a genetic predisposition to nicotine addiction (OST, 2005a, p19). In the second, '*A Safe Community',* increases in cocaine use and social disorder

are set as necessitating the use of cocaine vaccines in school children where the doctor, parent and the school agree, and their compulsory use in anyone arrested who tests positive for illegal drugs, along with all those in prison or on community sentences (OST, 2005a, pp.29-30). Although the final report contained less than 2 pages on the views of the participants on the vaccines, it stated that:

'Support for immunisation either to prevent a potential future dependency or to block the effects of specific substances was very limited, primarily on the grounds that it would infringe freedom of choice. Even where people were making decisions that were harmful either to themselves or to others, the majority view was that it is necessary to protect freedom of choice. The majority concluded against childhood immunisation of this type after discussion of a range of issues. Parents' desire to protect their child against harm and the release of money for the health service were given as possible arguments in favour of immunisation. On the other hand, safety was a major concern; the fear that the immunisation itself might have unintended negative effects was voiced. Even if the effects of some substances could be blocked, a genetic predisposition to dependency could lead to use of other, more dangerous substances. They also thought that limited knowledge and some scepticism of science in this area, combined with uncertainty over whether a predisposition to dependency would lead to actual dependency and the removal of future choices for the recipient. The ADDISS group pointed out that, unlike MMR, debate around which was framed within the context of public health, immunisation against potential future substance dependency was a human rights issue. The already-noted scepticism about genomics was also central to the above debate... Using blocking vaccines on illicit substance users, in the interests of protecting the wider community against crime, was also viewed negatively. It was seen as coercive, open to abuse by authority and, in the end, ineffective for reasons similar to those voiced above. Those with the inclination to use illicit substances would find other drugs to use in place of those rendered ineffective by a blocker. There was, however, considerable support for voluntary use of blockers (OST, 2005b, pp27-28).

Although the project outputs were generally well considered by stakeholders the Action Plan was not published and the reports were referred by the sponsoring ministry to the Academy of Medical Sciences, AMS, to consider the societal, health, safety and environmental issues raised by the advances described in the report before any official recommendations were made. Although the then Department for Innovation, Universities and Skills, DIUS, stated that the government would give a written response to the AMS report within 12-18 months of its publication, an independent evaluation of the Foresight programme carried out in 2006 by PREST at the University of Manchester found that opinions of the reason for the referral to the AMS varied:

'The 'official' reason is that the Academy is going to examine implications of the project for future health policy. This is to be welcomed if it leads to policy relevant advice being given based upon evidence. However, the fact that the Health Minister did not attend the project's launch event was interpreted by some interviewees as unease in the Department of Health as to the project's controversial subject matter. The referral to the Academy also raised the suspicion that the project was being "kicked into the long

grass", particularly as the review timetable is scheduled for one year. The evaluation was unable to assess the validity of these suspicions. However, it was clear from interviews that stakeholders are unlikely to allow the messages in the BSAD reports to fade away, even if it is the case that the project's evidence may be difficult for Ministers, or their civil servants, to fully endorse at the present time' (PREST, 2006, p59).

However, to date no official response to the findings of the BSAD project has been made. The politically sensitive and contentious nature of drug use and addiction is probably unsurprising to the reader, and budget deficits and political change have done little to open up public debate on the philosophy and evidence for drug use reduction. More recently, the subject was once again dragged into the headlines of the UK media by the debate that surrounded the rotation of cannabis from Class B to C and back to B over the course of the previous decade, which culminated in the sacking of Professor David Nutt as the Chair of the UK Government's Advisory Council on the Misuse of Drugs, ACMD. Nutt clashed with government ministers over his well-known stance that illicit drugs should be classified according to the scientific evidence of the harm they cause, such that alcohol and tobacco should be considered more harmful than LSD, ecstasy and cannabis (Nutt *et al*, 2007). In January 2009 with the publication of 'Equasy – An overlooked addiction with implications for the current debate on drug harms' in the *Journal of Psychopharmacology* the debate escalated (Nutt, 2009a). In this Nutt sought to raise the question of why society tolerates or encourages certain forms of potentially harmful behaviour but not others, such as drug use, by arguing that the risks associated with horse riding were comparable to those of taking ecstasy. After numerous public conflicts with then Home Secretary Jacqui Smith, Nutt's 2009 *Eve Saville* lecture at King's College London (Nutt, 2009b) brought the debate to a head, and he was sacked by Smith's successor, Alan Johnson, in October 2009. In a letter to the *Guardian* Johnson stated that Nutt 'was asked to go because he cannot be both a government adviser and a campaigner against government policy... as for his comments about horse riding being more dangerous than ecstasy... it is of course a political *rather* than a scientific point' (Johnson, 2009, italics added). Nutt responded in the *Times*:

'In July this year I gave a lecture on the assessment of drug harms and how these relate to the legislation controlling drugs. According to Alan Johnson, the Home Secretary, some contents of this lecture meant I had crossed the line from science to policy and so he sacked me. I do not know which comments were beyond the line or, indeed, where the line was, but the Government has lost its major expert on drugs and drug harms and may indeed lose the rest of its scientific advisers in the field... My sacking has cast a huge shadow over the relationship of science to policy. Several of the science experts from the Advisory Council on the Misuse of Drugs (ACMD) have resigned in protest and it seems likely that many others will follow suit. This means the Home Office no longer has a functioning advisory group, which is very unfortunate given the ever-increasing problems of drugs and the emergence of new ones. Also it seems unlikely that any "true" scientist — *one who can only speak the truth* — will be able to work for this, or future, Home Secretaries' (Nutt, 2009c, italics added)

Nutt went on to create the Independent Scientific Committee on Drugs in January 2010, which states its aim 'to provide scientific findings *free from the constraints of policy making and politics*' (ISCD, 2011). Although the ACMD continues, the *Police Reform and Social Responsibility Bill 2010-11* (HO, 2011), seeks to alter the restrictions on the membership of the ACMD defined under Schedule 1 of the *Misuse of Drugs Act 1971* (HO, 1971). The proposed changes remove the requirement for the ACMD to be composed of at least one person with wide expertise in each of six scientific specialities and for other members to have wide and recent experience of social problems connected with the misuse of drugs. Its quiet inclusion in a seemingly unrelated Bill has incensed non-for-profit groups such as the UK Cannabis Internet Activists (formerly the Legalise Cannabis Campaign) (UKCIA, 2010) and the Drug Equality Alliance (DEA, 2010) who are highly critical of the lack of evidence-based drug policy.

Unfortunately, as the discourses from both sides demonstrate, rather than invoking a considered debate on the role of scientific evidence in policy, or the co-construction of scientific facts (cf. Latour, 2007), these episodes appear only to have entrenched the descriptive and normative belief that 'science' and 'politics' can be separated. This thesis however builds on the decades of Science and Technology Studies, STS, scholarship that precedes it, which has sought to demonstrate that science has never operated in a political vacuum, but is rather always a part of the socio-political landscape in which it is situated. In this work then, I overtly line up with the social constructionist perspective derived from STS; Hacking (2000) begs however that we seek first not a definition of social constructionism, but rather the point. Mine is a simple and local claim; that the contemporary 'drug problem' and the medical model of addiction need not be conceptualised as they currently are. Within this local claim is the aim of raising consciousness that the current arsenal of medical drug treatment was not inevitable. My political message then perhaps terminates prematurely, for I do not intend to join the majority in enthusiastically criticising the status quo, with the aim of changing or overthrowing the order of things. I recognise the need for overtly critical accounts of the medical model of addiction such as those propounded by Szasz (1996, 2003) and Peele (1977, 1990). However, having spent a year volunteering at a residential drug rehabilitation centre in a socio-economically deprived neighbourhood, so too can I see the value of the medical as opposed to judiciary approach to particular patterns of repetitive drug use that are heavy and highly consequential (Schneider, 1978). Rather, as Andersen (2003), my aim is to think within, but also critically in relation to, an already established system of meaning.

So to all those that align themselves with the nature fundamentalists depicted by Latour (2003), who would want facts to pop up mysteriously from nowhere and refuse to participate in a discussion about what the world was like before, the subsequent examination of the historical and

sociological perspectives of drug use and addiction will appear entirely fatuous. However, for anyone that concedes only that things have not always been the way they are, then hopefully it may provide an interesting account of how the contemporary 'drug problem', the medical model of addiction and biotechnologies for inoculating against addiction are shaped by the social and political context.

The review, and political message, will continue in the rest of this chapter by examining the dominant essentialist construction of 'the drug problem' through a brief critical assessment of the role of statistics within a positivist epistemology as seen in the US Office of National Drug Control Policy, ONDCP, and the previous UK government's *2008-2018 Drug Strategy* (HO, 2008). Drawing on post-structuralist and Foucauldian critiques of medicine and constructivism derived from Science and Technology Studies it then explores how addiction has come to be understood and regulated in the twenty first century in the different socio-political contexts of the UK and the US. The development of immunotherapies for addiction will then be examined in more detail, setting them within the context of the 'laboratory logics' from which they emerged, and which have since gone on to enable and constrain the techniques, technologies and practices that are considered legitimate ways to construct addiction (Campbell, 2007). It will conclude with a brief analysis of the relationship between constructionism in particular, and sociology in general with other disciplines, such as biology, and suggests that if we are to develop a less partial and limited understanding of addiction as a simple additive construction then each discipline needs to recognise the value and limitations of the other. Chapter 2 will explore the rise of Technology Assessment in the 1970s, and the impact of theoretical contributions from STS and other disciplines on how it evolved in the 1990s. The rise of more constructive and participatory approaches to technology assessment will be briefly reviewed as both the conceptual framework for this thesis, and its operational agenda. It will then continue to provide a detailed account of the methodologies used to address the key questions raised in this thesis around the development of vaccines for addiction.

The rest of the work will then form a largely empirical examination of immunotherapies for addiction. Part I of the thesis can be seen as assessing the role of the technology as a form of anatomo-politics aimed at disciplining and normalising the individual addicted body. Chapter 3 will form a brief literature review of the ways in which the official dominant discourses and practices of medicine have constructed the individual addict through the diagnostic criteria of the American Psychiatric Association's Diagnostic and Statistical Manual from the first edition in 1952. Chapter 4 then acts as a counter-force, demonstrating how members of the lay population have responded to, or challenged, the clinical gaze, both as active participants in the medicalisation of addiction and as sites of potential resistance (Lupton, 1997). Following on from this, Part II will

focus on the ways in which the state has sought knowledge and power over the social body, exploring the tensions between older forms of biopolitics which acted on the whole population, and the shift to newer forms which seek to govern populations through the control of risk. Chapter 5 will examine the new forms of public health which characterise advanced liberal democracies and seek to demonstrate the extension of clinical gaze into the everyday lives of the population by charting the rise of epidemiology and the shift away from a focus on the individual addict onto the problems associated with addiction on an aggregate level, focusing on developments from the 1950s (Bunton 1997; Miller and Rose, 2008; Nettleton, 1997; Rose, 1999a, 1999b). It seeks to highlight the ways in which technologies of the self have increasingly been articulated in somatic terms, where certain lifestyle factors have come to be understood as themselves disease entities by virtue of their irrationality in a culture which increasingly prioritises health as the key manifestation of the modern self-reflexive, autonomous agent. Again, the discourses of key actors are then empirically examined; in Chapter 6 they will be used to countervail the techniques and practices of control and discipline inherent in older forms of biopolitics aimed at the whole population through the potential strategy of mass childhood immunisation for addiction. In Chapter 7 the focus will shift to technologies of the self, or the ways in which technologies of domination are internalised and reproduced by individuals in the context of their parental role as guardians of their children's future health and happiness, and the willingness or resistance of parents to further the medicalisation of addiction by seeking or accepting vaccination against addiction for their child. It will conclude by considering the wider implications of the findings on the notion of the neo-liberal individual which underpins the dominant discourses of biomedicine and bioethics. It will also identify potential 'loci for realignment' in the endogenous futures of the vaccines (Schot and Rip, 1996), and reflect on the value and success of framing this thesis as an exercise in constructive technology assessment.

1.3. LIES, DAMNED LIES AND STATISTICS: MEASURING SOCIAL PROBLEMS

According to the 2009/10 British Crime Survey, BCS, about one in three people aged 16 to 59 had used one or more illicit drugs in their lifetime, with 15% using a Class A drug at least once. Following recent trends, cannabis was the most commonly used type of drug in the last year, followed by powder cocaine, with an estimated 800,000 16-59 year olds using powder cocaine in the last year, which is approximately 0.8 million adults. Since 1996 when the BCS began to measure drug use the levels of reported Class A drug use in the previous year have remained relatively constant, with a decrease in the use of hallucinogens being offset by an increase in the use of cocaine. Of the estimated 500,000 (7.3%) 16-24 year olds who took a Class A drug last

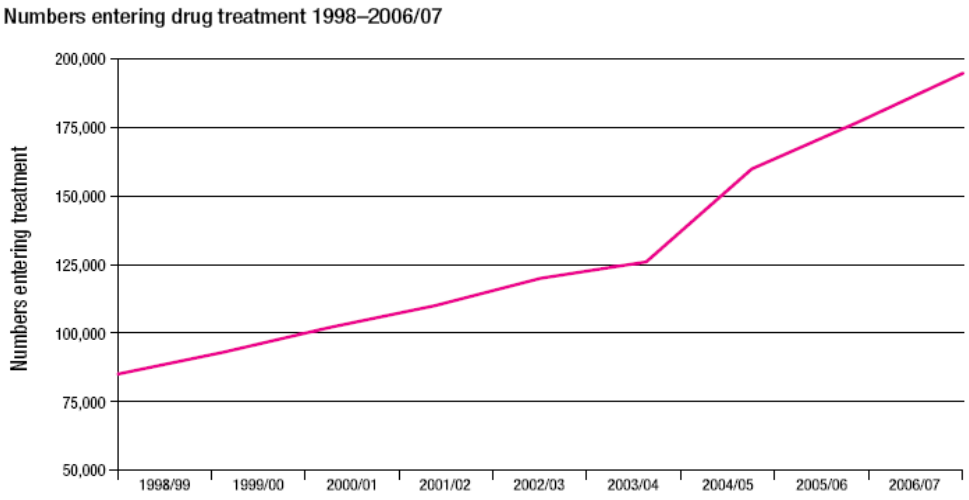
year, over 73% admitted to using cocaine (Hoare and Moon, 2010). Of these, problem Class A users, which are said to include half of all young cocaine users, are estimated to cost the economy as much as £17.4 billion per year (Godfrey *et al*, 2002). In addition, according to the Office for National Statistics, ONS, in 2008 about 22% of men and 21% of women smoked cigarettes in the UK (ONS, 2010) with the 'social cost' of smoking put at £2.4bn (HC, HSC 27-II, 2000). By comparison according to the 2009 US National Survey on Drug Use, 8.7% of persons aged 12 and over had used one or more illicit drugs in the preceding month and 1.6 million using cocaine (SAMHSA, 2010) and the overall cost of illicit drug abuse was put at $143.3 billion in 1998 (Bouchery *et al*, 2001). In addition, in 2009 about 33.5% of men and 22.2% of women smoked cigarettes in the US (SAMHSA, 2010) with the 'social cost' of smoking put at between $68bn (McCormick *et al*, 1997) and $181bn (NIDA, 2006a) in recent years.

Consequently, addiction to different forms of legal and illegal drugs is seen as one of the most important and intractable social problems facing contemporary Western societies. However, one should never let the figures beguile, otherwise, unlike the judicious Stephen J. Gould, we might falsely believe that we will be dead in eight months (Gould, 1985). Rather, given the almost ubiquitous presence of various figures purporting to demonstrate the true extent of the drug problem in official and scientific discourse, these numbers can, and should, be subjected to a critical analysis.

In *Lies, Damned Lies, and Drug War Statistics,* Robinson and Scherlen (2007) critically examine the claims made by the US Office of National Drug Control Policy, ONDCP, as the official mouthpiece of the federal government and the agency which forms the basis of federal drug policy. For example, under the claims made by the ONDCP regarding success in reducing drug use, the 2000 Strategy claimed that 'since 1996, the number of current users remained steady with statistically insignificant changes occurring each year' and presents a figure alongside showing a decline in drug use trends since 1985. However, if the 1985 statistic is removed, a new figure clearly indicates that there has been no decline in drug use since the ONDCP was founded in 1988, which would suggest that it has not been successful in its aim to reduce drug use. Further, while there has been no change in overall drug use since 1988, there has been an increase in past-month drug use but this is not highlighted, again giving the impression that the policies of the ONDCP have been successful where they have not. By intricately examining the statistics used by the ONDCP, Robinson and Scherlen (2007) demonstrate how the repeated inappropriate use of statistics and visual graphics serves not to provide accurate assessment of policy initiatives, but rather misuses statistics to present a misleading picture of the nation's drug war that justifies the dominant ideology 'that illicit drug use is bad, never acceptable, supply-driven, and must be fought through an ongoing war' (p9).

There is no similar comprehensive review of the use of statistics in drug policy in the UK, but perhaps just one example taken from the 2008-2018 UK Drug Strategy (HO, 2008) will serve to demonstrate a similar leaning towards inaccuracy and the misleading presentation of findings.[1] The example relates to the section titled 'Delivering new approaches to drug treatment and social re-integration' which sets out the 2008–2011 Public Service Agreement target, PSA 25, which relates to the number of drug users in effective treatment. PSA 25 was issued as part of the 2000 Spending Review, and aims to 'increase the participation of problem drug users in drug treatment programmes by 55% by 2004 and 100% by 2008 (baseline 1998) and to increase year on year the proportion of users successfully sustaining or completing treatment programmes.' (HM Treasury, 2007). For PSA 25, the proxy by which it is to be measured and compared is the National Indicator of the number of drug users in effective treatment (NI 40). If putting to one side the debate of what is to constitute a 'problem drug user' or 'effective treatment,' surely this would become an entirely straightforward and uncontroversial matter of recording the number of patients within drug treatment units, and comparing this to the records of the previous years. If the government has been successful in meeting PSA 25 then we would expect to see that between 1998 and 2004 the number of drug users in treatment had increased by 55%, and that between 1998 and 2008 it had increased by 100%. Conversely, if these targets have not been met, surely logic would demand we should conclude that the government had not been successful in meeting PSA 25. The visual representation of the number of drug users entering treatment between 1998 and 2007, as given in the 2008-2018 Drug Strategy (p28), is reproduced below in Graph 1.

Graph 1: Number of drug users entering treatment between 1998 and 2007 in the UK



[1] NB. The current 2010 Drugs Strategy (HO, 2010) had not been published when this analysis was undertaken.

The graph would seem to show a clear and steep rise in the numbers entering treatment since 1998, when the previous Drugs Strategy was brought out, and the text states:

'More people are receiving treatment, with the number in contact with treatment services increasing from 85,000 in 1998 to 195,000 by 2006/07 with the target to double the numbers in treatment achieved two years early' (pp27-28).

A rise from 85,000 to 195,000 (a percentage increase of roughly 129.4%) is an impressive rise; however, we are informed in small print under the graph that:

'In 2005, the National Treatment Agency commissioned the National Drug Evidence Centre, University of Manchester, to re-examine the baseline for the number of people in drug misuse treatment in 1998/99. This revision in the baseline was quality assured by the Office for National Statistics and had approval from the then Home Secretary, Charles Clarke. The estimated figures above are a projected trajectory from an adjusted baseline of 85,000 in treatment in 1998/99' (p28).

Perhaps entirely innocuous, but the Drugs Strategy fails to give a reference for the report, which through much internet trawling can be established as the 2005 *Report re-examining the baseline for the number of persons in drug misuse treatment during 1998/99,* produced by the National Drug Evidence Centre, NDEC. This report however is not to be found on the output section of the NDEC website, or indeed elsewhere on the internet, although it is also cited in the NTA report titled *Statistics from the National Drug Treatment Monitoring System 2004 - 2005* (NTA, 2006). However, while 'weblinks are included for all references, when available' (p36) the NDEC report is again conspicuously missing from the list. Nonetheless, helpfully this report does contain a section titled 'Trends in Numbers Treated' and we are presented with a table and some text, shown below in Table 1:

Table 1: Trend in the estimated or projected number of individuals in contact with UK drug treatment services from 1998/9 to 2004/5

Table 7.1.1: Trend in the estimated or projected number of individuals in contact with drug treatment services from 1998/99 to 2004/05

Year	Reported figure	Increase from previous year %	Increase from 1988/99 %
1998/99	85000[1]	-	-
1999/00	91000[1]	7	7
2000/01	99000[1]	9	16
2001/02	116000[1]	17	36
2002/03	115500[1]	0	36
2003/04	125545	9	48
2004/05	160453	28	89

[1]See Appendix 2 "Notes on Numbers in Treatment Series"

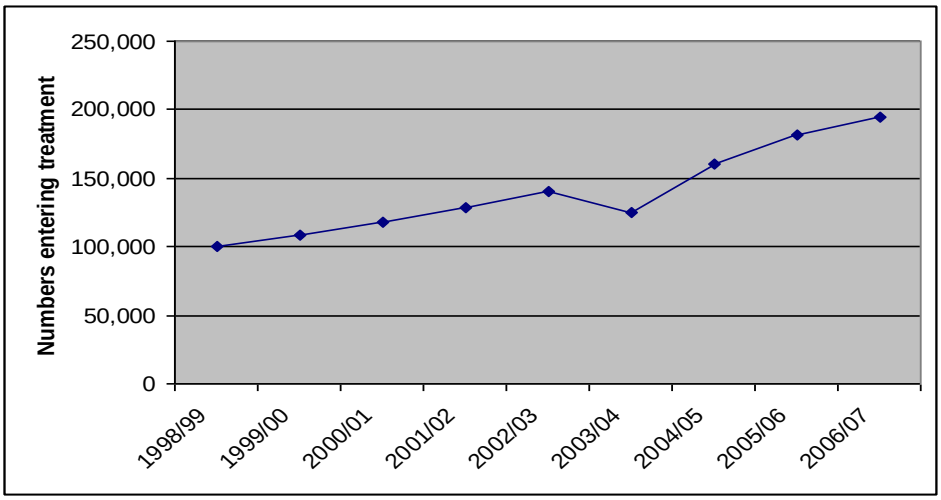
> 'During 2004/05 NDTMS recorded 160,453 individuals as being in contact with structured treatment services. Progress towards the PSA target of doubling the numbers in drug treatment has been measured from an estimate of the number of individuals in contact with treatment services in 1998, using trends in the RDMD and NDTMS data. *Although headline figures are not comparable, the year-on-year trends using the different systems and counting methodologies can still be used to estimate the overall change in the numbers treated'* (NTA, 2006, p31, italics added).

While it is not evident which numbers are depicted by the label 'headline figures', or why they are not comparable, (and consequently why they are none-the-less comparable), or which figures constitute estimates and which are projected, we are at least referred on to Appendix 2, which contains the following information about the numbers in treatment:

- '1998/99 – Originally published as 100,000, based on a reduction from the original 2000/01 estimate (118,500). Now estimated as 85,000, based on a reduction from a revised estimate (102,100) of the 2000/01 census figure and with a reduction (1/1.03 – based on an analysis of 2003/04 data) for regional overlap.
- 1999/00 – Originally published as 109,000, based on based on a reduction from the original 2000/01 estimate (118,500). Calculated as a reduction from the revised 2000/01 estimate, as per the revised baseline estimate, the estimated figure is 91,000 (87,500 – 94,500).
- 2000/01 – Originally published as 118,500, based on treatment census. Taking into account problems with the original methodology, this has been revised to 102,100 (see "Re-examining the baseline for the number of persons in drug misuse treatment during 1998/99") and can be further adjusted (1/1.03 – based on an analysis of 2003/04 data) to allow for regional overlap not accounted for in the revised figure, which gives an estimate of 99,000.
- 2001/02 – The Department of Health originally published a provisional figure of 128,200, based on the first year of NDTMS. If the published figure is adjusted to take account of regional overlap (1/1.03 – based on an analysis of 2003/04 data), a higher level of reporting by GPs (further 1/1.014 – based on a comparison of 2002/03 with 2003/04 data) and inclusion of Tier Two agencies (further 1/1.056 – based on a comparison of 2002/03 with 203/04 data2), the resulting estimate is 116,000.
- 2002/03 - The Department of Health originally published a provisional figure of 140,900. This was based on a variety of methodological assumptions about the NDTMS data for 2002/03 which are known to have resulted in an inflated figure. The Bridging Exercise concluded that, in order to produce comparable figures, it would be necessary to inflate the figures for the subsequent year from 125,913 to 153,806. If the 2002/03 figures are reduced by an equivalent proportion, the resulting estimate is 115,500' (NTA, 2006, p35).

With a reduction from a revised estimate apparently necessary every year due to 'problems with the original methodology' and later from 'methodological assumptions… which are known to have resulted in an inflated figure' until 2003/04, at which point it became evident that 'in order to produce comparable figures, it would be necessary to inflate the figures for the subsequent year', and to further reduce the 2002/03 figures 'by an equivalent proportion', it becomes hard to believe that the numbers could claim to signify anything at all. As an interesting aside however, if a new graph is created (see Graph 2 below), from the estimates of the number of drug users in treatment, before the *necessary* revisions were carried out, a very different picture appears.

Graph 2: Alternate representation of the number of drug users entering treatment between 1998 and 2007 in the UK



This graph, less painstakingly edited, shows the numbers entering treatment in a less favourable light with regard to PSA 25, actually indicating a dip in the number between 2002/03 and 2003/04 when the government introduced the Drug Intervention Programme, aimed specifically at reducing re-offending by engaging offenders in treatment. Furthermore, if the baseline of 1998/1999 is not re-assessed at 85,000 but is kept at the original estimate of 100,000 then the government failed to reach its target of increasing the number of drug users in treatment by 55% between 1998 and 2004, and neither did it meet its target of increasing the numbers in treatment by 100% two years early, both of which are used as evidence that PSA 25 has been met with early success, adding weight to the government's approach to drug treatment and social re-integration.

Still remaining blinkered to the looming definitional spectres, let us continue what appears to be a simple matter of numerical (non) accuracy and return to PSA 25, but this time direct attention to the latter part, that of *increasing year on year the proportion of users successfully sustaining or completing treatment programmes,* and ask how the proportion of users successfully sustaining or completing treatment programmes is calculated. Accepting the stipulated but undefended proxy of success - retention in treatment for 12 weeks or more - let us examine how this measure, surely a straightforward dichotomy, is recorded. Although not specified in the Drug Strategy, a report issued by the NTA, on *Improving treatment effectiveness through improvements in early retention – the measurement of attrition* (2005) reveals that successful retention will be based on all those clients newly presented to treatment in the reporting period who have been discharged at or after 12 weeks, or retained in treatment 12 weeks or over but not discharged. Those counted within the attrition rate are those discharged before 12 weeks. Seemingly quite simple, if a new client is undertaking certain specified forms of treatment for 12 weeks or more they are

to be counted as a success, whereas if they leave the service before 12 weeks, the drug treatment is said to be unsuccessful. However, the report freely acknowledges that:

'It is recognised that *by including clients not discharged in the measure of retention, there may be an incentive for services not to discharge clients even if they have exited treatment*. While we would not expect services to do this, NDTMS will monitor and audit expected levels of discharge and produce reports where clients show no activity on their records, but are indicated as still being in contact due to no discharge date being present. Similarly, *while it is possible for a client to be retained for 12 weeks – having only been triaged and not having started a treatment intervention* – we will be monitoring where this is occurring frequently. An explanation may be requested on the status of these clients and why they are in contact for that length of time without commencing an intervention… *there will be a time lag of 21 days after discharge before a treatment journey is reported as having ended, to allow for the possibility that a subsequent episode of treatment might commence within that 21-day period*' (pp2-3, italics added).

Consequently, in measuring the amount of clients 'successfully' sustaining or completing treatment programmes, i.e. remaining within treatment programmes for 12 weeks or more, the numbers represent not only those actually engaged in, or having completed, some form of treatment programme for twelve weeks, but also those who have been triaged, but have not started a treatment intervention, which is perhaps analogous to presenting oneself at Accident and Emergency and being assessed by the triage nurse, then waiting 12 weeks to see a doctor. It also includes those who have actually left treatment (perhaps because they were not finding it effective) but who have intentionally not been removed from the books in order to bolster retention rates, and those who have officially exited treatment after 9 weeks, since it is possible they may enter another treatment programme. Success indeed, even within the narrow confines stipulated by the Drug Strategy, and with so much latitude available in assessing retention rates one may think it would be impossible to fail the reach the target of increasing year on year the proportion of users successfully sustaining or completing treatment programmes.

Indeed, according to the 2008 Drugs Strategy, 'three-quarters of new entrants to treatment are *now* retained in treatment for 12 weeks or more, which is the minimum period that can have a lasting impact on entrenched drug use' (p28, italics added). While this is not explicitly connected to whether government has met the target of increasing year on year the proportion of users in treatment, the rhetoric of the use of the word *now* implies to the reader that three-quarters of new entrants to treatment were not retained in treatment for 12 weeks or more *before*. However, according to the NTA media release on 18 October 2007: 'More than 60,000 (75 per cent) of new clients remained in structured treatment for 12 weeks or more – when treatment is more likely to be effective – following triage assessment in 2006/7. This is a slight fall from 76 per cent in 2005/6' (NTA, 2007). As such, the rhetorical use of 'now' is misleading since it implies the

government has successfully met the target of increasing the number of drug users successfully sustaining or completing treatment programmes *every year*, when in fact in the reporting year the figure has actually fallen.

While perhaps more reserved in rhetoric, the UK Drug Strategy is no less subject to the misleading use of statistics and visual graphics than its American counterpart. This may be accounted for by artful manipulation, but it may also be simply due to inadequate reporting of methodology. If the former is more accurate then perhaps the reader would just shrug, well aware already of the many political interests that reside in the presentation of official statistics. If it be the latter then they may conclude that the statisticians charged with reporting the social trends of the day are, like Mark Twain, beguiled by the figures, particularly when they have the arranging of them. In either case however there are serious issues for anyone adhering to a version of statistical positivism (Abercrombie *et al*, 2000). A founding principle of the scientific methodology is that researchers must explicate their method if other researchers are, in principle, to possess the means by which to replicate their findings and contribute their sightings of black swans (Popper, [1959] 2002). If the semantic dimension of realism is accepted; that we should construe the language of scientific theories literally as statements that are about the objective reality of entities, then the values that constitute the scientific method so understood must be adhered to. By either wilful manipulation of the data, or incompetent handling of the numbers, the requirement of relying upon non-arbitrary and non-subjective criteria for developing, accepting and rejecting claims, hypotheses and theories is not upheld (Longino, 1990). In so doing the stipulated goals of traditional realists in discovering the truth (Maxwell, 1962, Musgrave, 1985) and the lesser demands of constructive empiricists in attaining empirical adequacy (Van Fraasen, 1980) are thwarted. The outcome does not provide an accurate assessment of the drug problem but merely generates and defends a given ideology that construes drug use as inherently wrong.

It could be argued that this does not indicate a problem with the perspective, but rather the use, or misuse, of the statistics by those in power. However, a much deeper criticism resides in the figures themselves, which arguably conceal the edicts of their own construction. In *Statistics in Britain 1865-1930: The Social Construction of Scientific Knowledge* (1981), Donald MacKenzie demonstrated the role of social interests in the development of statistical theory in Britain. Drawing on work from the 'strong programme' in the sociology of knowledge, MacKenzie examined Galton's regression and correlation, Pearson's correlation coefficient and Fisher's theory of statistical inference, in order to establish how social interests affected the very content of statistical knowledge. In order to do so he traced connections between beliefs and social positions that originated in the social organisation of science and society that affected the content of scientific knowledge:

'Interests or experiences constrain the set of beliefs 'appropriate' to occupants of these positions. 'Appropriate' beliefs will be ones justifying a group's privileges, advocating an advance in its situation furthering its coherence or the interests of its members and reflecting salient features of the typical experiences of its members' (p5).

Hacking (2000) has questioned whether MacKenzie was successful in refuting regression, correlation coefficients or chi-squared tests, in the sense of taking the thesis on its own terms and showing it to be false. Rather, he claims that by concentrating on the impact of extra-scientific roles, MacKenzie has described the social construction of statistical methods, but left them intact, unwittingly promulgating the misconception that the natural science method is, or at least could be, asocial. However for Hacking, in MacKenzie's (1990) later work *Inventing Accuracy: an historical sociology of nuclear missile guidance,* the extra-theoretical function of defining missile accuracy is successfully defended and the possibility of a 'correctly' defined accuracy if refuted, by demonstrating that standard measures of accuracy correspond to the interests of the parties involved and not to some 'ideal' measure of accuracy.

In the literary Nobel Prize winner Luigi Pirandello's 1921 play '*Six characters in search of an author*', one of the characters declares: 'A fact is like a sack... when it's empty it won't stand up. And in order to make it stand up you must first of all pour into it all the reasons and all the feelings which have caused it to exist' (in Greenfield, 1979, p103). Latour and Woolgar (1979) have since put forward a strong explication for how facts are themselves constructed, and it seems hard to maintain that the current depiction of the drug problem is *simply* a fact. The uncritical use of such ubiquitous categories as drugs, addiction, dependence and, more generally, deviance and disease, as *a priori* conjectures that claim to map an objective reality which is decontextualized and ahistorical obscures the fact that they did not emerge deterministically from an accretion of scientific discoveries, but rather have been constructed by the actors and institutions who promulgated, internalised and reproduced them through discourse (Klaue, 1999, Reinarman, 1993). But that is not to deny materiality its rightful place. As Latour (2003) is quick to point out, social constructivism has gone terribly wrong when material reality is at stake and 'things' consist of or in their social ties, and the 'soft and superficial links' of laws, culture, media, politics and so forth are said to be made of the 'harder stuff' of power relations (p29). The concern of social constructivism is, or should be, the process through which any thing, including matters of fact, have been built since: 'facts are not brought by storks any more than are babies' (p28). Albeit without the blasé smile, I will write that constructed reality is not either constructed or real, nor is it both; reality can only be known through its constructions but it is no less the real for that. However, it does mean that biological facts cannot, of themselves, offer an adequate explanation of why what was seen as an unremarkable behaviour or vice could come to be seen

at the turn of the twentieth century as a deviant or pathological identity, capable of undermining individual volition and in need of biomedical treatment (Redfield and Brodie, 2002).

As such, the spirit of this thesis derives more from the genealogy of Nietzsche and Foucault than a concern with historical teleology or the search for ultimate truths. Following Andersen (2003) I want to swap ontologically over-determined theory for epistemologically driven thinking, which leads to questions that ask not what, but how. As Andersen depicts, the latter is concerned to *de-ontologise* its object, to replace questions that ask what it means that something exists, and what the fundamental possibilities are for deciding whether statements are true, objective or scientific, with an *empty* ontology that is restricted to only saying 'reality is' (pp xi-xiii). Consequently the main issue becomes that of how the world came into being as a direct result of the specific perspectives held by individuals, organisations, or systems, which brings us to the aggrandised shadow of the definitional spectre which has been beckoning.

1.4. CLAIMS MAKING AND THE SOCIETAL REACTION FRAMEWORK

Kitsuse and Circourel (1963) argued over four decades ago that statistical unreliability should not be regarded as merely a technical and organisational problem, but also as a matter of differences concerning the definition of deviant behaviour. Official crime statistics reflect 'specifically organizational contingencies which condition the application of specific statutes to actual conduct through the interpretations, decisions, and actions of law enforcement personnel' (p137). Their point is not a technical one of whether statistics are a valid measure of crime, but rather that official statistics are themselves sociologically relevant data since '*rates of deviant behavior* are produced by *the actions taken by persons in the social system* which define, classify and record certain behaviors as deviant' (p135, italics in original). There simply is no way to objectively define such terms as 'effective treatment' and 'problematic use' beyond what we collectively agree upon. The social problem then, and its effects, which the statistics purport to measure exist primarily in how they are defined and conceived of in a given society. It is the societal definition and not the objective makeup of a given social condition that determines whether the condition exists as a social problem, since it is the collective societal definition that gives the social problem its nature, lays out how it is to be approached and shapes what is to be done about it (Blumer, 1971).

Prior to the twentieth century there was no clear demarcation between 'recreational' and 'medical' use of drugs, with the use of opium common among all sections of the population,

whether for medical or semi-medical reasons. The drug use of Coleridge and his opium-inspired Romantic friends such as Thomas De Quincey, author of *The Confessions of an English Opium-Eater* ([1821], 2003) in the nineteenth century is well known but the public disapproval which cemented recreational drug use as a 'way of life' in the twentieth century was absent. However, personal and literary accounts of drug use have seldom promulgated an O'Leary-esque ([1964] 1995) view of mind-altering substances as unequivocal spiritual awakening; rather, they have denoted the dangers of the dual edged sword of enlightenment and enslavement. While Baudelaire could extol the virtues of hashish and opium in *Les Paradis Artificiels* ([1860] 1996) so too would he warn:

'The man who by the strength of his will can deliver himself, after having long been under the dominion of opium or hashish, and despite the weakness engendered by the habit of his servitude, bears a resemblance to an escaped prisoner. He inspires in me more admiration than does the prudent man who, having always carefully avoided temptation, has never transgressed. With respect to opium-eaters, the English, frequently employ terms which can only seem excessive to those innocent souls who have never known the terrors of that species of ruin: "*enchained", "fettered", "enslaved"*! Chains indeed, compared to which all others - chains of duty, chains of illegitimate love – are nothing but gossamer threads and spiderwebs! Appalling marriage of man to himself' (p59).

Similarly, in *The Milk of Paradise,* Abrams wrote that for Coleridge and De Quincey: 'the great gift of opium to these men was access to a new world as different from this as Mars may be; and one which ordinary mortals, hindered by terrestrial conceptions, can never, from mere description, quite comprehend' (in Schneider, E. 1945, p786). But Coleridge himself was to write Byron in 1816;

'The strength of my constitution has prevailed over the effects of year long errors and imprudences commenced most innocently and grown into the Tyranny of a Habit before I was aware of my Danger. I refer to the daily habit of taking enormous doses of Laudanum which I believed necessary to my Life, tho' I groaned under it as the worst and most degrading of Slaveries -in plain words, as a specific madness leaving the intellect uninjured and exciting the feelings to a cruel sensibility, entirely suspended the moral Will - *Video meliora proboque Deteriora sequor*[2] was the motto of my Life -as far as this process of slow self-destruction was concerned' (Coleridge to Byron, in Griggs, 1930, p1096).

However, although the link between psychoactive substances and literary creativity has long been established as significant (cf. Day and Smith, 2003, Hayter, 1968; Ober, 1968) the self-conscious recreational use of drugs did not occur until the late nineteenth century. Berridge (1988) traces

[2] I see and approve the better course, but I follow the worse.

the historical antecedents of drug subculture in the UK to the consciously experimental use of hashish and opium to enable the expansion of inner consciousness and a separation with the external world in literary circles in the decadent movement of the 1890s, followed by its extension to broader circles in the First World War; and finally, the vogue for anything American in the drug 'scene' of the 1920s. However, she argues that they remained an incidental part of wider literary, artistic, and upper-class interests until the 1960s, when highly structured groups with a distinct pattern of life centred on drug use emerged from within the working-classes. Indeed the changing demographies and geographies of drug takers can be seen as crucial in shaping the construction of addiction in dominant discourses in both the UK and the US, changing the societal reaction and the type of legal and social controls put into effect. The slippery road from enlightenment to spiritual degradation so oft covered in these personal accounts of years gone by has shifted in two key ways; the first person narratives no longer come from the isolated drawing rooms of so-called 'higher culture' (Nietzsche, [1878], 1995) but the multitude of rooms and halls of Alcoholics Anonymous and its many descendents, and what was a moral journey has become a medical one, with the symbolic chains of slavery that bound the will to desire, replaced with a literal loss of autonomy brought on by maladaptive changes in the mesolimbic system. This reconstruction of the addict is not just prosaic; rather how we define the spectre of the addict directs how we approach the 'problem' of drug use, and how we define and make known the drug problem in turn constructs the addict. As Reasons (1974) explicates, looking at the phenomena identified as social problems at different times or in different societies 'should indicate that *there is nothing inherent in a phenomenon which makes it a social problem*' (p382, italics in original).

There has been a proliferation of social histories of opiates (Courtwright, 2001; Dikotter, Laamann and Xun, 2004); cocaine (Gootenberg, 1999; Spillane, 2002); tobacco (Zhou and Gilman, 2004); caffeine (Bealer and Weinberg, 2001) alcohol (Valverde, 1998; Willis, 2002), drug and alcohol (Tracy and Acker, 2004) and global drug histories (Davenport-Hines, 2001) in the past decade. However, dominant formulations of the 'drug problem' continue to take a Lombrosian view of deviance, regarding it as an attribute, inherent in a certain kind of behaviour, aiming to objectively examine the causes for the existence, maintenance and growth of drug addiction using a scientific methodology (Gibbs, 1966). For those adhering to this perspective, the 5000 year history of psychoactive drug use for the treatment of physical pain and mental distress, ritual and spiritual ceremonies and celebrations, and for pleasure appears largely irrelevant. Drug policy remains focused on short-term solutions to what are perceived as urgent problems requiring immediate action if the modern epidemics of drug use, objectively evidenced by statistics, are to be controlled. But as Perdiguero *et al* (2001) stress, social problems are the result of tendencies that have evolved over decades or centuries, and as such can be much better understood if we attend to the circumstances that have led to them and the broad social changes that have taken place.

Locating the weight of the solution on immediate, mainly biological factors overshadows the weight of socio-cultural considerations in proposals for health interventions, and downplays the central role of the local in public health, insofar as it refers to the living conditions and practical life of human groups.

Precisely who or what is deviant depends upon a firm understanding of the norms (Pfohl, 1985). The nature of a deviant behaviour can continually change, both in formally enacted rules and in informal social groupings, since deviance is 'viewed not as a static entity but rather as a continuously shaped and reshaped outcome of dynamic processes of social interaction' (Schur, in Neff and Orcutt, 1978, p376). This approach to social problems, which can widely be described as the societal reaction framework, has its roots in the symbolic interactionist paradigm of the Chicago School which experienced a resurgence of popularity in the 1960s. While the first key sociological perspective to deviance had originated from the work of Durkheim and Merton, with an emphasis on macro-level structures and institutions, this positivist tradition was challenged by members of the US Society for the Study of Social Problems who emulated their pragmatist origins in arguing that truth should be seen not as eternal and unchanging principles, but a product of concrete experiences and language (Marshall, 1998).

Interested in the micro-level study of individual and small group interaction, symbolic interactionists emphasised the importance of giving attention to subject meanings or definitions in order to understand human activity and the processes through which deviance was socially constructed, and was particularly influential in the development of the labelling theory of deviance (Plummer, 2000). Labelling theorists introduced a new relativism into the study of deviance by addressing a number of definitional issues such as what the processes were by which deviance was identified, and what the consequences of the application of the label were for both the individual and society (Marshall, 1998).

Howard Becker, the leading American proponent of labelling theory, argued in *Outsiders* ([1963] 1973) that 'deviance is not a quality of the act a person commits, but rather a consequence of the application by others of rules and sanctions to an 'offender'' (p9). No act of deviance is in itself deviant, rather the label of deviance is applied when others observe the behaviour and react to it by labelling it as deviance. Once a behaviour is defined as deviant, persons committing the act are segregated from society which creates 'outsiders', where in turn this segregation leads to the symbolic reorganisation of the self and social roles, and the continuation of the deviant behaviour now expected of them by conforming society. Cohen ([1972], 2002) would later similarly argue that these processes of labelling can induce amplification of deviance, by isolating the deviant from conventional society and constraining them to employ a deviant identity as a means of

defence, attack, or adjustment to the problems created by the societal reaction. Both would emphasise that forms of behaviour should not be seen in themselves as differentiating deviants from non-deviants; 'it is the responses of the conventional and conforming members of the society who identify and interpret behaviour as deviant which sociologically transform persons into deviants' (Kitsuse, 1962, p253).

However, while many labelling theorists were situated within a symbolic interactionist paradigm with its emphasis on micro-level day-to-day interaction, other studies would draw on functionalist paradigms, moving the emphasis away from the processes by which individual persons came to be identified as deviant and the impact of this on their subsequent career, and refocusing on societal reaction at large and the macro-level processes by which certain behaviours came to be labelled as deviant by socially powerful groups (Nuehring and Markle, 1974). Within the latter framework many studies have been written on the social construction of drug use as deviance (cf. Markle and Troyer, 1979 and Nuehring and Markle, 1974 on smoking; Reasons, 1974 on narcotics). All emphasise that the claims making activities of groups should themselves form the distinctive subject matter of social problems that sociologists should study, since these activities form the process by which societies define and maintain a putative condition as a problem and without which the social problem would cease to exist (Kitsuse and Spector, 1973). Within these accounts, Gusfield's (1966, 1967) work on the construction of excessive drinking as deviance through the American Temperance Movement is regarded as seminal and given that the attempt to define drug addiction as disease can be argued to be derived from, and secondary to, the more important attempt to define alcoholism as disease, it is this account that will be examined in more detail (cf. Parssinen and Kerner, 1980).

Gusfield (1967) argued that the public affirmation of a norm through law and government action expresses the public worth and legitimacy of one sub culture over others. When these norms are threatened by acts which deviate from them, they incur a reaction from those who conform and uphold the norms. Whereas for Durkheim the nature of the societal reaction differs in relation to the frequency of the deviant act or the actual threat to the existence of the norm, for Gusfield the reaction depends on the symbolic import of the act of deviance for the status of the norm where deviance can broadly be divided into three forms: repentant, sick and enemy. The 'repentant' deviant is seen to suffer a moral lapse from a cultural norm they none-the-less aspire to: 'The open admission of repentance confirms the sinner's belief in the sin. His threat to the norm is removed and his violation has left the norm intact' (p180). Acts carried out by the 'sick' deviant are irrelevant to the norm, and neither attack or defend it since: 'the sick person is not responsible for his acts. He is excused from the consequences which attend the healthy who act the same way' (p180). The last category contains those most dangerous to publicly affirmed

values, since they are neither sick nor repentant, but are rather the upholder of an opposite norm: 'he accepts his behaviour as proper and derogates the public norm as illegitimate' (p181). These categories are not static and deviant acts or behaviours can pass from one moral status to another, which accounts for the historical changes often found in the treatment of deviants such as alcoholics, drug addicts and other 'criminals'. In particular, when the deviant and designator perceive each other as enemies, if anything changes to increase the power of the deviant to attack the norms of the dominant social group, the struggle will centre on the maintenance or change of the legal norm as the ultimate symbol of social power and status:

'The public definition of behaviour as deviant is itself changeable. It is open to reversals of political power, twists of public opinion, and the development of social movements and moral crusades. What is attacked as criminal today may be seen as sick next year and fought over as possibly legitimate by the next generation' (p187).

Within this context, Gusfield proceeds to examine drinking as a changing form of deviance through the rise of the American Temperance movement, to highlight how cultural conflicts find their expressions in the symbolic functions of the law. He argues that the drinker began to be seen as an object of social shame in the early nineteenth century with the growth of temperance organisations, which sought to replace patterns of heavy drinking with the norms of abstinence and sobriety. While the moral condemnation of those within temperance organisations could not prevent drinking and drunkenness completely, those that persisted were defined as repentant, thereby affirming the definition of respectability that matched the ideals of sobriety of the middle class. However, in the 1840s the rapid influx of Irish Catholic and German Lutheran immigrants saw the characteristics of the urban poor change greatly, bringing with it a more accepting culture of drinking. By the 1850s the issue of drinking had become a general clash over cultural values and persistent heavy drinkers became a threat to the dominant ideology and were redefined as the 'enemy'. However, although the temperance movement sought political allies it was limited by the opposing values of the urban electorate, which polarised during the Prohibition campaigns (1906-1919) and during the drive for repeal (1926-1933), greatly intensifying the symbolic significance of victory and defeat. For Gusfield, even though Prohibition measures were limited in their enforcement, the symbolism couched in the law made it clear whose ideology was being upheld. However, after repeal, public affirmation of the temperance norm subsided and with it the definition of the deviant changed again; by 1933 chronic alcoholism had begun to be reconstructed as a disease in the US and the 'enemy' was being transformed into the 'sick.' Gusfield argues that because the designation of illness casts acts of deviance as irrelevant to the norm, supporters of Temperance and Prohibition were hostile to efforts to redefine the deviant character of alcoholism and deeply opposed to reports which took a less moralistic view. Although power struggles ensued between those seeking to legitimise a disease model of

alcoholism and those seeking to retain a criminal model, new agencies concerned with drinking problems gradually excluded Temperance supporters from their domains, shifting the onus for action away from police enforcement towards the medical establishment. With the establishment of the Yale School of Alcoholic Studies in 1940 and the National Commission on Alcoholism in 1941, the foundations of addiction as disease were firmly laid and the moral disapproval with which alcohol use was viewed purportedly diminished.

However, while Gusfield's account is deft at highlighting some of the political, social, and economic interests vying to define certain phenomena as problematic and those attempting to counter such recognition, the paradigmatic allegiance to symbolic interactionism and functionalism results in a failure to address the politics of medicine itself (Turner and Samson, 1995). Gusfield depicts the 'sick' deviant as irrelevant to the norm; they neither attack nor defend it in lieu of their status as sick. While he doesn't intend that designating a person as sick is merely seen as a matter of establishing a medical fact, but rather a social designation since following Parsons ([1951], 1991) 'sick role', it has significant consequences for the reciprocal obligations the person has with others, the effort to define a practice as a consequence of illness is seen to be a political issue that exists outside of the institution of medicine itself. As such while medicine operates as an institution of social control, by designating the label sick and removing the threat of the deviant act from the stability of the norm, the motivation of the medical institution is justified solely on the descriptive level of demarcating disease from non-disease. The medical profession is not pitted against the supporters of Temperance and Prohibition but is rather set apart from other forms of political and social power which vie for legitimacy, and the politics of medicine itself are not addressed (Andersen and Kaspersen, 2000).

There have been many criticisms of the labelling perspective, some of which derive from its roots in symbolic interactionism, such as the challenge that it neglected issues of power and social structure, failed to locate labelling processes historically within particular social structures and was narrowly preoccupied with the interaction between deviants and lower-level agents of social control, ignoring the governing elites in whose interests these institutions actually operated. Others claimed it ignored the sources of deviant behaviour, was limited in its application, too deterministic in its conception of the labelling process and that it presented criminals as victims (Davis, 1975; Gibbs, 1966; Neff and Orcutt, 1978). Further, it has been argued that it failed to develop the conceptual and methodological tools necessary for the rigorous analyses of the processual phenomena involved in definitional reactions to deviance, and its teleological character of explanation has also been targeted in line with more general criticisms of functionalism which appeared in the late 1960s (Andersen and Kaspersen, 2000; Marshall, 1998; Pfohl, 1985).

Plummer (1979) has argued that many of these criticisms were unfair and arose from a misunderstanding of the aims of the labelling theorists. They couldn't explain why some people were criminals and not others, but their aim was never to locate the aetiology of the condition or behaviour, rather it was explicitly uninterested in the primary causes of deviance and sought instead to understand the social processes by which some conditions and behaviours, and not others, came to be regarded as deviant. However, at around the same time that these critiques abounded, there was a wider transition from a largely uncritical applied sociology *in* medicine, to an externalised and critical sociology *of* medicine, which moved focus to the issues of power between doctors and patients and between medicine and the state. This led to a corresponding shift away from symbolic interactionism and functionalism, which neglected the politics of medicine, to various Marxist paradigms which were far more critical of health care organisations and the healing professions (Cockerham, 2005; Pilcher, 2004; Turner, 2004).

1.5. FROM BADNESS TO SICKNESS: THE MEDICALISATION THESIS

Freidson (1970) provided an alternative to the functionalist view of medicine as a beneficent and politically neutral institution, depicting it rather as a group of actors' intent on professional autonomy. Zola (1972) subsequently put forward his medicalisation thesis, emphasising the process whereby more and more areas of everyday life were coming under the jurisdiction of the medical profession, regardless of its ability to deal with them effectively, and its presence as an institution of social control. The thesis was extended by Conrad and others who stressed the definitional issue; that the essence of medicalisation consisted in defining a problem in medical terms, using medical language to describe it, adopting a medical framework to understand it, or using a medical intervention to 'treat' it, thereby acting as a means of social control (Conrad, 1992). Theoretically the key addition it would make to the sociology of social problems was the emphasis that it is those with power who create norms and label deviants, and that this must include medical professionalisation itself. Further, proponents such as Schneider (1985) emphasised that abstractions such as 'social forces' and 'social context' had no place in a sociology of social problems, distancing themselves from the earlier perspectives, since:

'Definitions are contingent not on historical circumstances but on the particular collective activities of particular people at particular points in time. While the cultural surround differentially provides symbolic categories and behavioral scenarios as resources for these activities at different historical times, it is people acting together – not 'social context' – that use, make, and change meanings in social life' (p233).

From this perspective Schneider (1978) has examined the construction of excessive drinking as a disease, viewing it as a social accomplishment. Schneider links the twentieth century 'success' of the disease concept of alcoholism to three developments – the work of the self-help group Alcoholics Anonymous, AA, founded in 1935, the establishment of the scientific Yale Research Center of Alcohol Studies in 1943, and the influential work of the physician and director of the Yale Center, E.M. Jellinek. The post-Prohibition founding and subsequent growth of AA propounded the view that alcoholism was not a mental illness, brought about through poor moral judgement to know what is wrong, a lack of self-control and self-reliance, but was rather an allergy of the body, the result of a physiological reaction to alcohol. Although medical opinion was sceptical of this formulation, by identifying alcoholism as a bona fide 'disease' or medical condition, individual drunkards became victims, who ought to receive medical treatment rather than moral scorn and punishment. For Schneider, AA's implicit disease concept is found in steps one to three of the famous 'Twelve Steps' to recovery. In the first and most fundamental, 'we admitted we were powerless over alcohol-that our lives had become unmanageable', Schneider sees the concept of the 'loss of control' that was to become the foundation of the 'Jellinek formulation'. The 'power greater than ourselves [which] could restore us to sanity' of the second step, is seen to be that of medicine, with the physician taking on the role of 'God', exerting control over the legitimacy of sickness and disease designations and admission to treatment through Parson's ([1951], 1991) sick role. The third, '[We] made a decision to turn our will and our lives over to the care of God *as we understood Him*', although sounding traditionally religious was to be interpreted on the basis of the individual's own biography, which for Schneider is akin to the acceptance of a regimen prescribed by a physician for a disease.

As Schneider (1978) details, the work of Jellinek was crucial to the spread and popularisation of the disease definition of alcoholism. In an important paper published by the World Health Organisation in 1952, Jellinek sought to make a clear distinction between problem drinking and alcoholism as disease. Although both types were seen to have an underlying psychological or social pathology that led to drinking, only the latter, where sustained drinking over a number of years had resulted in a loss of control, was to be regarded as addiction and therefore a disease. As he notes, such a distinction was important for the viability of the disease view given the socio-political context in which alcoholism was primarily regarded as a moral failure, to be dealt with as criminal behaviour: 'first because it serves to define the boundaries within which medicine could (and should, according to Jellinek) operate; second, because it suggests that forms of deviant drinking not properly called disease should be managed only on the level of applied sociology, including law enforcement' (p367). Non-disease forms of drinking remained moral problems to be met on moral terms, but disease forms deserved the attention of, and treatment by, the medical community.

However, Jellinek offered no definition of addiction, and the key demarcation between problem drinking and drinking behaviours indicative of disease lay in the physician's diagnosis of a loss of control. After Jellinek's death, Mark Keller, his colleague at the Yale Center who became the leading spokesperson for the disease concept of addiction, tried to refine the key criteria for the diagnosis of addiction:

'Would the individual be expected to reduce his drinking (or give it up) in order to avoid the injury or its continuance? If the answer is yes and he does not do so, it is assumed – admitting it is only an assumption – that he cannot, hence that he has "lost control over drinking", that he is addicted to or dependent on alcohol. This inference is the heart of the matter. Without evident or at least reasonably inferred loss of control, there is no foundation for the claim that "alcoholism is a disease" except in the medical dictionary sense of diseases… caused by alcohol poisoning' (Keller, 1962, in Schneider, 1978, p369).

As Schneider (1978) argues, the salient criterion then is an inference that the individual would give up if they could. If alcohol consumption is regarded by others to be excessive and the cause of harm either to the individual or to others, and the individual does not cease to drink, even though they are aware of the 'obvious' harms it is doing, it is assumed they are not in control of their will, regardless of their desire. This loss of will is said to be explained by the medical model of addiction, however, as Schneider argues, predicating this inference of loss of control in a cultural system in which the values of rationality, personal control, science and medicine are given prominence, directs the designation of disease to the affirmation of dominant cultural and institutional values. In some aspects, Schneider (1978) draws on Gusfield (1967), viewing the medicalisation of deviant drinking behaviour and the rise of the disease concept of alcoholism as a transformation of non-normative behaviour from the status of a sin, to that of a crime to finally a sickness, which is akin to Gusfield's functional typology. For Schneider however, based on the foundations of medicalisation in a critical sociology of medicine, the application of the label becomes an instrument of political control by members of the dominant healing group in their ever expanding drive for professionalisation whereby:

'Treatment and therapy, allegedly employed in the individual's and community's interest, became the 'reasonable' and humanitarian solution. The historical trend whereby persons deemed incapable of wilful criminal or wrong intent have been subjected to 'treatment' rather than punishment has been called the 'divestment' of the criminal justice system and the rise of the 'therapeutic state' (1978, p363).

The medicalisation thesis has been applied not only to 'deviant' social behaviours such as compulsive gambling (Rosecrance, 1985) hyperactivity and other childhood behaviours (Conrad, 1975) and Attention Deficit Hyperactivity Disorder in adults (Conrad and Potter, 2000) but ordinary, 'normal' conditions of life, such as the menopause (Bell, 1987), and more recently, race

(Witzig, 1996). However, while such critiques have been very successful, especially in terms of highlighting how medical discourses have tended to individualise and problematise cultural and historical variations in behaviour, they are also subject to critique on a number of different levels.

The 'orthodox' version of medicalisation, such as that propounded by Conrad and Schneider ([1980], 1992) was challenged by Strong (1979) for its extreme and sweeping claims about the professionalisation of medicine and the role of medicine in society. While he accepted that the medicalisation critique provides a series of checks and balances to medicine's own preferred image of itself and the professional dominance upon which this rests, Strong argued that sociologists were themselves imperialist rivals to the medical profession. They too were seeking to expand their own domain, and the social model of health and illness they themselves advanced was a much better vehicle for medical imperialism than the much criticised biomedical one. Further, the medical profession was not a single entity but rather there were many factions within it and therefore evidence from one condition or area cannot simply be extrapolated to the profession as a whole. Williams (2001) has revisited Strong's (1979) criticisms and assessed their importance for the shape of debate today. Williams main criticism of the orthodox version of medicalisation is that it fails to recognise the value that people place in the outcomes of medicine such as good health, the relief of pain, and recovery from illness, and further discounts the ways that patients willingly participate in medical dominance and may indeed seek medicalisation. By focusing on the 'failures' of the medical profession, and not the 'successes' such as coronary artery by-pass, renal dialysis, hip replacement, cataract surgery, blood transfusion and so forth, it denies the validity of the everyday experiences of the lay public in modern Britain. In emphasising the limitations of medical intervention, medicalisation critiques have too frequently ignored the physical and social contributions of medicine, and as recent empirical studies of lay experience have shown, modern medicine is often viewed by people as a critical resource rather than simply curative or oppressing. Indeed, lay voices should become 'important arbiters in these and other debates, providing a much needed series of empirical checks or balances to broader theoretical claims and contentions' (p142).

Further, while the orthodox medicalisation thesis was to successfully politicise the professionalisation of medicine, it did not challenge scientific knowledge itself or the realist belief that there was an objective underlying biological or natural reality which scientists could, in principle, have access to. For example, in *Deviance and Medicalization: From Badness to Sickness* ([1980] 1992) Conrad and Schneider viewed labels such as 'sickness' 'illness' and 'disease' as 'instruments of political control rather than scientific achievements' (p361). The disease concept of alcoholism is portrayed as stemming from 'variously interested parties, rather than to substantive scientific findings' such that it is depicted as 'primarily a social rather than a scientific

or medical accomplishment' (pp370-371). Again, when speaking of David Davis' research on alcoholics that found that some people had returned to social or normal drinking practices after leaving treatment facilities, which was subject to severe criticism upon publication as invalid and premature, Conrad and Schneider report that 'it was almost an act of heresy rather than simply reporting an objective finding' (p105).

It was within this context of the medicalisation critique and the wider anti-psychiatry movement of the 1960's and 70's, opposed to a realist view of psychiatric illness, that Foucault's *Madness and Civilisation* arrived in 1961 (2006). Criticising the eighteenth century reconstruction of madness as a disease by Dr Benjamin Rush in the US, the founding father of both the Temperance movement and American psychiatry, and the rise of 'scientific' and 'humanitarian' treatments of the insane by Pinel and Tuke in Europe, Foucault argued that such 'moral treatments' were in fact no less controlling than previous methods. Rather, as madness became a curable disease, the chief symptom of which was loss of self-control, such treatments sought to restore the power of self-discipline to those who had lost it by imposing a universal form of morality from within. The patient was restored to sanity by the transfusion of the will of the physician, through repeatedly enforcing patterns of judgment and punishment until they were internalised and reproduced, in order to reawaken in the patient a sense of the moral order from which they had become divorced (Foucault, 2006).

Perhaps the greatest import of Foucault's early work was to emphasise that disciplinary power was not located solely with physicians, but was rather diffuse and localised, operating through knowledge and embodied in the day to day practices which produce particular individuals, institutions and cultural arrangements. This became more prominent in his later work with the use of 'biopower' as a key guiding notion that differentiates the forms of power the state exerts over its citizens, by acting both on the individual body and on the body politic (Foucault ([1976] 1998). Foucault links the rise of biopower in the eighteenth century to major transformations in the relationship between the state and its citizens. Prior to the classical age, the power of the sovereign over the population was that of the right to 'take life' or 'let live', where juridical systems of control would ensure the sovereign right of *prélèvement*, or deduction and death; the power to seize wealth, goods, services, labour and life by coercion and direct force (p89). However, the historical developments in the material and social realms following the seventeenth century Renaissance in the West, such as industrialisation and urbanisation, led to a shift away from collective and centralised conceptions of rule and social order, and also altered the ontological foundations of individual identity. As Heller, Sosna and Wellbery (1986) have discussed, the rise of 'individualism' in the eighteenth century, based on the political philosophy of the social contract, reconstituted the individual as a legal subject, a citizen inscribed with rights and duties, where the

state may only exert punishment if the individual's own actions break the terms of the contract which have been politically determined in advance. This view of the individual human subject as the maker of the world we inhabit matured into the now dominant autonomous self-representing individual of Western moral philosophy, so fundamental to modern definitions of the self and now institutionalised in an elaborate array of economic, legal and political structures.

For Hacking (1986), the emergence of the 'individual' in Western thought is intimately connected with the rise of social control, and the way in which we have come to understand normality and deviations from those norms. As Foucault ([1976] 1998) argued, law alone could not explain the new mechanisms of power of the state over its citizens; rather in a 'free society', maintaining the social order required shifting social control to the individual level, since the dominant capitalist values of rationalised labour and productivity were incompatible with a Dionysian pursuit of pleasure and the abandonment of self-control. The right of *prélèvement* became only one of a number of new and diffuse forms of power which worked to 'foster life' or 'disallow it', disciplining and controlling populations by monitoring and regulating bodies (p136). In the new social order, mechanisms of power didn't function predominantly through punishment or coercion, but through the normalising agencies of social investigation and scrutiny such as medicine, education, insurance and childcare which work to create self-control and social order, and the penal option becomes only the coercive end of a much broader continuum. Power is: 'not ensured by right but by technique, not by law but by normalization, not by punishment but by control, methods that are employed on all levels and in forms that go beyond the state and its apparatus' (p89).

Foucault depicted the new strategies of control as two strands of power, distinct yet linked by a cluster of relations, and inextricably bound up with the rise of the life sciences: disciplining the body and regulating populations. The former he termed an 'anatomo-politics of the human body', directed at disciplining the body to produce productive entities capable of assimilation into the new machinery of capitalist production. The latter, 'a biopolitics of the population', worked to adjust the population to meet the demands of the economic processes, by assiduously cultivating health and well-being through the regulation of the biological life processes of the social body such as the size and quality of the population, reproduction and sexuality, health and disease, and birth and death ([1976] 1998, p141). Rose (2001) illustrates this with reference to the two biggest state-sponsored biopolitical strategies of the early twentieth century across Europe and North America. First, the 'neo-hygienist' programme mediated between political concerns for the fitness of the nation and personal techniques for the care of self, by individualising earlier hygienic concern with external conditions and seeking to instil habits conducive to physical and moral health into every individual through the normalising processes of the domesticated home and the school. The second, the eugenics movement, also sought to maximize the fitness of the population, but by

relieving the economic and social burdens of disease and degeneracy in the future by acting upon the reproductive decisions and capacities of individuals in the present.

Turner (1997) sees Foucault's interest in the 'institutions of normative coercive', such as the law, religion and medicine, as an exploration of how medicine and religion exercise a hegemonic authority over individuals by explaining their problems and providing solutions for them. Such power need not be violent or authoritarian, and is not repressive, but is rather legitimated and productive as it becomes central to the way in which individuals voluntarily engage in the conduct of everyday life. Although *Madness* was quickly taken up by the anti-psychiatry movement and used to demonstrate the despotic tendencies of psychiatry, Foucault (1988) himself argued that what he had wanted to elucidate was the interaction between 'technologies of power', which determined the conduct of individuals and submit them to certain ends, and 'technologies of the self', whereby individuals engaged in self-discipline. Of key importance to Foucault's later work was the interrelationship of these technologies, which constituted the new art of government, essentially concerned with the question of how best to manage individuals, goods and wealth such that the state would prosper, in the way a good father would manage his family affairs ([1978], 1991). As Foucault (1988) acknowledges however, in his earlier work he tended to emphasise technologies of domination and power over those of the self, and it was not until later in his career that he elaborated more fully on his conception of the self and governmentality; how we come to know and understand ourselves and act on these selves through self-discipline, and the interaction and way in which forms of social control become internalised and constitutive of self-discipline (Turner, 1997). However, there are many readings of Foucault, and scholars have differed markedly in their interpretations of whether the body itself was entirely discursively fabricated, or whether there was an essential biology that continued across time (Armstrong, 1997). The perspective taken here is akin to that of Lupton (1997), where the phenomenological body is an active agent in the constructions of the discourses which surround it. As Shilling argues:

'Bodies may be surrounded by and perceived through discourses, but they are *irreducible* to discourse. The body needs to be grasped as an actual material phenomenon which is both affected by and *affects* knowledge and society' (Shilling, in Lupton, 1997, p103, italics in original).

As such, lived experience and the ways in which people respond to external discourse and the strategies that attempt to discipline them are crucial, offering insights into how the clinical gaze or the discourses and practices of medicine are resisted and contested by individuals (Lupton, 1997). It also mitigates the criticisms of Strong (1979) and Williams (2001) noted above, recognising that individuals are often willing participants in medicalisation, actively engaging in practices they consider important to their own well being. However, depictions of the rationally calculating, self-reflexive and self-maximising autonomous individual of Western liberal philosophy of which

Foucault was so critical cannot fully encapsulate the practices by which people reproduce or resist techniques of domination (Bunton and Petersen, 1997). Rather, as Lupton (1997) argues, with the impact of post-structuralist theory, notions of subjectivity which acknowledge the 'fragmented self' or 'contradictory self' have been posited, recognising the emotional and irrational aspects of self and the ambivalence of subjectivity, where the ways in which people come to understand themselves and interact with others is seen to be dynamic and contextual rather than static. Drawing on post-structuralist and Foucauldian critiques of medicine, new versions of the medicalisation thesis have emerged, which coincide with versions of constructivism derived from other perspectives, such as those within STS (cf. Bijker, Hughes and Pinch, 1989; Bijker and Law, 1992; MacKenzie and Wajcman, 1999). All emphasise that medical knowledge itself is not simply a given and objective set of 'facts', but rather a belief system shaped through social and political relations which in turn mediates these relations, analogous to the earlier discussion of the social construction of statistics (Gabe, Elston and Bury, 2004, White, 2003). Consequently, a broadly Foucauldian perspective has been used to frame this constructive technology assessment of the development of vaccines for addiction.

However, before the developments of the post-WWI era and the rise of behavioural pharmacology are examined, it is important to elaborate the origins of the medical model of addiction in the developments of the eighteenth century charted by Foucault, since these were fundamental to the separation of 'Will' from 'Desire' which was to enable the medical model to emerge. Given the size of the volumes which have sought to trace the social history of alcohol, drugs or smoking in just one country, this sketch will necessarily be only provisional and partial, but by drawing on the work of a number of scholars who have been broadly based within a Foucauldian or constructionist framework, it will endeavour to highlight several of the major inter or intra- paradigmatic shifts that have characterised popular thought about addiction since the eighteenth century in both the US and the UK.

1.6. THE BIRTH OF THE MODERN ADDICT

As White (2000) has argued, the debate over the disease concept of addiction is not a meaningless intellectual exercise, for any framework for understanding alcohol and drug problems exerts a profound influence on the lives of individuals, families, social institutions and communities. The depiction of addiction as either a medical or moral phenomena holds important implications for treatment and responsibility since if addicted people are suffering from a disease they are in need of medical treatment instead of punishment, since the less (currently) voluntary a behaviour pattern is the less justifiable it is to punish people for being subject to it

(Kleiman, 2003). Janssens *et al* (2004) have argued that in the UK and France a medical anthropology is dominant, where drug use is primarily seen as an individual problem, with behaviour largely excused as the outcome of the disease and the addict is depicted as a patient in need of help. Conversely, in the US, Germany, the Netherlands and Sweden, where a legal anthropology is dominant, addiction is regarded as a societal problem and a self-inflicted condition where the addict chooses to use a certain drug knowing the risks involved and, as such, must be held accountable for their actions. However, as White (2000) emphasises, no single model of addiction has ever fully replaced its competitors; rather radically different conceptualisations of alcohol and drug problems have always co-existed and citizens have always been ambivalent about whatever model claimed temporary prominence. As such, the socio-political histories that have profoundly shaped how certain uses of alcohol and other drugs came to problematised, and the solutions and mechanisms of governance that were developed in response to these conceptualisations on either side of the Atlantic, will be briefly examined.

In Britain, 5% proof ales, ciders and mead were the staple drinks of the lower classes from at least the eighth century, due largely to the lack of safe water supplies uncontaminated by sewage, and hard drinking was built into the fabric of social life, but it was not until the eighteenth century, during the industrial revolution, that concerns were raised over the alcohol use of the working classes. At the end of the seventeenth century, encouraged by a range of legislation aimed at restricting brandy imports from France at a time of political and religious conflict and the opening up of the home distillation market, 60% proof gin became widely available (Dingle, 1972). With no historical or cultural regulations of use and large numbers of people from rural communities drawn into urban slums for unskilled labour, informal social controls and regulations around alcohol use broke down and consumption levels escalated as gin became the escapism for the working class masses living in deprivation and working long hours in factories, especially in London (Warner, 2003). The 'gin craze' led to moral outrage by the middle-classes and a series of Acts were passed from 1736 which aimed to control the use of gin and the moral degradation of the working classes through tax and regulation, as famously depicted by Hogarth's etchings of 'Beer Street' and 'Gin Lane', published in support of the 1751 Gin Act (Dillon, 2004).

As a new social order emerged during the industrial revolution in order to increase production, conformity was drilled into the masses as part of an agenda of 'betterment' through the early middle-class temperance movements which sought spiritual and legal reforms in the early nineteenth century (Abel, 2001). However, as Garland (1981) argues, the relationship between the dominant middle-classes and the lower classes in the nineteenth century was primarily one of repression and exclusion by coercive means. Confined by the daily effects of casual and seasonal employment, and debilitated by structural and environmental conditions such as bad housing and

sanitation, the conditions of life which produced unemployment, poverty, criminality and destitution of the lower classes were suppressed beneath a discourse of moral individualism, self-help and freedom by the ruling middle classes. The Poor Law and its institutions did not seek to address the structural effects of 'unfreedom' by directing relief to the prevention of poverty itself, but sought to suppress 'pauperism' and other moral categories of persons seen as a threat to the social order. For Garland, the Victorian prison and the Poor Law acted as the inverse of the 'social security net' of the twentieth century; not seeking to counter the social contradictions and problems of the market through welfare provision, but rather policing and removing the segments of the population who were unable to cope, effectively transferring the concepts of economic liberalism into the realm of punishment:

'In direct replication and support of broader ideologies their practices combined to constitute the offender as an individual subject, the carrier of responsibility, reason and liberty. The twin doctrines of individual responsibility and presumed rationality formed the basis for the judicial findings of guilt - since in free-market society the criminal actor - like his economic counterpart - was deemed to be in absolute control of his destiny. Reason and responsibility were absolute and essential attributes and since freedom was guaranteed by market society, there could be neither excuse nor mitigation for crime - at least none short of absolute insanity' (p31)

However, as the disjuncture between dominant ideology and the realities of life for the working class widened as problems with industrialisation and urbanisation multiplied during the nineteenth century and the conditions of the working class became more visible through the use of social surveys and measurement, concerns mounted over the decline of the empire and the moral and physical degeneration of the nation (Garland, 1981). As Valverde (1998) discusses, it was within this context that alcoholism as disease emerged, produced through the ongoing cultural debates which pitted science against law and religion as to the nature and extent of individual human responsibility that epitomised Victorian society.

Following the rise of the asylums in England and France, 'monomania' or 'moral insanity' had arisen as diagnostic categories, occupying the grey area between madness and reason, as a form of derangement that led people to commit violent crimes, but not akin to full-blown madness and not accounted for by 'an alienation of reason,' but rather viewed as 'lesions of the will' (p45). Subdivided into the three-fold classification of the faculties of the mind, 'dipsomania' was the term coined to refer to a particular form of volitional monomania that was commonly rooted in heredity. The meaning of the term shifted over time, from an initially broad definition of what is now termed alcoholism, to a restrictive emphasis on occasional bouts of drunkenness, and by the mid nineteenth century the treatment of dipsomaniacs was being hotly debated. Although some regarded dipsomania as a degenerative nervous disease, and distinguished it sharply from

habitual drunkenness as a 'vicious custom', others argued that they should be subject to the legal sanctions applicable to those suffering from moral insanity, since both were diseases of the will. Advocates of the institutionalisation of inebriates drew on parallels with compulsory vaccination, arguing that although the liberty of the subject was important, the welfare of society was more sacred (Valverde, 1998). However, in an era that had come to be dominated by the popularisation of Darwinian evolution, explanations for Britain's multiplying difficulties were increasingly sought in the interaction of changing environmental conditions and organic adaptation, through a branch of evolutionary science known as degeneration theory. By the 1880s and 1890s, the belief that the rapid growth of the towns and the transformation of Britain from a rural to an urban society were having a profound and deleterious effect upon the physical health of the population, especially the labouring poor, was pervasive (Soloway, 1982). Degeneration theorists were critical of the traditional religious and scientific notions of free will, and proposed a new relationship between alcohol and the will. Blaming moral vices for causing physical degeneration, heavy drinking became popularly and medically regarded as part vice, part disease, and was easily assimilated into theories of degeneration. As the consumption of morphine and other drugs became more visible in the 1880s, they were problematised by analogy to drinking and treated by British physicians as part of the much wider problem of inebriety, rather than as a unique problem to be discussed singularly (Parssinen and Kerner, 1980).

Founded in 1884, the work of the Society for the Study of Inebriety, SSI, subsequently popularised the belief that inebriety was a disease, to be dealt with through medical intervention, rather than as a vice, which would be subject to criminal law and moral disapproval. Narcotics were subsumed within this, commonly accepted to be less harmful to society than alcohol, but more detrimental to the individual (Parssinen and Kerner, 1980). According to the president of the SSI, Sir William Collins, drinking was 'a disease of the will ... and assuredly a disease in which the individual possessed has in many instances a most essential cooperative influence in his own worsement or betterment' (Berridge, 2004, np). While the moral and medical approaches to addiction were not distinct, the outcome was to move towards a medico-legal view of addiction, defined by its scientific and specialist focus, and away from what was seen as an unscientific view based on social reform and morality that was promulgated by health and social reformers (Porter, 2006). By the end of the nineteenth century, the construction of the addict as lunatic had faded, and the category of dipsomania had become synonymous with the legal categories of 'habitual drunkard' or 'habitual inebriate' which constructed alcoholism as a degenerative nervous disease and would go on to provide the basis of the model of alcoholism as 'loss of control', popular in the post WWII period (Herd, 1992). However, as Valverde (1998) argues, as addiction was naturalised into a disease of the will, its ontological nature remained obscure, a 'hybrid object,' both physical and spiritual. While inebriety could be taken as evidence of an inherited 'neuropsychopathic

constitution', an abnormality of the nervous-mental structures, drug treatments were confined to restoring a weak nervous system and recovery ultimately demanded moral repair through the strengthening of the will. Although some physicians viewed moderate intake as relatively harmless, degeneration writers increasingly came to regard alcohol as a 'racial poison', sympathising with temperance concerns that were intertwined with, and reinforced by, scientific eugenic fears (p52).

Garland (1981) argues that these discourses of degeneracy and eugenics combined with the threat of a working class alliance around demands for state provision of welfare, to necessitate a shift, away from a penal system of control based on repression and exclusion, to more systematic and penetrating forms of discipline through the normalising functions of the Welfare State. As a multitude of official investigations turned to combating the degeneration of the nation through the positive powers of social hygiene, housing and free school meals, marginalised sections of the population that were deemed 'unfit' and a threat to the new social order, such as vagrants, the 'feeble-minded' and inebriates, were diverted into a newly extended penal realm which was intended to provide facilities for those whose 'irregular mode of life' was seen to require administrative intervention and segregation (p40). It was in this context that doctors first came into a relationship with the state, through campaigns to secure legislation establishing a state-funded treatment structure for inebriates of all classes, such as the British Habitual Inebriates Act of 1898 (Berridge, 1997). As Parssinen and Kerner (1980) argue, nineteenth century medical men were appropriating certain functions previously exercised by priests to become the new guardians of morality, transforming old sins to be confronted and overcome into diseases to be cured, carving out a new autonomy for themselves by the power they wielded first in the medical schools, and eventually in major teaching hospitals. For Garland (1981), this laid the ideological and institutional basis for the positive administration, segregation and normalisation of large sections of the population through opening up the logic of coercive assistance, which enabled the state to police not only individual acts through the courts of law, but to inspect and control individuals themselves. However, as Valverde (1998) notes, the Act itself cannot be taken as an instance of the relentless medicalisation of deviance since the physician was accorded no role in the diagnosis of the condition and the Act did not attempt to construct a homogenous population of medicalised inebriates, but rather fragmented it. Treatment remained differential, with poor and often female individuals subsumed under the category of 'feeble-mindedness' and sent to inebriate reformatories where they were subjected to the same techniques of moral therapy used in the asylums, and privately paying middle and upper class patients entering 'retreats' or benefiting from a more empowering form of pastoral care with their personal physicians (Valverde, 1998).

As Berridge (2004) argues, although the utility of moderate alcohol and drug use had been controversial in the mid to late nineteenth century, by the turn of the twentieth century the focus of the temperance movement in Britain had shifted away from the elimination of all drink to the reduction of licences, and to temperance education as part of social hygiene. However, as concerns mounted over a cocaine 'epidemic' spreading in the army after prostitutes were found selling cocaine to soldiers in the First World War, drug addiction emerged in Britain as an entirely separate issue in both professional and public literature (Berridge, 1988; Parssinen and Kerner, 1980). As Berridge (2004) highlights, the divergence between alcohol and drug use can be understood in terms of a number of technological, political and cultural factors. For alcohol (and later with smoking), technological change enabled the mass-market production and sale of a standardised product, conversely, as the hypodermic syringe became widely available it led initially to the restriction of the opiate market and a more medicalised model. Further, while there were substantial alliances between the alcohol industry and political interests, with alcohol taxes of crucial importance to western finance, the production and trade in opium products and coca was more confined. These interacted with their changing cultural positioning, and whilst the part medical, part social concept of moderate drinking was successfully defended, non-medical moderation for drugs disappeared in the late nineteenth century as acceptable practice, and was replaced by medicalised maintenance.

In comparison, although commonly situated in mid-nineteenth century America, both Levine (1978) and White (2000) stress the importance of recognising the emergence of alcoholism as disease in the US through the temperance movements of the eighteenth and early nineteenth centuries. In contrast to Britain, as Martin and Midgley (2003) argue, America can be seen to be a country founded as a nation of 'individuals', born of dissatisfied middle-class English men and women, who emigrated to America for religious, political, and economic freedom and the chance to prosper in a new land. During the political upheaval of the last half of the eighteenth century as the colonists sought independence from the British Empire, John Locke's ideas on liberal political theory had a formative influence, with the American Declaration of Independence of 1776 based on Locke's proposition that governments derived their just powers from the consent of the governed (Rodriguez, 2007). Although it must be acknowledged that the right-bearing individual of liberal contract theory in America can only be meaningfully seen to have been embodied in the white and male population (Armitage, 2004), this cultural and political heritage had a marked influence on the emergence of the disease model of alcoholism.

As Lender and Martin (1982) have explored, although the settlers brought with them a cultural allegiance to beer, finding colonial beers 'not good replicas of those brewed in England' they turned to local ingredients or planted foreign fruits on their arrival in America, and by the late

seventeenth century a fundamental shift in colonial drinking preferences was well under way (p30). By the early 1700s, after the first commercial distillery had opened in Boston, rum had become the most popular beverage in the colonies and is cited with the credit for 'weaning the colonials once and for all, from the tastes of the Old World' (p30). The American tavern of the eighteenth century became a key social, cultural and political institution in every town and levels of alcohol consumption were far higher than they are today. But as Levine (1978) has argued, people were regarded as drinking, even excessively, 'because they wanted to, and not because they "had" to... alcohol did not permanently disable the will; it was not addicting, and habitual drunkenness was not regarded as a disease' (p493). Although the clergy, and especially the Puritans may have chastised against habitual drunkenness as a sin and a vice, and warned of the eternal suffering awaiting the drunkard in the next life, inebriety was not regarded as a social problem; individual drunkards were not viewed as symptomatic of a wider moral degeneration of the nation and there were no attempts to eradicate drunkenness from society. Drunkards were generally left to their own devices if able to support themselves, or grouped among the dependents in the local community and treated in the same way as the rest of the poor if they could not (Levine, 1978).

However, as settlements spread West in the eighteenth century, grain whiskeys began to compete with rum, which was too bulky and expensive to ship far inland. With the arrival of droves of Scottish and Irish immigrants who flocked to the frontier from the 1730s, bringing their distilling skills with them, by the end of the eighteenth century American grain spirits had become the staple diet (Lender and Martin, 1982). Alcohol consumption tripled between 1780 and 1830 and a pattern of socially disruptive 'frontier drinking' arose, as the community norms that had long contained drunkenness in colonial America began to break down (White, 2009). In response the temperance movement formed and would continue to become the largest nineteenth century mainstream mass movement in America, and it is from the work of its founding father, the physician Benjamin Rush, that both Levine (1978) and White (2000) locate the new paradigm of addiction which would evolve into the disease model of modern thought.

Drawing on Foucault's ([1973], 2003) work, Levine (1978) argues that the key distinction between the traditional habitual drunk and the modern alcoholic lies in the shift of the clinical gaze, from the external behaviour of the drunkard to their inner experiences and subjectivities. In the traditional paradigm, where the subjective experience of the drinker was even considered, they were described as 'one who loved to drink to excess'. 'Desire' and 'Will' were identical; if the individual desired to drink it was because drink was the object of their will. If the individual desired not to drink, it was because refraining was the object of their will. Thus when a drunkard

had a drink before them, they could freely choose to drink or to refrain; which they chose would depend on which seemed more agreeable.

'The point, of course, is that in choosing to drink or to get drunk, the drunkard chooses his pleasure, his "love"... There was nothing inherent in either the individual or the substance which prevented someone from drinking moderately, drinking was ultimately regarded as something over which the individual had final control. Drunkenness was a choice, albeit a sinful one, which some individuals made' (pp496-497).

However, Rush's work, embedded in Locke's differentiation between 'Desire' and 'Will', began to portray the drunkard as an individual who had completely lost their ability to drink moderately; it was not that they desired to drink, but that their will was diseased in some way, which resulted in an inability to prevent themselves from drinking to excess. Importantly for Levine the shift to the inner world of the drunkard, which made the emergence of a disease model of alcoholism possible, was a part of the more general shift to a medical model of deviance that was emerging by the end of the eighteenth and beginning of the nineteenth centuries in Europe and the US as part of the new worldview of the middle class. The structural requirements of daily life for self-reliant, self-making entrepreneurs and their families, and the assumptions of the individualistic worldview, meant that the chief concern of temperance supporters and the middle class in general was self-restraint. This resulted in a general 'inwardness' or reflexivity by which conformity was assured and the social order maintained, and a rising concern with the inner experiences of the drunkard (Levine, 1978).

The decline of the concept of evil in theology and moral philosophy was replaced by the optimism of the Enlightenment that society could be free from crime, poverty, insanity and drunkenness; deviance became unnatural and problematic, reconstructed as a social problem that could be solved. Levine (1978) quotes Boorstin who observed that: 'when the Jeffersonian came upon the concept of evil in theology or moral philosophy, he naturalized it into another bodily disease; a disease indeed of the moral sense, but essentially no different from others' (in Levine, 1978, p164). Like asylum advocates, temperance supporters were interested in helping people develop and maintain control over their behaviour and actions, building almshouses, penitentiaries, orphan asylums and reformatories to extend the techniques developed for treating the mentally ill to all those who had failed to regulate themselves properly by building up the dormant or decayed powers of self-control through discipline, routine and hard work (Levine, 1978). Importantly, although many authors (including Gusfield, 1967) depict the temperance movement solely as an attempt by one class or status group to change the behaviour of another, Levine (1978) argues that it was also self-interested activity. For temperance supporters, the wide availability and pervasive consumption of alcohol was regarded as the source of most social problems, which by virtue of the immediate effects of intoxication prevented people from living

moderate and restrained lives. Alcohol was therefore perceived as *inherently* addictive, its short term effects which reduced self-control and inhibitions seen to give rise to the inability of drunkards to control their behaviour over the long run, and therefore capable of destroying the lives of even the finest and most pious of citizens. Indeed, contrary to much thought, which depicts the disease model of alcoholism as apposite to the moral foundations of temperance ideology, both Levine (1978) and White (2000) argue that while moderate drinkers were derided as the 'enemy' by temperance supporters, the habitual drunkard was routinely viewed as 'sick' and a victim, and until the end of the nineteenth century the temperance movement had a largely sympathetic view of their plight.

Levine (1978) argues that developments in thought since, while important, are intra-paradigmatic and do not represent a gestalt shift in thought, since the modern conception of the alcoholic similarly focuses on the inner experiences of the individual and defines addiction as a disease because of the involuntariness of the behaviour. Further, Rush's belief that alcoholism was a progressive disease, the chief symptom of which was the loss of control over drinking behaviour, and whose only remedy was abstinence, later became the chief keystone of Alcoholics Anonymous, AA, and the work of Jellinek and others at the Yale Center of Alcohol Studies. As Levine notes, by shifting the gaze onto the inner world of the alcoholic:

'Ultimately, one is only certain that a heavy drinker has passed over the line to alcohol addiction if that person reports experiencing irresistible desires for the substance – if there is, in Jellinek's term, loss of control. From such a definition of the problem – as behavior beyond the control of the will – stems the tendency to view habitual drunkenness as disease, and the potential for a sympathetic attitude toward the alcoholic' (p499).

But as the twentieth century progressed temperance campaigns began to focus less on alcohol itself and more on its effects on the drinker, and especially its effects on society, as hostility to the political influence of saloons grew, regarded as a breeding place for crime, immorality, labour unrest and corrupt politics (Levine, 1978). As attention shifted away from the subjectivity of the drinker to the inherent dangers of alcohol on society, addiction came to occupy a less central role in the ideology of the temperance movement, which began to shift away from its broad reformist orientation, toward a single-minded concern with Prohibition as a means of engendering reform and the much maligned 'noble experiment' began in 1920 (Berridge, 2004).

1.7. REDISCOVERING ADDICTION AND THE INTERNATIONAL AGENDA

In the post WWII era the temperance ethos that had given rise to both prohibition and to medical theories of inebriety as a disease of the will was regarded as old-fashioned. The belief that morality consisted in suppressing desire came to be supplanted by Freud's views on the 'pleasure principle' and 'enlightened hedonism' which focused on channelling the pleasure of alcohol into 'healthy', moderate consumption, that could take a positive function in the new consumer-society (Valverde, 1998). In the vacuum that had been created after the original moral entrepreneurs of addiction as disease lost interest in furthering the concept towards the end of the nineteenth century, psychiatry came to dominate the field of addiction research and treatment until the 1960s (Warhol, 2002). Psychiatry as a profession itself dominated by the theories of Freud and psychoanalysis, addiction was depicted as symptomatic of an underlying conflict of the personality, an artificial or unnatural dominance of the 'Id' and dissolution of the ego; a disorder of desire resulting from disinhibition, regression and the substitution of artificial pleasures for real ones (Campbell, 2004).

Meanwhile, alcohol science emerged in the US as a new field, seeking to promote a scientific approach to moderate drinking which could transcend the legacy of prohibition, by acknowledging pleasure while monitoring dysfunctions (Valverde, 1998). Crucially, as the disease model of alcoholism was rediscovered by Jellinek and his colleagues in the mid-twentieth century, the source of addiction shifted from the drug itself to the individual body. As Levine (1978) argues, this was imperative to the new success of the disease model of alcoholism, since by reconstructing alcohol as both socially acceptable and at the same time, addicting to some people, it could now become acceptable to the masses and the only popularly and scientifically accepted person-specific drug addiction. When alcoholism came onto the international agenda in 1951 with the first meeting of the Alcoholism Subcommittee of the World Health Organisation, WHO, they emphasised the importance of alcoholism both as a disease and a social problem, and noted the need for a view on alcoholism that was medical and scientific, and not 'confused with political and social action against alcohol' (WHO, TRS No. 42, 1951, p4). They sought to define alcoholism in a way that was consistent with the expertise drawn from the different countries that made up the committee, agreeing on the term 'alcoholism' to denote 'any form of drinking which in its extent goes beyond the traditional and customary "dietary" use, or the ordinary compliance with the social drinking customs of the whole community concerned, irrespective of the etiological factors leading to such behaviour' (p5). Following Jellinek, (who was a specialist Consultant to the committee) alcoholism was viewed as a series of stages, each with a different significance for prognosis and treatment. The first stage was characterised as 'symptomatic drinking' where alcohol was taken to deal with a current problem derived from physical

conditions, psychological factors or social circumstances. In such cases, psychiatry emphasised that if the underlying problems that led to symptomatic drinking were addressed, it may be possible for the patient to resume moderate controlled drinking.

The second stage was characterised as a progression from the first, whereby the use of alcohol to mitigate problems became itself an issue, causing physical, psychological or social problems which could only be mitigated by the further use of alcohol. This was regarded as far more serious than symptomatic drinking, and was the 'condition of true alcoholism', which could also be termed 'addictive drinking' (WHO, TRS No. 42, 1951, p6). As Jellinek had never formulated a definition of addiction itself, and requiring one which would satisfy all the members, they looked to the work of the WHO Expert Committee on Drugs Liable to Produce Addiction, set up as the Expert Committee on Habit-Forming Drugs in 1949 to carry out medical and scientific evaluations of the abuse liability of dependence-producing drugs. They had put forward a definition of addiction as: 'a state of periodic or chronic intoxication, detrimental to the individual and to society, produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include: (1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; (2) a tendency to increase the dose; (3) a psychic (psychological) and sometimes a physical dependence on the effects of the drug (WHO, TRS No. 21, 1950, pp6-7). They demarcated addiction producing drugs from habit forming drugs as those that 'may be taken repeatedly without the production of all the characteristics outlined in the definition of addiction and which is not generally considered to be detrimental to the individual and to society' (p7).

This definition of addiction and its key characteristics reflected the history of the Expert Committee on Drugs Liable to Produce Addiction, founded in order to make recommendations to the United Nations Commission on Narcotic Drugs on the control measures that it considered appropriate, thereby playing a central role in the international drug control system. Since which drugs were defined as 'addictive' by the committee would have important implications for trade and commerce in 1952 in their third report the committee further clarified the distinction between 'addictive-forming drugs' and 'habit-forming drugs'. Addictive drugs were described as drugs whose 'specific pharmacological action, under individual conditions of time and dose, will always produce compulsive craving, dependence and addiction in any individual' (WHO, TRS No. 57, 1952, p10) Although addiction was believed to develop sooner in individuals whose psychological make-up led them to seek escape in the pharmacological action of drugs, 'sooner or later there must come a time when the use of the drug cannot be interrupted without significant disturbance, always psychic (psychological) and sometimes physical... Such drugs cause individual and sociological damage and must be rigidly controlled' (p10). By contrast habit-forming drugs were those that never produced compulsive craving, 'yet their pharmacological action is found

desirable to some individuals to the point that they readily form a habit of administration, an habituation' (p10). Psychological make-up was considered paramount in the use of such substances, which 'cause no sociological damage and do not need rigid control' (p10). They also clarified the grey area between the two categories for drugs whose:

'[P]harmacological action is intermediate in kind and degree between the two groups so that compulsive craving, dependence and addiction can develop in those individuals whose psychological make-up leads them to seek and find an escape in drugs. With these substances psychological make-up is the determining factor but pharmacological action plays a significant role. In some instances individual and sociological damage may develop, but since the incidence of the damage is not general, the type and degree of control of drugs of this group is better left at present to national consideration' (p10).

It was this definition of addiction that the Alcoholism Subcommittee settled on, with the reservation that the second symptom, that of a tendency to increase the dose, was not necessarily present in alcohol addiction, such that alcohol remained a borderline substance, part habit-forming, part-addiction forming, reflecting the reconstruction of alcohol as only addictive to vulnerable individuals. The more serious nature of addictive drinking impacted on the aim of the therapy: 'It must be recognized that such an individual cannot expect again to become a moderate drinker; the aim of the therapy must therefore be the achievement of complete abstinence. It is clear that some irreversible change in the individual has taken place, and it remains for further research to demonstrate the extent to which the irreversible change rests on psychological and physiopathological factors' (WHO, TRS No. 42, 1951, p7). The addict alcoholic could thus not hope to be 'cured' in the proper sense of the term; rather the aim was to arrest the condition by enabling the patient to remain permanently abstinent. Addiction to alcohol was presumed to have a physical basis, but as the lack of theories as to this physical basis implied that the treatment of alcohol was not 'purely a problem of internal medicine' and since excessive symptomatic drinking was a necessary prerequisite to the addictive phase, psychotherapy remained the mainstay of treatment.

After propelling the disease model of addiction to prominence, from the 1950s the role of alcohol in furthering the disease conception became more marginal, replaced by the growth of drug addiction science, or substance abuse research, as funding and institutional support for conducting abuse liability assessment expanded in the 1960s as drug use and addiction over-shadowed alcohol as the cause of social problems (Campbell, 2007). When the influential pharmacologist Maurice Seevers, one of the first generation of Americans professionally trained in pharmacology as it branched off from physiology in the 1930s joined the WHO Committee on Drugs Liable to Produce Addiction in 1951, he brought with him a firm body of internationally recognised work which sought to place addiction science on a more 'scientific' footing. Drawing

on the wider shift to experimental physiological research from the 1920s onwards, monkey colonies were organised as a means of developing an infrastructure for reliable experimental subjects for a variety of projects. For Campbell (2007), the monkey colonies were designed to create a research site where a particular kind of science could work: 'an experimental science designed to elucidate the neurophysiology of tolerance, dependence and withdrawal' (p29). Pharmacologists turned to animal models as a means to place their work on a more objective ground, by excluding psychological or subjective 'desire' for drugs from their research. Experimentation sought to show whether animals and humans responded similarly to drugs, and a set of meanings were attributed to the visual manifestations of animal behaviour and to the measurements of their physiological responses. Drugs were administered to the animal until they reached a 'steady state' where there was no change in heart rate or respiration, at which point they were interpreted as 'addicted'. The drug would then be abruptly ceased and another test compound or 'challenge' drug administered to measure withdrawal symptoms. Whilst psychiatry explained attraction to narcotics in terms of pathological character, pharmacology interpreted addictiveness as a chemical attribute of opiates that could be engineered away in future analgesics (Rasmussen, 2010).

However, as behavioural pharmacology began to take over from its parent discipline in the 1960s, the work of Charles R. Schuster and colleagues at the 'monkey colonies' at the University of Michigan began to displace the classical pharmacological approach, which moved away from a tight focus on basic research and physiological adaptations to drug habituation. Opposed to the hegemony of psychoanalysis the new breed of enthusiastic behavioural pharmacologists 'threw themselves into the political fray' taking on responsibility for policy, treatment and prevention as new political opportunities opened up in the early 1970s (Campbell, 2007, p187). The eclectic background of the behavioural pharmacologists, including Schuster, who had spent his early days playing jazz in Philadelphia, increased the social proximity between the researchers and the research subject, decreasing the isolation of the basic research laboratory and bringing new insights into the reinforcing properties of drugs. As Campbell (2007) writes, 'previous work had focused solely on chemical compounds that had visible, measurable effects on the bodies of monkeys and men. Now behavioral pharmacologists saw drugs as reinforcers of behavior, learning patterns and conditioned responses' (p188). This allowed them to invent new techniques, protocols and 'laboratory logics' for producing new knowledge about drug use and addiction; the self-administration model. The striking observation that nonhuman primates could be induced to self-administer the same drugs as humans to modulate their emotional and physiological states would revolutionalise the understanding of behaviour in the late 1960s and early 1970s.

As the self-administration model became the 'gold standard' of drug abuse research, it shifted the understanding of addiction away from mental and emotional states in favour of observable changes in behaviour. In direct contrast to the wider shift to population-wide assessments as epidemiology rose to prominence in the 1950s and 1960s, behavioural pharmacologists were not interested in inductive or deductive statistical measurements, but rather in the individual case, on the grounds that if an effect was properly demonstrated in one individual, it would eventually be found to be true of all. Although 'single-subject design' would ultimately lose out to statistical inference as seen by today's large-scale clinical trials, the focus on a single case reflected an interest in the human costs of addiction, and was in some ways the forbearer of contemporary 'individual treatment plans' in drug treatment. As Campbell (2007) elaborates, behavioural pharmacologists predicated their experimental and observational empirical approach on the inter-relationship of the 'microstructural foundation to the molar behavioral superstructure' and believed that physiological states and environmental contingencies modified drug effects (p183). However despite their recognition of complexity and multiplicity, Campbell notes that:

'Once complex transactions between drugs, behavior, and environment were recognized, behavioral pharmacologists acted to "strip away uncontrolled conditions" and reveal the lawfulness of behavior and its roots in "causally determined events"'(p186).

Although behavioural pharmacologists recognised that physical dependence was 'neither a necessary nor sufficient condition for addiction', terms such as 'addiction', 'habituation', 'pleasure', 'euphoria' and 'craving' gradually faded from official terminology due to difficulties in quantifying and operationalising such concepts, to be replaced with 'drug self-administration', 'drug seeking' or 'drug taking behaviour' (p186). Behavioural pharmacologists saw the knowledge they produced as relevant not only for understanding drug abuse but also for treatment and prevention, and after the commercial success of chlorpromazine in the treatment of schizophrenia in the mid-1950s, the search of medications for all psychiatric disorders had begun, revolutionising the approach to drug treatment.

1.8. HISTORICAL FLESH AND BIOETHICAL BONES

It was within this context that immunisation strategies aimed at modifying the behavioural effects of drugs were first developed, when Schuster and Bruce Wainer alongside colleagues at the University of Chicago began investigating the generation of opioid antibodies in the early 1970s. However, before the main social and ethical issues of vaccinations for addiction are addressed, it is worthwhile to put some 'historical flesh on bioethical bones' as Campbell (2007) has done in her

work on the monkey colonies of the University of Michigan, since it is these developments that were to produce a whole new set of 'laboratory logics' which would go on to enable and constrain the techniques, technologies and practices that are considered legitimate ways to construct addiction.

Supported by the US Public Health Service, Schuster and Wainer's work demonstrated that it was possible to generate antibodies specific to morphine molecules in rabbits (Wainer, *et al*. 1972, 1973). They went on to show that rhesus monkeys could be induced to produce antibodies against opiates, and that the action of heroin that reinforces its self-administration could be blocked (Bonese, *et al*. 1974). However, the antibodies produced by the vaccine were highly specific to the drug used to develop them, such that a heroin vaccine would not be effective against drugs in the opioid family. It could be overcome by high doses of heroin, and there were problems with lesions and sores developing in the monkeys (Bonese, *et al*. 1974). With the emergence of naltrexone onto the market, an opiate antagonist, or blocker, that could not be easily overcome and was effective against all classes of opioids, a heroin vaccine became largely perceived as ineffective and unnecessary, and shortly after their publication Schuster dropped the work (Brownlee, 2007). Wainer continued to investigate the basic opioid pharmacology, examining the immunochemical and biologic properties of antibodies against opioids (Wainer, *et al*., 1974, 1976). Schuster joined him once more in 1978 to publish an article on the effects of passive immunisation against morphine on heroin self-administration in monkeys, finding that changes in heroin self-administration behaviour were observed which were similar to those achieved with low doses of naloxone, an opioid antagonist used in cases of overdose (Killian, *et al*., 1978). Schuster then went on to other research projects, and in 1986 became the Director of the National Institute on Drug Abuse, NIDA, the key federal institute sponsoring and supporting substance abuse research in the US, and the supporters of 85% of the world's research on the health aspects of drug abuse and addiction (NIDA, 2011a).

Immunisation strategies for drug addiction then lay dormant for over a decade, and did not really resurface as viable entities until the 1990s, when NIDA began to provide logistical and financial support. Although at the end of the twentieth century there was seen to be a range of effective pharmacological treatments for heroin, nicotine and alcohol dependence, cocaine dependence had proved to be a highly treatment-refractory condition (Shearer and Mattick, 2003). Various pharmacological approaches had been tried, such as longer-acting agonist drugs that aim to block the effects of the drug by acting on the same molecular targets as cocaine without producing its euphoric effects (e.g. methylphenidate), and drugs that indirectly change the effects that cocaine has on the brain by acting on other neurotransmitter systems, such as the serotonergic system (e.g. fluoxetine) (Hall and Carter, 2002). However, none of these approaches produced an

effective pharmacotherapy for cocaine dependence (DeLima *et al*, 2002) and this lack of success prompted a revival of the immunological approach which aims to stop cocaine in the plasma before it enters the brain, now described as 'pharmacokinetic' (Gorelick, 1997; Sparenborg *et al*, 1997). Broadly speaking, these new approaches can be divided into two categories:

(1) Active immunisation, which seeks to stimulate the immune system to produce antibodies that recognise and bind to the specific drug molecules or the active metabolites with resultant drug-antibody complexes that are too large to cross the blood brain barrier. Small molecules such as nicotine and cocaine and other psychoactive drugs are not by themselves immunogenic and will not stimulate the immune system to produce antibodies (Pentel, 2004). However by chemically linking (or conjugating) the drug to a larger protein molecule, the resulting drug-protein molecule is capable of eliciting an immune response and the production of drug-specific antibodies when injected into the bloodstream (see Carrera *et al*, 1995, 2000, 2001; Fox *et al*, 1996; Fox, 1997; Kantak *et al*, 2000, 2001; Kosten *et al*, 2002; Martell *et al*, 2005) and;

(2) Passive immunisation, which does not seek to elicit an immune response, but rather infuses monoclonal antibodies, mAb's, so-called because they have been cloned from a single antibody-producing mouse cell in the laboratory, which directly bind to the drug molecules (see Carrera *et al*, 2004; Kantak *et al*, 2000, 2001; Norman *et al*, 2008; Proksch, Gentry, and Owens, 2000). Passive immunisation can also be achieve with catalytic monoclonal antibodies, catmAb's, which aim to increase the rate at which the drug is metabolised, or broken down in the body (see Baird *et al*, 2000; Briscoe, *et al*. 2001; Deng, *et al*. 2002; Gouverneur *et al*, 1993; Homayoun, *et al*. 2003; Janda *et al*, 1993; Landry, 1993; Mets *et al*, 1998).

Both active immunisation and passive immunisation operate by binding to the drug and altering its fate in the body (Pentel, 2004). In both cases, if the drug is taken after immunisation the antibodies bind to the drug molecule making it too large to pass through the blood-brain barrier. In both cases, if immunisation was completely effective this would mean that the drug was no longer biologically available and, while the desire to take the substance may still be present, the ability to experience the psychotropic effects would be gone. In principle then, vaccination against a particular drug could mean that an addict would never again experience its effects, making future use worthless and offering permanent rehabilitation (Shearer and Mattick, 2003).

The same immunological approaches can potentially be applied to a range of psychoactive drugs, and immunotherapies are currently being developed for nicotine, cocaine, methamphetamine and phencyclidine (PCP) (see table 2 below for an overview of clinical development).

Table 2: Overview of clinical development for immunotherapies for addiction (ordered by target drug)

Primary Research Group	Commercial partners	Product	Target Drug	Immunological approach	Stage of Clinical Trials
Fox *et al*, ImmuLogic, US	Celtic Pharma (previously Cantab, previously Xenova, previously ImmuLogic)	TA-COC	Cocaine	Active	Phase II
Cerny and Cerny, Switzerland	Chilka Ltd	~	Cocaine	Active	Pre-clinical
Janda *et al*, The Scripps Research Institute, US	Drug Abuse Sciences	ITAC	Cocaine	Active	Pre-clinical
Janda *et al*, The Scripps Research Institute, US	Drug Abuse Sciences	COC-AB	Cocaine	Passive mAb	Pre-clinical
Norman *et al*, University of Cincinnati, US	None	2E2	Cocaine	Passive mAb	Pre-clinical
Landry *et al*, Columbia University, US	MedImmune Inc.	15A10	Cocaine	Passive catmAb	Pre-clinical
Pentel *et al*, University of Minnesota, US	Nabi Biopharmaceuticals/ Glaxo-SmithKline	NicVAX	Nicotine	Active	Phase III
Maurer, Bachmann *et al*, Cytos, Switzerland	Cytos Bio-technology/ Novartis	NIC002	Nicotine	Active	Phase II
Fox *et al*, ImmuLogic, US	Celtic Pharma (previously Cantab, previously Xenova, previously ImmuLogic)	TA-NIC	Nicotine	Active	Phase II
Svensson *et al*, Karolinska Institutet, Sweden	Independent Pharma AG	Niccine	Nicotine	Active	Phase II
Langer *et al*, MIT, US	Selecta Biosciences	*t*SVP	Nicotine	Active	Pre-clinical
Janda *et al*, The Scripps Research Institute, US	Drug Abuse Sciences	~	Nicotine	Active	Pre-clinical
Janda *et al*, The Scripps Research Institute, US	Drug Abuse Sciences	~	Nicotine	Passive mAb	Pre-clinical
Owens *et al*, University of Arkansas, US	InterVexion	METH-mAb	Meth-amphetamine	Passive mAb	Pre-clinical
Janda *et al*, The Scripps Research Institute, US	Drug Abuse Sciences	MET-AB	Meth-amphetamine	Passive mAb	Pre-clinical
Owens *et al*, University of Arkansas, US	InterVexion	PCP-mAb	Phencyclidine, PCP	Passive mAb	Pre-clinical

However, to date there have been no clinical trials with passive approaches, either using mAb's or catmAb's, and while acknowledging both approaches to immunisation, this thesis will focus on active vaccines, since there are a number of products in clinical trials. Further, because of the ability of active vaccines to produce a lasting immunological response, they have been seen to raise questions and issues *sui generis* in the field of addiction treatment, and have consequently

dominated any bioethical discussion of immunotherapies for addiction. Specifically, it will centre on the development of active vaccines for nicotine and cocaine addiction, as they are the only two to have progressed into clinical trials, and form an interesting case as a licit and illicit drug.

Active immunotherapies for addiction could be used in broadly two ways: 1) Therapeutically, for the treatment of established drug addiction; 2) Prophylactically, in children before they are addicted, or before they have ever used a drug (Harwood and Myers, 2004). The prophylactic use of the vaccines refers to their 'off label' use. The current round of clinical trials is focused on testing vaccines in adult males and non-pregnant females who are being treated for drug dependence or drug overdose. As a consequence, these new medicines will be licensed only for these groups. However, once a new product is approved, clinicians have the discretion to use it 'off label', i.e. for conditions and groups not approved by regulatory authorities. Recent US experience with human growth hormone, which is now given to normal healthy children who are simply shorter than average, has demonstrated that off label prescribing can radically change the main use of a medicine, creating a multi-billion dollar market for a drug that was initially launched to treat the rare condition of pituitary dwarfism (Conrad, 2005).

The potential introduction of vaccine technology offers important social and public health benefits. However, these psychopharmacological treatments also create new responsibilities of constant risk-management by self-monitoring, modification and improvement, blur the boundaries between cure, normalisation and enhancement of capacities, and introduce profound social and ethical implications for the twenty first century. At the behest of the state they have already been the subject of inquiry in the US (Harwood and Myers, 2004), Australia (Hall and Carter, 2002, Hall, Carter and Morley, 2002) and the UK (Ashcroft, Campbell and Capps, 2005). They have also caught the attention of the Center for Cognitive Liberty and Ethics in the US (2005) and there have been significant publications by Cohen (1997), Hall and Carter (2004, Hall, 2002, 2005) Ashcroft and Franey (2004) and Hasman and Holm (2004). The report by the US *National Research Council Board on Behavioral, Cognitive, and Sensory Sciences* (Harwood and Myers, 2004) concluded that their off-label use was likely, and recommended that NIDA support preclinical studies of the potential safety and efficacy of these products when given to vulnerable populations, such as pregnant women and adolescents. They also suggested NIDA support studies of the likely extent and nature of off-label use, and examine factors and incentives that would promote or retard such use, and what opportunities exist for policy makers to intervene 'should the patterns of off-label use depart from what is in the best interest of the society', and the behavioural, ethical and social risk associated with protective therapy in minors, and articulate clinical practice guidelines for their use, or discouragement (p6).

While all these works have been important contributions to the social, legal and ethical debate surrounding the new technology, with the exception of the CCLE report, these have come almost exclusively from within the field of bioethics, predicated on the concepts of autonomy, beneficence, non-malificence and justice (Messikomer *et al*, 2001). Within such discussion the question of their use voluntarily by adults has been left largely untouched as ethically unproblematic, and the dominant bioethical issue in relation to their use therapeutically has been the potential for vaccines for illicit drugs to be used coercively within the criminal justice system. However, it is the ability of active vaccines to be used prophylactically that has received by far the most attention in the literature. They are seen to raise completely novel questions and issues in the field of addiction treatment, as previously, pharmaceutical intervention could only assist once an addictive state had already been reached (Harwood and Myers, 2004). However, in the next chapter, this thesis will draw on work from the sociology of bioethics to argue for the need for empirical evidence to open up debate to wider perspectives that could perhaps still alter the developmental trajectory of the vaccine technology (Rip, Misa and Schot, 1995).

1.9. SUMMARY: A MODEST MESSAGE

Bury (1986) has argued that since social constructionism assumes the relativity of all knowledge, so it must itself be constrained by the same forces as scientific knowledge, and hence there can be no way of differentiating discovery from invention. So too has Williams (2001) leveled a number of criticisms against these Foucauldian perspectives, namely in the same vein as Strong's (1979) criticisms of their orthodox predecessors: the need for restraint. Williams challenges that these new perspectives not only 'debunk' medical 'truth' claims, but claim jurisdiction over the entire body, fabricated as discursive entities, to give their claims to know and explain the world superiority over those of any other. He refers to what Craib describes as the 'manic psychosis' of sociology *qua* constructionism which:

'Rejects, or better `ejects' threatening knowledge and then re-internalises it as the object of sociological knowledge, passive and unthreatening. Once this is done it is not possible to discover anything very new; from our omnipotent position we already know what is happening - we have an imagery of scripts or discursive practices, of the imaginary and the symbolic, and all we have to do is apply them to redescribe the world. We cannot discover anything new (Craib 1997, p14 in Williams, 2001, p151)

Conrad (1992) responded to such criticism by arguing that displaying the social and contextual nature of knowledge such as how medical categories emerge did not necessarily mean the knowledge was false, and acknowledging that it is important to distinguish between sociological

investigation of how knowledge is developed and sustained, and how the knowledge is to be evaluated. Conrad warns that Bury's (1986) criticism should caution researchers about the limits of constructionism, but it does not compromise its usefulness for sociological studies; 'the bottom line is that medicalization analysts create new understandings about social processes involved in the construction of medical knowledge, which may or may not lead to evaluation of the process of that (biomedical) category or knowledge' (1992b, p212). Craib's solution to this dilemma is simple; constructionists in particular and sociologists in general should accept our limits and limitations, and acknowledge that other disciplines, like biology, do have important things to contribute to our own partial knowledge of the world and our place within it, to remain open to the possibility that this recognition may force us to rethink our own theories and, consequently, to perhaps become somewhat more humble in our claims (Craib, in Williams, 2001, p141).

Undoubtedly, if sociologists are to hope to have some influence on health policy, as Brown (1995) has encouraged us to do, it is incumbent on social scientists to avoid further dividing the two cultures by dismissing the reflections made by the psychiatric profession itself. While medical education has historically often failed to adequately situate the individual patient in a cultural, community, or population context, so too social medicine has often neglected the opportunities inherent in clinical care for social and behavioural intervention (Brandt and Gardner, 2007). It is worthwhile to note that many of the criticisms and insights offered by the social constructionist perspective have been heard and voiced by those most closely involved in the clinical creation of diagnostic criteria. In 1988, Leon Eisenberg, a pioneer of American psychiatry well known for conducting the first clinical trial testing psychiatric drugs in children, wrote an editorial titled '*The social construction of mental illness*'. In it he argued that all mental disorders were socially constructed and that medicine did not simply register what was objectively 'out there' in nature. But for Eisenberg that did not entail a belief that biological entities would not exist as phenomena in the world if we did not recognise them:

'Indeed, it is precisely their existence that provides the necessity for trying to make sense of them if we are to diminish human suffering. However, the concepts we invent to account for disease come to shape not only the observations we make and the remedies we prescribe, but the very manifestations of disease itself. Concepts of pathophysiology are 'constrained fictions'-'constrained' in that they must at least approximately match events in the world -'fictions' in that their ability to make sense of those events, or even to predict them, does not establish that they correspond to the connecting principles of nature' (Eisenberg, 1988, p1).

For Eisenberg and many others inside of the psychiatric profession, diagnosis was the key to enabling medicine to cast a prognosis, which was of immense value to the patient and their family in planning for the future. Undeniably, the personal accounts of mainstream personalities with

mental health issues, recently published in a special issue of the *Journal of Mental Health*, demonstrates the positive and productive impact that a diagnosis of mental health can have (cf. Gallop, 2010; Pratchett, 2010; Vonnegut, 2010). But if the ultimate criterion for the longevity of a classification is utility, as Eisenberg freely acknowledges, 'the difficulty is that there is not one utility but many utilities, each serving different purposes' (1996, pxiv). These utilities range from clinical treatment decisions and insurance reimbursement to courtrooms, social-services agencies, schools, prisons and governments (Jutel, 2009). Examining the historical and cultural conditions under which addiction-as-disease was constructed and the specific actors and institutions that promulgated it should not be taken to imply that the lived experience of what is called addiction is therefore any less acute or compelling; but it does invite attention to a closer analysis of the uses of disease discourse and the different institutional arrangements and modes of treatment that follow from these definitions.

As such this thesis aims to provide a critical overview of the construction of the new technology in the dominant discourses of policy and bioethics in order to elucidate how socially structured interests affect the positions that are accepted as the conventional solutions to these issues by locating them in the broader historical and cultural context of which they are part. The empirical chapters will broadly follow the main bioethical issues cited above that have received the most debate within policy oriented scholarship, looking first to the issues of coercion and constraint in the use of the new technology, then to the arguments put forward for mass childhood vaccination, and finally, discourses specifically examining parental rights over their children. Each chapter will explore the underlying constructions of addiction and their implications in key actor groups, in order to guide empirically grounded interpretations of the potential benefits and drawbacks of the use of the technology.

Before progressing to Chapter 2, which will outline the methodological basis for this research, and the theoretical underpinning of constructive technology assessment, I must draw to a close this review. I need not say much more, only that while the perspectives I have charted and their respective strengths and weaknesses are inextricably bound to many deep and unresolved ontological and epistemological issues, my political message was modestly put, and I hope it will be heard above the clamour of the battle that proceeds on either side; the contemporary 'drug problem' and the dominant biomedical model of addiction need not be conceptualised as they currently are. And this surely cannot be thought monomaniacal since it can perhaps be summed up visually with the help of two drawings from a book that is commonly found in the children's fiction section of all bookshops (Saint-Exupery, [1945], 2002, pp5-6).

Illustration 1: ‘Drawing Number One’

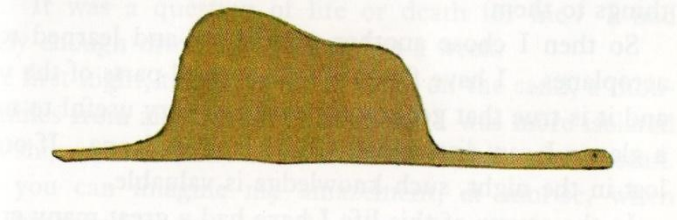
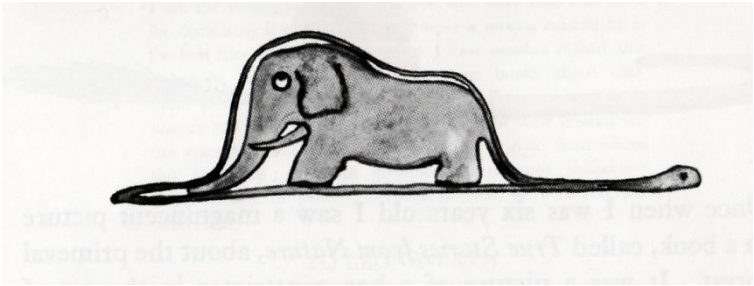


Illustration 2: ‘Drawing Number Two’



2. THE OPERATIONAL AGENDA OF A CONSTRUCTIVE TECHNOLOGY ASSESSMENT

'We still carry the historical baggage of a Platonic heritage that seeks sharp essences and definite boundaries which... leads us to view statistical measures of central tendency wrongly, indeed opposite to the appropriate interpretation in our actual world of variation, shadings, and continua. In short, we view means and medians as the hard "realities," and the variation that permits their calculation as a set of transient and imperfect measurements of this hidden essence'.

Stephen Jay Gould, 'The Median Isn't the Message' (1985, p18).

2.1 TECHNOLOGY ASSESSMENT AND THE NEED TO 'OPEN UP' DEBATE

Technology Assessment came to prominence with the US Congressional Office of Technology Assessment (OTA), established in 1972 to provide Congressional members and committees with objective and authoritative analysis of the complex scientific and technical issues of the late 20th century (Rejeski and Woblg, 2002). It served as a model for similar organisations worldwide, including the UK's Parliamentary Office for Science and Technology, POST (Norton, 1997). Its closure on September 29, 1995 was greeted by many with dismay, and there are calls to restart it, with advocates arguing that whilst the model was not perfect, it nevertheless proved essential in widening and deepening S&T planning (Epstein, 2009). However, others also closely involved in the OTA, such as Vary Coates have argued that any attempt to recreate an institutionalised capability for policy-oriented TA in the US 'need not, and probably should not, use the late OTA as its institutional model' (Coates *et al*, 2001, p8). As Remmen (1995) has discussed, early TA assessment in the US and Europe in the 1970s was primarily aimed at technological forecasting, aiming to identify the direct consequences of new technologies to establish a firmer basis for governmental decision making on their implementation. Although early on in the history of TA, it became clear that projects must involve multiple perspectives, these were typically 'experts', and alternative forms of understanding and different value structures were regarded as peripheral (Rodemeyer, 2005). But accurately predicting future technological advances in an era of increasing pace of change was difficult, and in reacting to the social consequences of technologies only once they were fully developed, an emphasis on technical solutions proved unsustainable. As Rip, Misa and Schot (1995) have argued, any legitimate approach to managing technology in society has to address the dependent and yet problematic relationship between society and technology: 'The modernist adventure, one could say, is now confronted with its limits. And technology – one of the carriers of this adventure, and an icon of modernity – is part of the problem' (p1).

Given the preceding discussion on the social constructionist interpretation of medical knowledge, it is not surprising that many social scientists have reacted against the exogenous and linear model of technology presented in these models (Est and Brom, 2010). But as the field has evolved, due in part to theoretical contributions from STS (cf. Bijker, Hughes and Pinch, 1989; Bijker and Law, 1992; MacKenzie and Wajcman, 1999), alternative structures, locations, processes, and methodological approaches to TA have been created in several European countries which have sought to address some of these problems (Coates *et al*, 2001). Further, scholarship on the Public Understanding of Science has led to a growing acceptance of the gross inadequacies of a deficit model of public understanding, which positions the 'public' as empty vessels in need of scientific knowledge in order to overcome ignorance and mistrust (cf. Gregory and Miller, 1998; Irwin and Wynne, 1996). Proponents of more participatory approaches to TA have questioned the adequacy of limiting participation to experts, and has emphasised public demands for greater participation in important decisions which have applications for their everyday lives (cf. Durant, 1999; Joss and Bellucci, 2002; Kluver *et al*, 2000).

With its origins in the work of Arie Rip and others at the University of Twente in the Netherlands alongside the Netherlands Organisation of Technology Assessment (now the Rathenau Institute), an independent organisation set up by the Dutch Ministry of Education, Culture and Science, the approach known as Constructive Technology Assessment, CTA, has since gained wide recognition (Schot and Rip, 1996). CTA crucially emphasises the central tenet of STS; the co-production of technology and its effects. By emphasising that technological change is a continuous process, where technology, society and the environment are co-shaped during research, development and the application of technology in society, CTA aims to highlight the options available in the development of the technology and influence its transformations. CTA then aims to shift the focus of technology assessment away from assessing fully articulated technologies, by integrating social and environmental criteria early on in research construction and planning, and not merely waiting to react to their development. In this way it has been said to create a new democratic negotiating space between the actors involved in the design process and actors who are affected by technology, thus proposing a new more democratic means of managing technology in society (Est and Brom, 2010).

Similarly, Sarewitz (2005), one of the founders of the Centre for Nanotechnology in Society at Arizona State University has argued that the greatest error in conventional TA lies not in the unrealistic expectations of accurate predictions, but in the linear view of how decisions should be made, where rational analysis is separated from democratic decision making, marking the separation of science from the study of the social outcomes of science. He has called for a move towards real time technology assessment, RRTA, which relies on the key insight that products of

science and technology do not appear magically but emerge from choices made by people working in institutions designed by people. In such a move from conventional TA to RTTA the questions of whether the long term results of some specific discovery or line of research actually are predictable becomes irrelevant. Rather, what is at stake is the realisation that decisions were made with a view toward future outcomes, and that it was these decisions that strongly determined what types of knowledge and innovation would be created and who was likely to benefit from that knowledge and innovation. By creating opportunities for researchers and members of the public to reflect on the values that both nanoscale science and engineering researchers and various publics hold (and on their interactions themselves), RTTA aims to anticipate socio-technical developments, to enable more effective deliberation and social learning early on in the innovation process. This should increase the likelihood that decisions and outcomes will be more attuned to the needs and aspirations of the broader society (Guston, and Sarewitz, 2002).

Schot and Rip (1996) put forward three generic strategies for CTA, one of which is 'loci for alignment', which are strategic attempts to create actual spaces, forums or institutionalised linkages where 'supply' and 'demand' can meet and interact, offering opportunities to modulate developments. One such loci they refer to are forums such as dialogue workshops, consensus conferences and so forth, where the process of participation stimulates anticipation learning and reflexivity. However as they note: 'most often, these forums are temporary loci, and they are used in a context distant from technology development. Feedback is limited, and the outcomes have little force by themselves' (p262). Est and Brom (2010) have looked at the incorporation of 'Ethical, Legal, and Social Issues', ELSI, research into genomics and nanotechnology research programs in Europe and the US as attempts at 'loci for alignment'. ELSI research aims to identify the impact of science and technology early on so that future social, environmental, and health problems can be avoided, by embedding socially desirable solutions in the design of the technology itself, or by regulatory practices. Originating from the US in 1990 as part of the Human Genome Project, HGP, ELSI research has since come under much criticism.

One of most salient was that the ELSI programme was effectively tagged onto the HGP downstream, and that by focusing on the implications of the HGP, it left very little room for discussions of whether the HGP should in fact proceed. Experts set clear boundaries around which areas were and were not open for social consideration, allowing professionals to manage concern without undermining their preferred direction of research and practice (Kerr and Cunningham-Burley, 2000). A second criticism was that in effect the ELSI programme made very little impact, since there was no clear way in which it could influence policy outcomes (Fisher, 2005). The UK has since conducted a few national-level participatory TA activities, such as the

1994 National Consensus Conference on Plant Biotechnology, based on the "consensus conference" method of the Danish Board of Technology, and Citizen GMO in 1998. However, the European Commission funded project, EUROPTA, which investigated participatory TA practices across Europe, found that they made no impact on either public or private policy, since again no formal link was established to feed the issues back into policymaking and they narrowly focused on technical issues and building consensus rather than opening up the topics for wider debate (Kluver *et al*, 2000).

As Wilsdon and Willis (2004) have argued, in much TA the framing of debates and the range of issues open to discussion have focused too far on questions of risk in the application of new technologies, while questions around ownership, social control and the social ends towards which research should be directed have been ignored. The previous UK Government's 10 year strategy for science and innovation (DTI, 2004) acknowledged a move away from the 'deficit model', and a commitment to enable public debate to take place 'upstream' in the science and technological development process, and not downstream where technologies are waiting to be exploited but may be held back by public scepticism. However, in practice this commitment has still been criticised for its reliance on expert knowledge and analysis, for framing debates narrowly on questions of risk in the application of new technologies, and for positioning public engagement in a vacuum with no link back to the research choices and innovation priorities of scientists and industry or the decision-making process of policy makers (Wilsdon and Willis, 2004). This is clearly evidenced in the UK Government's Foresight programme, which although considered to be a key international player in world Technology Foresight and assessment, has been heavily criticised for its linear approach to technological development and lack of citizen engagement (Tait and Lyell, 2002). Indeed the Foresight Brain Science and Addiction, BSAD, project was unusual for its inclusion of lay voices as well as those of experts, but again there was no focus on interaction or negotiation between the public stakeholders with experts, and no link back into policy. When combined with the lack of political will behind it, as was the case in ELSI, the BSAD was doomed to failure (Fisher, 2005).

Another criticism of ELSI, the same of which can be said of many of the subsequent programmes it has given rise to, is neatly captured in the testimony of Langdon Winner before the US House Science Committee on the societal implications of nanotechnology in 2003. Asked his opinion regarding the appropriateness of the ELSI program as a model for the American Nanotechnology Preparedness Center, which aimed to integrate research on societal concerns with technical research and development, Winner remarked:

'The professional field of bioethics... (which might become, alas, a model for nanoethics) has a great deal to say about many fascinating things, but people in this profession rarely say "no"' (Winner in Fisher, 2005, p324).

Described by bioethicists as the work of determining what is right and wrong about scientific developments, and consequently the duties and responsibilities of scientists in relation to these developments, the technological determinism inherent in bioethics is clear (López, 2004). As a medically framed perspective, bioethics acts not as a source of critical oversight to biomedicine, but rather as an 'opportunity for ethics experts to cope with dilemmas generated by technologies, which came to be seen, ironically, as value neutral in their creation even while they were problem-causing in their effects' (Stevens, 2000 in López, 2004, p876). By directly incorporating and leaving unchallenged a biomedical model of addiction, bioethics' support of a biomedically oriented public health becomes a *fait accompli*, and the values embedded in definitions of disease and disability are taken for granted (Kerr and Cunningham-Burley, 2000). Bioethics disciplinary origin in the Anglo-American tradition of analytic philosophy has resulted in rational, formal, abstract, and largely deductive modes of analysis and argumentation, together with the concepts of autonomy, beneficence, non-maleficence and justice, epitomising the movement (Messikomer *et al*, 2001). While these origins are claimed to conform to the ideals of a pluralistic society with a need for legal policy that transcends the particularism of religion and culture, bioethics incorporates implicit beliefs, norms and values through its disciplinary origins in analytical philosophy and uncritical acceptance of biomedical models of disease. The implicit or explicit assumptions of universal morality, largely consequentialist modes of reasoning, the primacy of autonomy as instrumentally valuable in achieving well-being, and Western ideas of rationality and independence work to narrow bioethical debate about human life to one centred on proper techniques and means (Evans, 2002). Indeed one of the foremost criticisms of bioethical discourses by sociologists is its failure to ground moral argumentation in empirical data, with the result that it has been accused of 'cultural myopia' by refusing to acknowledge and take into account situated moral reasoning as it occurs in the social world (DeVries, 2004).

The growing awareness of the implicit normativities within facts and technology has led to the developing field of enquiry known as empirical ethics, which as DeVries (2004) argues, is dissolving the distinction between normative practical philosophy and descriptive social science, challenging that lay people's common-sense intuitions documented by social scientists ought to have a place in moral theory of knowledge. Scully, Banks and Shakespeare (2006) have questioned models of bioethics which place the bioethicist not as just another citizen capable of debating what constitutes morally defensible ethical practice or policy, but as a moral expert, possessing formidable reasoning using conceptual analysis, linguistic analysis or cost-benefit such that it is the definitive voice in moral debate. Rather, they make a strong case for the

reasonableness of lay people to deliberate matters, demonstrating that they do not rely on crude moral intuitions or arbitrary thin forms of moral reasoning, but in the context of discussing particular scenarios within group discussions can articulate basic moral norms, question them, acknowledge competing moral considerations, and provide cogent arguments in support of their initial presumptions. This then makes a convincing argument for more democratic, populist forms of collective moral deliberation, which would also aid bioethical discourse in overcoming its cultural myopia.

Wilsdon and Willis (2004) challenge that such a substantive form of upstream public engagement would not only change the relationship between science and public decision making but also the very foundations of knowledge on which science rests, such that its aim is to: 'make visible the invisible, to expose to public scrutiny the values, visions and assumptions that usually lie hidden.' (p24). Given the political nature of the relationship between technology and society they also argue that this could help shape a more deliberative democracy, which emphasises that people's views are shaped by the way they encounter or engage with an issue, rather than being a reflection of innate opinions or preferences. Thus people's views, and the technology they are reflecting on, ought to be shaped simultaneously, such that the innovation process and public engagement occur in parallel. But in order to have an effect, engagement must occur at an early stage, before it is too late to alter developmental trajectories once political, economic and organisational commitments are already in place.

Ashcroft and Franey (2004) have argued that while prospective technology assessment is always hard, the social context of the use of vaccines for drug addiction is of central importance, and the degree to which we consider addiction a medical condition, a social problem, a moral problem or a personal problem for the addict is critical. Further, they maintain that there are profound questions of principle at stake, such as whether preventative vaccination violates the potential user's right to an open future, their right to exercise the putative virtues of abstinence, and whether, if addiction can be treated effectively, there is any value in prevention. Since these new technologies have the potential to reshape our social attitude towards drug use, as well as our ideas of human agency and society generally, they call for pragmatic clinical trials and good sociological studies into current and former cocaine users' views of strengths and weaknesses of this approach, since the social context of cocaine use will be of paramount importance in the likely success or failure of the vaccine.

However, perhaps reflective of the dominance of professional bioethics, only the UK Foresight BSAD project has collected any empirical data on the potential user perspective of the vaccines. Whilst illuminating, as discussed in Chapter 1 it was only as an adjunct to a wider project, and

included only three users of illicit substances. The data occupied only 2 pages of the final report, and the methods of analysis were not described (Beddoes and Rudat, 2005). To date there has been no other empirical data collected on the perspectives of the potential users of this new technology. Again, only the BSAD project has collected any empirical data on the perspectives of experts, and this was only in the form of a small quantitative survey of nine pharmaceutical companies, not directly involved in immunotherapies for addiction (Ragin, 2005). This was only as a subunit of a single question where respondents were asked to indicate whether they thought that the development of vaccines for the prevention and treatment of addiction and problematic drug use was likely within 5, 10, 15, 20 years or never, with the possibility of adding comments if desired.

The Committee on Immunotherapies and Sustained-Release Formulations for Treating Drug Addiction was set up by the US National Research Council and Institute of Medicine in 2002, in response to a request from NIDA to identify behavioural, ethical, legal and social issues that may be raised in determining who should be given these medications they were funding, and under what circumstances (Harwood and Myers, 2004). Their report contains much rich information and insightful commentary, but it is largely divided along disciplinary lines of expertise. Although they engaged with some of the researchers most closely involved in the development of the vaccines, their commentary was largely restricted to the appendices on the mechanisms of action of the technology and the clinical trials (cf. Kosten and Kranzler, 2004; Pentel, 2004). Professional bioethicists, such as Thomas H. Murray, the President of the prestigious bioethics institute the Hasting's Center in the US, were engaged to answer questions on the ethical issues (Murray, 2004), and lawyers those on their prophylactic use in minors (Miller and Klanica, 2004). Although the report is likely to become seminal in the field as debates around the use of the vaccines grow, the appendices remain as separate entities, with the insights of one lost to the next. But as we have seen above, there is a need for interaction and negotiation between experts, and between experts and wider publics, if technologies are to be reflexively shaped during their development. Where this does not happen, developments may necessitate a public relations exercise in damage control after the event, as was arguably the case with Citizen GMO, or indeed the development may never reach the end user, if regulatory and other socio-technical networks are not stabilised to enable the product to reach the market and become embedded in clinical practice (Webster, 2007).

In many ways, immunotherapies for addiction may seem to be already too far along the development process to be consciously shaped by any insights CTA could cast. Indeed, a special debate on the vaccines that took place in the *Journal of Medical Ethics* did not occur until Aug 2004, when the vaccine technology was already well into clinical trials and predicted to hit the

markets by 2006/2007, and the BSAD public consultation was conducted in 2004; indicative both of the tendency in bioethics to focus on questions of risk in the application of new technologies and for public engagement to occur downstream, where technologies are waiting to be exploited. Certainly, as the HGP ELSI, there is no room for discussion as to whether such research should have proceeded in the first place, having been conducted now for over four decades.

However, as can be determined from the many incarnations the technology has been through in order to proceed onwards to the market, and particularly so in the case of the active cocaine vaccine, TA-CD, it is clear that its development has not been straightforward. Rather, a closer look at the development of the technology demonstrates that the interaction of a variety of material, political, economic and social factors have continuously set back the clinical trials and hence their arrival on the market. Of key importance here is that while much of the bioethical debate has proceeded as if the vaccine technology provided lifelong immunity, currently, active immunisation would require booster shots, perhaps as frequently as every 3-4 months (cf. Pentel, 2004; Kosten and Kranzler, 2004). While this is often regarded as merely a 'technical hitch' by those writing within the bioethical and legal professions, it is an example of one of ways in which publics, if genuinely engaged in open debate, could perhaps still alter the developmental trajectory of the vaccine technology. Certainly, despite NIDA's central efforts in providing financial and logistical support, political, economic and organisational commitments are not already in place, at least not for immunotherapies for illicit drugs. Although both the small pharmaceutical companies in the forefront of developing active nicotine vaccines, Nabi and Cytos, have very recently found global pharmaceutical companies willing to take on their active nicotine vaccines, no immunotherapy for illicit drugs has yet been taken up by a large pharmaceutical company, and without NIDA's support it would most likely never see the light of day.

However, there is perhaps still some room for conscious co-production. Acknowledging the choices made by people working in institutions with a view towards future outcomes, which determine who is likely to benefit from the innovation, alongside the need for more democratic forms of collective moral deliberation, is something this thesis aims to redress in some way. Perspectives such as CTA and RTTA pose questions such as: what is the range of choices available to those making decisions, what are the interests and motives guiding these decisions, how do these relate to the complex social settings within which the decisions are made, and how do results interact with socio-economic cultural and political factors to yield social outcomes? These questions provide not only the intellectual orientation, but also the operational agenda, which builds in a capacity for reflexiveness which extends an awareness of conscious choice into science and technological institutions and the decision making processes themselves (Sarewitz, 2005). Although not able to create physical spaces in which developers and users can interact, this

research has tried to identify 'loci for alignment' through the discourses of those involved in the development, application, regulation and use of the vaccines. While this is certainly no substitute for the process of interaction itself, by embedding myself as a researcher in the socio-technical worlds of the participants, I sought at least to try to understand the paths that actors tend to follow, in order to be better placed to articulate the endogenous futures; 'the emerging and partially stabilized patterns and structures which shape action and thinking – and thus what happens' (Rip and te Kulve, 2008, p61). The hope is to offer some opportunities to modulate developments in productive ways, or at least to suggest what we may learn from the development of vaccines for addiction.

2.2 EPISTEMOLOGICAL CONSIDERATIONS IN STUDY DESIGN

A comparative research design was chosen, focusing on two case studies of an illegal drug (cocaine) and a legal drug (tobacco/ nicotine) in the context of the UK and the US. While acknowledging all approaches to immunisation, this thesis focuses on active vaccines, as it is the ability of these to produce a lasting immunological response that has dominated any bioethical discussion of immunotherapies for addiction. It specifically centres on the development of active vaccines for nicotine and cocaine addiction, as they are the only two to have progressed into clinical trials, and raise interesting questions about how the technology is being shaped by different political agendas as well as posing significant questions about personal freedom as opposed to social norms.

A comparative research methodology was used in order to provide an analytical framework for examining and explaining social and cultural differences across the UK and the US, with the US seeing all forms of illegal drug use as abuse, whilst at the same time placing greater emphasis on individual civil liberties. Ragin (1989) notes that comparative social scientific research is frequently defined as research that uses comparable data from at least two societies; however, he argues that rather than defining comparative social science by its special data or special types of data, it is better defined by its distinctive goals. In particular, he argues that it is distinctive in its use of macrosocial units, not as a data category, but as a meta-theoretical category, where the aim of comparativists is to explain and interpret macrosocial variation. In terms of the unit of analysis then, Ragin (1989) states that in comparative research, data collection and analysis typically proceeds at the level of the individual, but seeks explanation at the macrosocial or societal level to account for the pattern of results obtained. Comparative research then also tends to be historically oriented interpretative work, in the sense that exploring how social and historical contexts affect social phenomenon is seen as the key to understanding, explaining and

interpreting specific historical outcomes that have been chosen for study because of their significance for current institutional arrangements or for social life in general. Further, comparativists tend to be interested in examining the specific historical experiences and trajectories of particular countries as cases in themselves, rather than seeking to find relations between variables characterising broad categories of cases (Ragin, 1989). Similarly, Hantrais (1995) defines research as cross-national and comparative if an individual (or team) sets out to examine particular issues or phenomena in two or more countries with the express intention of comparing their manifestations in different socio-cultural settings using the same research instruments, in order to seek explanations for similarities and differences or to gain a deeper understanding of social reality in different national contexts.

In particular, given the emphasis placed on the importance of contextualisation in CTA, cross-national comparisons have here been used in an attempt to identify the specificity of the social forms and institutional structures surrounding the development and potential use of the vaccines in the UK and the US, and to look for explanations of differences by referring to the wider social context. As Hantrais (1995) argues, the use of comparative research as a means of providing contextualisation also offers a means of evaluating the solutions adopted for dealing with common problems or to assess the transferability of policies between different countries or cultures. In order to achieve this and to critically assess and contribute to the emerging debate around the use of the vaccines, it was decided that documentary analysis would be used to examine the official discourses surrounding addiction in both the UK and the US, as described in more detail under Section 2.3. As extensively addressed in the literature review, because constructionism provides the theoretical framework to this thesis, documents were viewed as displaying a particular version of social reality (Pollner and Emerson, 2002). As such, documents are treated as a source of primary data in their own right, since they are the product of human creation and display the ideas, theories or commonly taken for granted principles of those that created them, and are always located within the constraints of particular social, historical or administrative conditions and structures (McCulloch, 2004; Punch, 2004). However, because a constructionist perspective of text was so inherent to this thesis, a broadly documentary analytic perspective was also taken to the literature review overall. Consequently, it was decided that the primary documentary analysis would be integrated into the thesis overall, rather than presented as separate empirical chapters, alongside the interview and focus group data. As such, the boundaries drawn around the documents examined, and the analysis itself, have been further justified through integrating the findings alongside wider literatures.

The main empirical drive of the research was to elicit discourses that would not otherwise have been available, since there are few accounts of the historical and contemporary development of

the vaccines. The desire to access more technological, social and ethical discourses about the nature of the vaccines led to the selection of qualitative, informal methods of data collection, in accordance with the aims of the research, since these provide considerably more latitude for the participants to construct their own discourses around topical issues they regard as important, rather than those imposed by the researcher (Black, 1999; Mason, 2001; Robson, 2002). In addition they allow more nuanced and complete accounts from the participants, which means that a more detailed and in-depth analysis is possible (Brannen, 2004). Subsequently, semi-structured interviews were conducted to examine the development and prospective governance of the vaccines in both the UK and the US in order to explore a number of themes such as: the current state of development and medium-term prospects for vaccine technology; the potential benefits and risks of the technology; the main applications/ markets; the regulation of clinical development and product marketing; the ethical issues raised by vaccine development; and the ways in which drug addiction and treatment were being constructed in relation to these. Participants were drawn from the areas of policy, research, industry, clinical practice and regulation. Alongside these, a series of focus groups were conducted with potential users of these new technologies in the UK, including a) parents/ legal guardians of children under 16; b) smokers and ex-smokers c) socially integrated cocaine users and d) (ex)cocaine users in treatment facilities. The groups explored ideas about the nature and treatment of addiction; the issues raised by their potential use, and the rights and responsibilities of the state and citizens, and those of parents and children. Connected to the constructivist framework used is the fundamental belief that language is both constructive and constitutive of social life and that participants in research cannot be taken as a mirror reflection of either an 'inside' or 'outside' reality (Potter and Wetherell, 2001). As such, interviews and focus groups were analysed as a social encounter, with talk viewed as socially and contextually constrained (Mason, 2002). This approach recognises that participants' attitudes are likely to be both complex and subject to change, and that at a different point in time, and in a different interactional context, they might offer a different range of explanations (Murphy and Dingwall, 2003). However, the emphasis on interaction and context in the analysis does not preclude the possibility of obtaining knowledge of the social world beyond the encounter (Miller and Glassner, 2004). Rather it aims to understand how meaning is co-produced both within the culture in which it is framed and within the specific interactional encounter in which it was produced (Best, 2003; Danforth and Smith, 2005).

Lastly, in keeping with Craib's (1997) call for limits on constructionism discussed earlier, Latour's (2003) reminder that materiality should not be denied its rightful place, and the CTA emphasis on the co-production of technology and its effects (Schot and Rip, 1996), the researcher actively sought to understand the actors' worlds by openly engaging with other fields in a variety of ways. The first was to take a third year Psychology Undergraduate module on the psychobiology of

addiction in order to develop a better understanding of the neurological, biological, physiological and psychological aspects of addiction, and promote a fuller comprehension of the mechanisms by which the vaccines operate. The second was to employ and refresh my own very partial knowledge of quantitative methods and statistics, through assisting teaching on a Masters course in Quantitative Methods with SPSS. The third was much more extended, and involved volunteering one day a week at a local residential drug rehabilitation unit in West Yorkshire, where I remained for a year. The motivation for this was not primarily one of abject academic interest in my topic, and I was certainly not ensconced in an ivory tower. Thrown somewhat hesitantly into the real world of drug treatment, amidst staff shortages and limited funds, through the time I spent there I became the vehicle of much tacit knowledge about the constraints and realities of drug treatment in practice. I also became privy to many of the residents' personal stories of lapse and relapse, joys and aspirations, despair and abuse, which have undoubtedly informed my understanding and comprehension. Fourth, I then spent two months traversing the laboratories, offices, and homes of those involved in the development of the vaccines across seven US states, spending up to 4 days with some interviewees aside from our allocated recorded interview time. Sitting in on lab meetings, listening to accounts of experiments, watching how rats are taught to self-administer, and examining all the technical equipment was surely seminal to my apprehension of the materiality of the vaccines and my thesis would certainly have been the poorer without it. Lastly, I exchanged the corridors of academia for the vast halls of Westminster palace, by undertaking a 3-month placement at the UK Parliamentary Office of Science and Technology. Here I undertook research into the use of Futures and Foresight methods in governments and parliaments, in order to help policy makers think ahead and engage with outside experts and the wider public. This experience provided an opportunity to meet many people involved in TA across Europe, which greatly augmented my understanding of policy-making and left me politicised and passionate about TA.

That said, these experiences do not form a direct part of the empirical data of this research. With an (over) abundance of data collected through interviews and focus groups, I did not think this work would have benefited greatly from the addition of formal ethnographic accounts (Dingwall, 1980). However, in the same way as cross-national comparative work, these experiences were invaluable in forcing me to adopt a different cultural perspective, in order to learn to understand the thought processes of another culture and to see it from the native's viewpoint, while also reconsidering my own discipline from the perspective of a skilled, external observer (Hantrais, 1995; Lipson, 1994). They enabled me to remain open to the normative expectations that people mobilised in their interactions, and to ground my data within the historical and cultural contingencies of the backdrops against which they occurred (Baszanger and Dodier, 2004).

2.2.1 Limitations

In setting out to collect and analyse data at the level of the individual, in order to explore how the specific historical experiences and trajectories of the UK and US can account for why vaccines for addiction have become more entrenched in the US than the UK, I would argue that epistemologically this work clearly belongs within the field of comparative studies. However, there are a number of key limitations which should be clearly acknowledged. First and foremost, it was not deemed feasible to conduct focus groups in the US due to the practical limits of the study and the time and resources that go into planning and conducting focus groups (Morgan, 1998); therefore, user discourses around the vaccines are limited to those of the UK. Further, as explained in more detail below (see 2.4.1), because experts directly involved in knowledge production around the vaccines were disproportionately based in the US, more interviews were conducted in the US than the UK. Given these limitations, the interview data was not directly comparable by sector, and could not be analysed in terms of the role of interviewees, as had been planned, for example: 'policymakers', 'researchers', 'clinicians', 'industry' and 'regulators'. Consequently, the empirical analysis has focused on the differing discourses constructed by potential users in the UK, and knowledge producers in both the UK and the US, in relation to the role of the vaccines as treatment and prevention. Although this could be argued to further the expert/ lay divide which STS explicitly tries to overcome, this was done solely for the purposes of analysing and presenting the data in a methodologically rigorous way.

As Hantrais (1995) notes, most researchers engaged in cross-national comparative work admit that such research, by its very nature, demands greater compromises in methods than a single-country focus. She cites problems arising in managing and funding cross-national projects, in gaining access to comparable datasets and in achieving agreement over conceptual and functional equivalence and research parameters, with attempts to find solutions to these problems involving negotiation and compromise and a sound knowledge of different national contexts. However, given the limitations outlined above, it could perhaps be argued that such methodological compromises mean that it is inappropriate to label this work as comparative research. This criticism is fully acknowledged, and given more resources, it would certainly have been desirable and possible to conduct equivalent focus groups in the US, and this perhaps would be a key area for further research. However, because knowledge producers were more heavily concentrated in the US, even given more resources, it is unclear how directly comparable data could have been collected and the compromises made in sampling in relation to the interviews resolved. Further, given the limitations of qualitative research more generally, and the specific sampling methods used here, which are discussed in more detail under each method, the data and analysis could not be argued to be generalisable in any statistical sense. That said, although it would be an

interesting avenue for future study, this thesis is not attempting to offer a positivist assessment of attitudes towards the vaccines for addiction in the UK and the US. Rather, it is being presented explicitly as a case study which seeks to offer new insights and a deeper understanding of key issues around drug use and treatment that are of central concern in both the UK and the US, and which may hopefully point to possible future avenues for research and study that have not previously been considered. Consequently, it has arguably achieved what Ragin (1989) asks of comparative research; that it tries to make sense out of different cases by piecing together evidence in a manner sensitive to chronology and that it offers limited historical generalisations on the basis of the enabling conditions and limiting means of context. None-the-less, these potential criticisms are taken seriously and comparative analysis of the data is restricted to the conclusion in order to emphasise the limitations of the data.

2.3 METHODS OF DATA COLLECTION I: DOCUMENTARY ANALYSIS

Documentary analysis was deemed an appropriate method to examine the official discourses surrounding addiction in both the UK and the US. Documentary analysis covers a wide variety of sources, including official statistics, photographs, texts and visual data, and was chosen as an efficient use of resources for the research question, as many official documents are easily accessible and available in abundance (Green and Thorogood, 2004; May, T, 2001). Most projects require the analysis of documentary evidence to some extent, often to supplement information derived from other methods, as, for example, when the reliability of evidence gathered from interviews or focus groups is checked (Duffy, 2005). However, here it was not used to support or validate other data for the purposes of 'triangulation'; rather it was viewed as a research tool in its own right, used to provide a rich and broad socio-historical context for the thesis (Bloyce, 2003).

During Year One it was decided to focus on contemporary official government discourses post-1990 in the US, and 1980 in the UK, since this is when the disease model of addiction became prominent in policy discourse. Systematic documentary analysis was to be conducted on government documents relating to drug policy and treatment, such as official publications, reports, media statements and minutes of meetings, using the 'United Kingdom Official Publications Database', UKOP, and 'The Catalog of U.S. Government Publications', CGP. UKOP is the official catalogue of UK official publications which combines the official catalogue of The Stationery Office with the Catalogue of Official Publications Not Published by the Stationery Office and provides the most comprehensive and up-to-date source of bibliographic information on

government publications in the UK post-1980. The CGP contains publications from the legislative, executive, and judicial branches of the U.S. government post-1978. Both search engines offer basic and advanced options where searches can be narrowed to specific collections or formats, enabling the researcher to set specific boundaries.

However, given the need to keep qualitative projects manageable and avoid the collection of too much data (Silverman, 2004), as the magnitude of the planned data collection became apparent during Year Two, it was decided to limit documentary analysis as a primary research tool to those areas where there was an identified data gap; this limited the type and amount of government policy documents analysed, but also broadened the use of documentary analysis to include discourses from industry and psychiatry.

2.3.1 Sampling considerations

A purposive sampling approach was used to select 'information-rich' documents (Krueger and Casey, 2000, p204). Boundaries were constructed to systematically limit and define the characteristics of documents (Vaughn *et al*, 1996). Documentary analysis of official policy discourse was restricted to the US' Office of National Drug Control Policy, National Drug Control Strategy, post-1995, and the UK's Home Office Drug Strategy post-1998. Systematic analysis was also undertaken on the reports of the World Health Organisation's Alcoholism Subcommittee post-1951 and the Expert Committee on Habit-Forming Drugs post-1949, after they were identified as seminal to the emerging understanding of addiction at an international level. Documentary analysis of industry-based discourses was restricted to patents relating to the active vaccines, and was conducted in order to explore more fully who was being constructed as potential target populations from an official industry perspective. This was done using systematic Boolean searches on Google patents, which returned approximately 400 issued patents. After eliminating records which were not primarily about immunotherapies for addiction, there were approximately 150 records. These were then systematically searched for reference to potential user groups. Lastly, documentary analysis was undertaken to provide additional data on the official psychiatric approach to addiction, using the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, DSM, post-1952 when it was created, and the International Classification of Disease, ICD, post-1948 when it became the responsibility of the World Health Organisation.

Because documentary analysis was systematically conducted around key under-researched areas, the documents examined should be representative of the particular social, historical or

administrative conditions and structures in which they were constructed (Punch, 2004). However, because the sampling frame was not as expansive as initially planned, and because a documentary analysis perspective was taken in regard to the literature review overall (as discussed above), it was decided that the documentary analysis would be integrated into the thesis overall, rather than presented as separate empirical chapters, alongside the interview and focus group data. As such, the boundaries drawn and the analysis itself have been further justified through integrating the findings alongside wider literatures. Much of the documentary analysis of policy discourses appears in the literature review, with Chapter 3 focusing on official psychiatric discourses, and industry-based discourses addressed in Chapter 6.

2.4 METHODS OF DATA COLLECTION II: INTERVIEWS

Semi-structured interviews were conducted to examine the discourses constructed by a number of professional actor groups involved in the development and regulation of the vaccinations. They were chosen in preference to structured interviews since they provide more opportunity for depth and complexity in the discourse than structured interviews, and provide more opportunity for the participant to orient to their own material, cultural and interpretative circumstances, rather than those imposed by the researcher (Holstein and Gubrium, 1995). To facilitate this, although an interview guide was used (see Appendix 9.17), questions were closely embedded in the context of the work and practice of the interviewees, to enable them to provide a fuller account of the endogenous futures of the vaccines from their perspective (Rip and te Kulve, 2008). The interviews were viewed as a social encounter, and interview talk as socially and contextually constrained, where the interviewer and interviewee actively construct some version of the world appropriate to what they take to be self-evident about the person to whom they are speaking and the context of the question (Mason, 2002, Silverman, 2001). This approach recognises that the respondent's attitudes are likely to be both complex and subject to change and that at a different point in time and in a different interactional context they might offer a different range of explanations (Murphy and Dingwall, 2003). However, by attending more to the ways in which knowledge is assembled than is usually the case in traditional approaches it is possible to understand both the meaning-making process and what is substantively asked and conveyed (Holstein and Gubrium, 1995).

In total 31 participants were interviewed in the UK and the US between May and October 2008 (10 UK; 21 US). The interviews in the US were conducted during a 2 month fieldwork trip between July and August 2008, for which funding was secured from the ESRC. Participants were contacted on a number of occasions before the interview, and a thorough route map and

schedule were maintained to ensure that the maximum number of key participants could be interviewed. Interviews lasted in time from 30 to 90 minutes, and while most were conducted face to face, 9 were conducted over the telephone due to budget or time constraints. All interviews were audio-recorded, which was particularly important since the researcher cannot rely on the reproduction of notes to construct the complex discourses used by participants (Silverman, 2004). The possibility of technical problems with equipment was always remembered and alternative preparations made wherever possible (Legard *et al*, 2003). All the interviews were transcribed in full. Ten interviews were outsourced to a professional audio-typist due to time constraints. A full confidentiality agreement was obtained prior to issuing the recordings, and written confirmation that the recordings had been destroyed after the transcripts were made was obtained (see Appendix 9.18). The rest were transcribed by the researcher.

2.4.1 Sampling considerations

Many authors within the methods literature agree that qualitative research should strive for generalisability, which means that selection decisions should integrate pragmatic considerations with a commitment to drawing samples in a systematic and principled way (Mason, 2002; Seale, 1999). Although there is considerable debate as to how this can be achieved, it demands that the researcher carefully considers the feasibility of negotiating access (Murphy and Dingwall, 2003). Given the constraints of the study the researcher decided that a purposive sampling technique would be used to achieve non-randomly sampled representativeness as it allows the researcher to target specific groups or categories that are deemed relevant to the research questions posed (Mason, 2002). As Hammersley (1992) suggests, this provides a sound basis for claims of general relevance, so long as rational decisions are made about the population to which generalisation is to be made, and evidence is collected and presented about the likely typicality of cases. If achieved, the researcher should be able to generalise within reason from the specific cases studied to the various subgroups and wider societies of which the participants were a part of at the time in which they were studied (Danforth and Smith, 2005).

In order to emulate this in practice, extensive preliminary research was carried out to identify the total population of key parties, and then to match this to the demands of limited time and funds. In order to determine the various people and institutions involved in the development of the vaccines in both the UK and US, as researchers and clinicians, systematic Boolean searches were conducted on PubMed, Web of Science and Google Scholar. Outputs were closely examined and a database made of all key researchers in the field and their affiliated university or industry. These were then followed up with searches on Google to find the groups and networks engaged

in research. A similar approach was used on Google to catch any groups located solely in industry who were not publishing results in peer reviewed journals. Leads were also followed up from existing reports on the vaccines, newspaper articles, and specific suggestions from people I had already contacted. In order to determine key figures in the potential regulation of the vaccines it was necessary to chart the processes by which new pharmaceutical drugs are regulated, such as the US Food and Drug Administration, European Medicines Agency and UK Medicines and Healthcare Products Regulatory Agency, to determine which channels the new therapies would be assessed under and thus which internal departments. It was also necessary to chart the processes by which drug policy and treatment is formulated and enacted, such as the US National Institutes of Drug Abuse and the UK Advisory Council on the Misuse of Drugs, as well as the processes by which standard vaccines are regulated and policy recommendations made, such as the UK Joint Committee of Vaccines and Immunology. Key bodies on addiction research and treatment were also charted, such as the UK National Addiction Research Unit at Kings College, London.

This was a long process as due to the prospective nature of this study, there was no data available as to whether active vaccinations for addiction would be subject to regulation and review as vaccinations for contagious diseases, such as through the UK Joint Committee of Vaccines and Immunology and the US National Advisory Committee on Immunization Practices, or through drug treatment agencies such as the UK National Treatment Agency and the US Substance Abuse and Mental Health Services Administration. Many of the people subsequently approached in their capacity as members of various institutional review bodies for vaccinations said they were willing to take part, but they had not heard of vaccines for addiction and felt they had nothing to contribute to the study. Although interviews were conducted with 3 people who had made this comment, which were very useful for deepening my own understanding, these interviewees were unwilling to discuss immunotherapies for addiction in a hypothetical way, because they felt it was outside their area of expertise. Although this was interesting, given the time and budget constraints of this study, alongside the vast number of bodies involved in regulation and policy recommendations, it was decided that the interviews in the US would focus on researchers involved in the development of the vaccines, and regulators and policy makers who had already come into contact with the vaccine. By comparison, the relatively low status of the vaccines in the UK meant that more attention was given to participants who might potentially come into contact with the vaccines in a regulatory or professional capacity. As such the UK sample included a more diverse array of policy, regulatory and key medical professionals who had not as yet had extensive experience with the vaccines, although they were all aware of their development. These were determined in a similar approach to that outlined above, and key medical professionals were selected by their affiliation to organisations such as the WHO Expert

Committee on Drug Dependence, the Royal College of Physicians Tobacco Advisory Group, the Royal College of Psychiatry Faculty of Addictions and the Society for the Study of Addiction.

Once the individual participants were selected from the organisations noted above they were approached directly except in the case of most prospective participants within the pharmaceutical industry, for whom an email address or telephone number could not be obtained on the internet. In these cases a 'gatekeeper' was used and upon telephoning the generic telephone line and explaining my intent I was generally asked to send an email to the administrator who would forward it to the relevant person (Holloway, 1997, Miller and Bell, 2002). The most difficult group to access were representatives of industry, which was expected due to the commercially sensitive nature of the vaccines, and the financial incentives in being the first company to get them to market. Although all the companies in the US identified as developing a form of the vaccination were linked to researchers also working in universities, which facilitated direct contact and access to industry researchers, direct contact with those involved in their management and marketing proved difficult. However, access to key participants in industry was later enabled by referral and personal introduction from other interviewees during the fieldwork. Overall, only a small number of potential interviewees declined to take part, due to time constraints or lack of interest, which was expected, and the majority response was very favourable.

2.5 METHODS OF DATA COLLECTION III: FOCUS GROUPS

Focus groups were chosen in order to explore the scientific and moral discourses constructed around addiction by lay people. Following much previous research, they were selected as a suitable research method to explore the views and understandings of lay people (Wilkinson, 1998). However, acknowledging that lay people will probably have little specific knowledge about the vaccinations does not, within a social constructionist framework, involve the marginalisation of their knowledge, since they are considered active subjects who are involved in constructing social reality through interaction (Cunningham-Burley *et al*, 2001). Focus groups also encourage participation from people who are reluctant to be interviewed on their own or who feel they have nothing to say (Owen, 2001). This latter issue will be further addressed through the use of case studies, which will couch the subject matter in terms of individual experiences with which participants can identify (Beddoes and Rudat, 2005). Focus groups are distinguished from one-to-one or group interviews by their explicit use of interactions between participants as research data (Kitzinger, 1994, Morgan, 1988 and Wilkinson, 1998). The researcher can use conflict between participants in order to clarify why people believe what they do, examine questions that people ask one another in order to reveal their underlying assumptions and theoretical frameworks, and

explore arguments participants use against each other to identify factors which influence individuals to change their mind (Kitzinger, 1994). However, the nature of the data obtained from focus groups will be treated similarly to individual interviews, whereby participants are regarded as active, and opinions and attitudes as both ambivalent, complex and subject to change (Murphy and Dingwall, 2003). As such it is presupposed that sense-making is produced collectively in the course of social interactions between people, which allows the researcher to understand how views are constructed, expressed, defended, or modified within the context of discussion and debate with others (Wilkinson, 1998).

A series of 8 focus groups (total 36 participants, 20 female/ 16 male) were conducted in the UK with the potential users of these new technologies between October 2007 and June 2009. Focus groups were confined to the UK due to the practical limits of the study and the time and resources that go into planning and conducting focus groups (Morgan, 1998). The groups ran for 90 minutes to 2 hours, but participants were always asked to put aside two hours in case of contingencies such as the delayed arrival of some participants (Morgan, 1998). They were conducted as 'self-managed groups' where the researcher maintains low involvement. This involves legitimating the participants' right to manage the discussion at the start of the session when the topic is introduced. As Morgan (1988) notes this approach is very useful where there is little existing knowledge from the participants' perspectives, and he provides researchers with a very useful set of guidelines for using this approach. In addition an assortment of materials, such as case studies, media articles, and 'game-playing' was used in order to contextualise what could be an abstract concept, and to enable participants to ground arguments in scenarios which are familiar to them (Beddoes and Rudat, 2005, Krueger, 1994, Morgan, 1988, Wilkinson, 1998; see Appendices 9.11 – 9.15). A pilot study was conducted in July 2006, during an ESRC MA in Research Methods to establish whether the methods chosen were appropriate and to develop skills as a group moderator. As a result, minor amendments were made to the wording used in the participant information sheets, and the case materials used in the discussions.

The groups were held in a location that was easily accessible for all participants. As pre-existing groups were used for the discussions, the 6 groups conducted for series 1 to 3 were held at a private residence of one of the group members, which is accepted practice where it is appropriate (Gibbs, 1997). When the project was submitted for ethical approval in January 2007 the Graduate Board of Studies raised researcher safety as a potential issue, especially in the context of the groups conducted for series 3 and 4. Day and Topp (2003) note that scant attention has been given to the issue of interviewer safety in drug and alcohol research, and that while the sheer volume of drug and alcohol research suggests there is minimal risk, precautions are necessary. They recommend interviewing participants at the centre where they are receiving treatment to

ensure the safety of the researcher, and stress the need for interviewer training and preparation; however, the participants of series 3 are being selected on the basis of being outside of treatment programmes and therefore this would not have been appropriate. Further, Wright *et al* (1998) conducted interviews with illicit drug users on behalf of the Centre for Social Research on Health and Substance Abuse and generally conducted interviews in the respondent's home to establish independence from drug teams and to promote trust. However, they were in liaisons with health workers and were advised in advance if the participant was known to be aggressive and thus might put the researcher at risk. Overall though, Day and Topp (2003) stress that all precautions developed should be dependent on the specific project and participants involved.

In the case of series 3, I felt there was minimal risk, and as one of the 'seeds' in both groups was already known to me, the Graduate Board of Studies agreed it was acceptable to conduct the group in their private residence, providing a mobile phone was taken, and a schedule of my movements left with the University. The groups for series 4 were conducted in the facilities adjacent to the residential centre from which the participants were recruited. As discussed above, I had already spent a year working with the participants of the groups in series 4, and felt capable of conducting the groups adequately. Following advice from the Graduate Board of Studies a peer from the University of York was present to help facilitate the group and ensure researcher safety. All the focus groups were audio-recorded and transcribed in full by the researcher.

2.5.1 Sampling considerations

A purposive sampling approach was used to select 'information-rich' cases in the UK (Krueger and Casey, 2000, p204). Boundaries were constructed to systematically limit and define the characteristics of participants (Vaughn *et al*, 1996). The four sets of groups were: 1) parents/ legal guardians of children under 16; 2) smokers and ex-smokers; 3) socially integrated cocaine users and 4) (ex)cocaine users in treatment facilities (see Tables 3-6 below for inclusion criteria).

Table 3: Inclusion criteria for parents/ legal guardians of child(ren) under 16 (FGS1)

1) They are a parent/ legal guardian of a child or children under 16 years of age at the time of the study 2) They are agreeable to the focus group being recorded 3) They are aged 18 years or above at the time of the focus group

Table 4: Inclusion criteria for smokers/ ex-smokers (FGS2)

1) They currently smoke or used to smoke on a regular basis and have ceased within the last five years 2) They are agreeable to the focus group being recorded 3) They are aged 18 years or above at the time of the focus group

Table 5: Inclusion criteria for 'socially integrated' cocaine users (FGS3)

1) They have used cocaine at least 25 times during their life-time 2) They have not followed any treatment aimed at modifying their use of cocaine in the last 2 years 3) They have used cocaine at least once in the 6 months prior to the date of this study (Points 1-3 taken from Kuebler and Hausser, 1997: 326). 4) They have a structured everyday life: a job, are a student or have other kinds of legal economic resources and a permanent residence 5) They have not had any contact with social authorities due to their drug consumption 6) They use cocaine during leisure time, outside their daily obligations (Points 4-6 taken from Rødner, 2005: 334-5 7) They agree to the focus group being recorded 8) They are aged 18 years or above at the time of the study (Points 7-8 taken from McLaughlin *et al*, 2000:437)

Table 6: Inclusion criteria for cocaine users in treatment (FGS4)

1) They have used cocaine at least 25 times during their life-time (Kuebler and Hausser, 1997: 326) 2) They are or have followed any treatment aimed at modifying their use of cocaine within the last two years 3) They are agreeable to the focus group being recorded 4) They are aged 18 years or above at the time of the focus group (Points 2-4 taken from McLaughlin *et al*, 2000:437)

Each series consisted of 2 focus groups, which was slightly under the recommended number of 3-4, but within the boundaries generally regarded as adequate in order to be able to obtain a varied set of data relevant to the question (Krueger and Casey, 2000). Carey (1994) notes that in selecting participants who meet the criteria for inclusion the researcher needs to consider the number of participants and the composition of the group in terms of prestige or status, since people are more likely to share information with others who are seen as similar and heterogeneous groups can cause conflict and the repression of the views of certain individuals. Each group consisted of between 3-6 participants, which is within the boundaries usually constructed in focus group research (Wilkinson, 1998). Reflective of the strong tradition of focus groups in market research, participants of focus groups are generally strangers (Bloor *et al*, 2001). The rationale for this is that people who regularly interact may be responding more to past experiences, events or discussions than to the immediate topic of concern (Krueger, 1994, Morgan, 1988). However, Kitzinger (1994) highlights that the use of pre-existing groups enables the researcher to explore how people might talk about the topic within the various and

overlapping groupings within which they actually operate. Given the aims of using focus groups this approach was seen as more desirable; however, every effort was still made to ensure that the groups were drawn from a diverse range of publics that met the overall criterion for inclusion, such as class, gender and race, which is the approach also used by Cunningham-Burley *et al* (2001). In this way participants were also more likely to be relatively homogenous in terms of prestige or status such as social class, occupation, age, education and family characteristics, which promotes an open atmosphere (Carey, 1994). Where this strategy is followed, the researcher is required to make initial contact with the gatekeeper of the group, and ask them to identify other potential participants from the pre-existing group who might be interested in the research (Holloway, 1997, Barbour and Schostak, 2004). Potential participants are then followed up by the researcher through a letter, phone call or email, as deemed appropriate by the gatekeeper. From approaching pre-existing groups in different locations it is possible to achieve a diverse sample.

Consequently, for series 1 (total 8 participants, 6 female/ 2 male), participants were recruited through the Parent liaison officer, PLO, at a local Primary School in West Yorkshire, and advertisement at a local community toddler daycare centre. After initial advertisement through the PLO, and at the daycare centre, potential participants were met and provided with a research participant information sheet and a sufficient number were willing to take part (see Appendix 9.1 and 9.5).

For series 2 (total 9 participants, 7 female/ 2 male) participants were recruited by advertising in strategic places, such as local community centres, libraries and shops, where permission was granted by the gatekeeper. However, this strategy did not manage to achieve the required level of interest, and was supplemented by a similar strategy of 'snowball' sampling to increase numbers, which is described in more detail below. This strategy was pursued in 2 different locations to ensure a wider diversity of participants, but both within West Yorkshire (see Appendix 9.2 and 9.6). However, due perhaps in part to the use of snowball sampling, although the participants ranged in age from 19 to 60, they were clearly biased to a younger demographic. Further, the groups did not include any participants who met the inclusion criteria as ex-smokers. Undoubtedly it would have been preferable from a methodological viewpoint to conduct an additional series of focus groups with ex-smokers, or current smokers in treatment settings, in the same way that cocaine users were divided into groups with current social users, and users or ex-users in treatment. However, it proved very difficult to locate treatment facilities for smokers that were outside of NHS premises. Under the terms of NHS Local Research Ethics Committees, LREC, specific ethical approval must be obtained for any studies using NHS-run treatment groups, including potential participants recruited by the patient or user's past or present treatment and NHS patients treated under contracts with private sector institutions (COREC, 2006). Given the

length of time required to gain LREC approval and the small-scale nature of this study, combined with the time and budget constraints of PhD research, it was decided not to pursue these groups. The impact of this limitation was considered as the data was analysed, and has been taken into consideration in the empirical chapters.

Series 3 (total 7 participants, 5 female/ 2 male) was recognised to pose particular methodological challenges and is discussed in more detail. It is widely accepted that research into illegal activities, such as cocaine use, presents huge methodological challenges, especially when the population are outside of treatment or harm-reduction institutional settings such as needle-exchange schemes (Faugier and Sargeant, 1997; Kuebler and Hausser, 1997). These problems arise from the lack of a sampling frame from which a random population can be drawn, the low visibility of such populations and the potential legal and social sanctions, which deter respondents from cooperation (Heckathorn, 2002; Magnani *et al*, 2005). While little has been written on the procedures and problems involved in researching these groups, there are a number of accepted methods available (Faugier and Sargeant, 1997). These can be roughly divided into location sampling and chain-referral sampling.

Targeted sampling (Watters and Biernacki, 1989) is the best known method of location sampling and involves ethnographically mapping the target population to identify subgroups which are then used as sampling strata, with quota samples then selected within each stratum. However, this approach can be seen to be practically limited here due to the time and resources required for a thorough ethnographic assessment (Magnani *et al*, 2005). The most common chain-referral method is snowball sampling, which entails identifying an initial number of subgroup members, according to a set inclusion criteria. While ideally the initial sample would be randomly selected this is not possible when researching hidden populations (Heckathorn, 2002). As such, 'ease of access' is the dominant means by which the initial sample is selected (Heckathorn, 1997, p174). These individuals are then used as 'seeds' and are asked to provide the names of a set number of other individuals who fit the inclusion criteria. The researcher then approaches these persons and asks them to participate. They are in turn asked to provide a fixed number of additional names, and the process continues until the target sample size has been reached or the sample becomes 'saturated' and no new information is generated (Faugier and Sargeant, 1997; Magnani *et al*, 2005).

The main concern with this method is that it contradicts the statistical assumptions of random probability based sampling methods, which means that the findings of the research cannot be directly generalised to the population of study (Atkinson and Flint, 2001). Furthermore, the sample is biased by both 'volunteerism' whereby the sample is biased towards the more

cooperative members of the group, and 'masking', where participants protect others by not referring them (Petersen and Valdez, 2005). In response to these problems, 'respondent driven sampling', RDS, has developed as a means to enable the calculation of selection probabilities such that it qualifies as a probability sampling method (Heckathorn, 1997, 2002; Salganik and Heckathorn, 2004). In brief, RDS, uses 'seeds' as temporary recruiters, whereby each seed is given a limited number of coupons with which to recruit their peers and are reimbursed for their effort. This also avoids 'masking', as recruits do not need to give their name or any contact information to the researchers, as the voucher contains a contact number of the researcher to call and arrange a time for the interview. They in turn are given the same number of coupons and the recruitment process continues. Within six recruitment waves or less it is estimated that the sample reaches 'equilibrium', in which a stable sample composition is reached that does not change during subsequent waves of recruitment (Magnani *et al*, 2005). While a recent development this method has already been taken up by the U.S. Center for Disease Control and Prevention and other international health organizations.

However, so far this technique has been applied to research involving structured interviews or surveys (see for example Johnston *et al*, 2006; Wang *et al*, 2005) and while one study has also used it within a focus group methodology (Draus *et al*, 2005) this was as an adjunct to longitudinal interviews where trust had been established, and not as a recruitment method for focus groups as a stand-alone study. Given the much higher level of involvement of the researcher in organising a focus group in comparison to an interview, it is doubtful whether a focus group could be successfully convened if the researcher did not have access to any contact information for the participants. Furthermore, RDS has primarily been taken up by researchers and organisations with a primary interest in the increased generalisability of the findings, and there is ongoing debate as to the superiority of this method in comparison to more conventional ones (Heimer, 2005).

A search conducted through 'Index to Theses' produced a number of previous theses that had used the above sampling methods to conduct qualitative research with illegal drug users, either as the focus or an aspect of their empirical work. These were roughly divided between those that had used various versions of chain-referral sampling to recruit participants (see for e.g. McCambridge, 2002, Morrison, 1993) and those who had recruited participants through drug treatment sites (see Cotton, 2005; McLaughlin, 2002; and Taylor, 1991). Given the financial constraints of this study, and the explorative, qualitative aim of the study, conventional snowball sampling is a suitable choice of method (Atkinson and Flint, 2001; Faugier and Sargeant, 1997). While this method is sometimes supplemented by advertisements in restaurants and newspapers (Rødner, 2005), it is reported that site-sampling is often impractical as restaurant managers and

social workers are unwilling to co-operate, and advertisements in newspapers can be expensive (Kuebler and Hausser, 1997). As such, potential participants were provided with wallet-sized advertisements and asked to pass them on to friends and associates who also fit the inclusion criteria. Each participant was then provided with more information if they were interested (see Appendices 9.3 and 9.7). Given the small numbers required for this research (a maximum of 10 socially integrated cocaine users) recruitment through informal social networks and chain-referral proved adequate. Groups were conducted in London and Durham to ensure as diverse a sample as possible.

Finally, participants for series 4 (total 12 participants, 2 female/ 10 male) were recruited through a residential drug rehabilitation centre in West Yorkshire, in which I had been volunteering for a year, between October 2006 and October 2007. This extended fieldwork was undertaken in order to gain a deeper understanding of drug treatment in practice and also enabled access to participants, not only in the practical sense of getting past the gatekeeper (Holloway, 1997; Miller and Bell, 2002), but also in enabling me to understand the norms of the groups, and to be able to facilitate the focus groups in a way that was sensitive to the participants. Participants were recruited through advertisements and word of mouth (see Appendices 9.4 and 9.8). It is worth noting an additional limitation here. The residential facilities were based around the Alcoholics Anonymous Twelve Step approach to treating drug addiction, which is largely based on abstinence from all drugs and psychoactive substances, and traditionally is associated with 'anti-medication' perspectives to drug rehabilitation (McLellan, Carise and Kleber, 2003). However, although residents were actively encouraged to attend various twelve step groups, and the programme was abstinence based, the use of licit medication was encouraged, and all residents were on a variety of prescription medications indicated for drug addiction and associated disorders. Further, as the centre was part of a charitable organisation and not maintained by the NHS, this meant that additional formal ethics approval was not required by NHS LREC, which enabled the research to be conducted within the time constraints of this study (COREC, 2006). While it would have been interesting to also conduct groups with participants recruited from outside of residential rehabilitation schemes, given the amount of time required to be able to do focus groups with these participants, it was not felt to be possible within the constraints of this study. However, the impact of this limitation was considered as the data was analysed, and has been taken into consideration in the empirical chapters.

2.6 METHODS OF DATA ANALYSIS

The data collected using the three different methods was analysed according to the conceptual frameworks detailed in the literature review and in this chapter. Because a representational theory of language was questioned, data analysis did not follow the 'conventional perspective' in which the contents of the participants' thoughts, beliefs and values are seen to be expressed in the neutral medium of language, such that the task of the analyst is to categorise and rearrange the content into a more logical formation (Baker, 2004). Rather, the analysis drew on insights from 'discourse analysis', a broad term that conceals a number of somewhat heterogeneous approaches, which differ in political engagement, epistemological and ontological claims and concepts and procedures (Wetherell, 2001). Here it was used to explore 'systems of social meaning,' by providing a framework that focuses on what both the content and construction of texts and verbal accounts convey (Ritchie, 2003). For documentary analysis this entailed focusing on the structure and textual devices used to construct the documents and on the ways in which they were actually being used (Ten Have, 2004). For the interviews and focus groups, the transcripts were analysed as interactional encounters, which means that the researcher examines the version of social reality produced in the context in which it was constructed (Potter and Wetherell, 2001). However, the critique by Holstein and Gubrium (1995) on the 'linguistically attuned' (p142) approaches as emphasising the 'hows' of the interview process at the expense of the 'whats' of lived experience has been taken seriously and the approach taken was heavily based on their work on the 'active interview' in an attempt to strike a balance.

Atlas Ti was used to facilitate a broad overview of the verbal data, and to enable systematic coding for thematic analysis. The content was examined in depth to establish the implicit or explicit normative frameworks that guided participant's opinions and perspectives, with attempts to identify structures and themes paying close attention to specific wording and grammar (Rodner, 2005). This revealed a number of key recurrent interconnected themes which were then subcategorised around various specific issues. Following Scully, Banks and Shakespeare (2006, p24), to provide an indication for which responses were widely held versus those given by only isolated participants the subsequent qualifiers have been used: 'most' or the 'majority' indicates that the point was made by at least one person in all or nearly all of the focus groups, and that the point was not explicitly rejected by the others, and that it was made by over half of the interview participants; 'many' or 'some' indicates the same for three to eight of the groups, or over a third of interviews; and a 'few' or 'a minority' indicates a response given by one to five individuals. All identifying names and features have been removed from the data to ensure participant confidentiality and anonymity, which is covered in more detail below. Where quotes are used in the analysis, interview participants are identified according to their location in the UK or the US

and by number, with their role identified at the end of the quote, e.g. US11: 'Quote' (Professor of Psychiatry involved in the clinical trials of the nicotine vaccine). As all focus groups were conducted in the UK they are identified by the letter F and by number, with the focus group series number and overall composition given at the end of the quote, e.g. F25: 'Quote' (drug user in treatment, S4/ G1).

2.7 ENSURING PROFESSIONAL AND ETHICAL STANDARDS

A deontological ethical position was adopted in this research, which involves treating the participants in an egalitarian way, and considering them to be active in the process of the research (Murphy and Dingwall, 2001). This is seen to reflect the methodological assumption of qualitative approaches, which emphasise that the process of research is integral to the ends of the research. This is manifest in the use of the term 'participants', since the use of the term 'subject' is seen as subverting the substantial ways in which the researcher is part of the process (Pope-Davis *et al*, 2003). While this becomes more prominent in ethnographic approaches where the researcher sustains a relationship with the participants for a long period of time, it is still regarded as important in the methods chosen. While there were no direct benefits to the participants in taking part, it was thought that the benefits to the research participants may include expression of citizenship, altruism, personal interest, activism and access to information (Fry and Dwyer, 2001). The researcher ensured that freely given informed consent was given according to Professional codes of practice, such as the British Sociological Association, BSA, (2002), which was adhered to throughout the research. Following the guidelines of best practice issued by the BSA (2002) and the Social Research Association (2003) focus group participants were provided with information sheets, which contained contact details, details on the aims and purposes of the research, study procedures, confidentiality and anonymity, storage and dissemination of data, ethical approval, and how they could access the results of the research (Silverman, 2004; see also Appendices 9.5 – 9.8).

These were tailored to the specific role of each group, and every attention was paid to ensure they were written in a manner that was accessible to participants. These were provided to potential participants before the group took place, so that they could consider the information and had opportunity to raise any questions. In the context of series 4, given the researcher's status within the facilities, every effort was made to ensure participants were aware the focus group was not part of their treatment, and that they did not have to attend. As I was aware that rates of literacy were very low, to ensure that the aims of the research were fully understood I went through the information sheet individually with each person who was interested, to provide

them with the opportunity to ask questions and voice any concerns. The information sheets were also read out at the beginning of each group, and participants were again given the opportunity to ask questions, which was done to improve comprehension and provide an opportunity for discussion (Roberts and Indermaur, 2003). Permission was sought from participants to record the groups, and they were provided with details of how they could be kept informed of the results of the study, and made aware that quotes presented in the research will not be edited, in acknowledgment that people may be surprised and upset to see that they do not speak in grammatically correct and complete sentences (Wengraf, 2004). Given the status of the interviewees, it was decided that it was appropriate to provide them with a shorter summary of the research, which covered the same criteria as the focus group information sheets, but in a more succinct way (Silverman, 2004). These were circulated prior to the interviews to enable participants to raise questions or concerns, and the main points were reiterated at the beginning of the interview, before recording commenced. Again, permission was sought from participants to record the interviews, and they were provided with details of how they could be kept informed of the results of the study. All participants were asked to sign a statement of informed consent at the beginning of the focus group or interview, after the details of the research on the information sheet had been verbally reiterated. In the case of the interviews, the information sheet and informed consent were put together in one document (see Appendices 9.9 and 9.16).

2.7.1 Confidentiality

The digital audio-files were stored on the researcher's own computer with a password to ensure that confidentiality could not be accidentally violated. As noted above, where references were made to third parties or to specific places that could identify the participants, these were erased from the recording and do not appear in the transcripts. Focus group series 3 raised specific issues of concern. The main ethical consideration here arises from the illicit nature of the activity, which would be discussed during the group. Although focus groups can be seen as less desirable than individual interviews when investigating a sensitive topic such as illicit drug use, since they inevitably involve the sharing of information between participants and the researcher has less control in protecting the privacy of the participants than in interviews, they are not necessarily inappropriate.

Research into sensitive, stigmatised or illegal behaviours fundamentally requires an assurance from the researcher that the information provided will remain confidential and that anonymity will be maintained, since otherwise research participants will not engage in research for fear of later prosecution. However, given that the researcher is also legally required to breach

confidentiality in a number of circumstances, the requirement of the researcher to obtain voluntary informed consent, in the shape of a signed consent form makes it ethically difficult to sustain an obligation to absolutely maintain confidentiality (Fitzgerald and Hamilton, 1997; Israel, 2004). In this context, the requirement of signed consent forms in certain types of research can be argued to unduly deter potential participants from taking part in the research for fear of later prosecution by the criminal justice system, and also to deter participants who wish to protect their identity from the researcher for various reasons (Coomber, 2002). Consequently, a number of criticisms have been levelled at this requirement, and a number of researchers have devised new strategies for ensuring that informed consent has been given, and also that guarantees of confidentiality can be met. Coomber (2002) and Roberts and Indermaur (2003) both suggest similar approaches using verbal consent. Roberts and Indermaur (2003) have developed their strategy in conjunction with the University of Western Australia and refer to two large-scale, high-profile studies in Australia that have utilised the method. Rather than taking written informed consent, prior to the conduct of interviews or focus groups the researcher reads out the information sheet and provides space for questions. Participants are then simply asked if they consent to take part in the research, and this is recorded on the interview schedule and the research continues. No identifying information is obtained, which removes the potential for information to be used against participants in legal proceedings, a strategy also put forward by Israel (2004). In addition threats to the validity of the data are reduced since potential participants are not deterred from participating by doubts that confidentiality will not be maintained which increases the representativeness of the sample, and also decreases self-protecting responses. Coomber (2002) further suggests that where concrete proof is needed that informed consent has been given the participant could be given a code number and asked to consent on audiotape.

These issues were carefully considered, and it was decided that as the participants had been recruited through the researcher's own informal networks and snowball sampling, and participants were not concerned about protecting their identity from the researcher, it was appropriate to follow the structure that had been used in the other focus groups. However, although participants provided written consent, they were asked to omit their surname to enable the researcher to maintain absolute confidentiality. Further, Morgan's (1998) advice was followed, which suggests that if there are ongoing relationships among the participants, which is the case where use is made of pre-existing groups and snowball sampling, a useful strategy is to ask the group to make up its own ground rules for protecting privacy. Consequently, about 5 minutes were set aside at the beginning of the group, after the information sheet had been read out to allow the participants to decide how they would limit what they disclosed about themselves and others. The same procedures were followed in series 4. Although in these groups

participants status as an illicit drug user was already known to officials, because they were all residing together, it was crucially important to ensure that participants did not disclose more about themselves and others than they considered appropriate, since this might have been detrimental to their relationships and recovery, especially given their familiarity with group sessions for twelve steps therapy. Consequently, more time was put aside at the beginning of the group to go through these concerns with participants and ensure they were comfortable and willing to take part. Where references were made to third parties or to specific places that could identify the participants, these were erased from the recording and did not appear in the transcripts.

2.7.2 Research participant reimbursement

No reimbursement was provided to participants who took part in the interviews. However, the participants in focus groups were reimbursed (see Appendix 9.10). This is accepted practice for focus group research (Morgan, 1998) and has been extended to groups involving illicit drug users (Draus *et al*, 2005, Ritter *et al,* 2003). Financial incentives are not considered a breach of ethics provided they are not sufficient enough to render consent involuntary (Fry and Dwyer, 2001). Participants in series 2 and 4 were each given a £10 voucher, to thank them for their time and reimburse them for any expenses they had incurred. For series 1, participants were each given a £20 voucher, and 2 participants were given a £10 voucher in addition to this for childcare. This discrepancy reflects the differential expenses the participants would have incurred to take part in the focus groups, with participants travelling further in series 1 due to recruitment through a pre-existing group, and having to take into account childcare. Following Draus *et al* (2005) participants in series 3 received £20 in cash in place of a gift certificate to minimise the traceability of incentives, and thereby ensure confidentiality of participants. Again, the higher amount to series 2 and 4 reflects the differential expenses the participants would have incurred to take part in the focus groups.

2.7.3 Formal ethical approval

A research proposal for this study was submitted to, and cleared by, the Sociology Graduate Board of Studies in January 2007. As discussed above, no additional formal ethics approval was required.

PART I: THERAPEUTIC VACCINATION OR AN ANATOMO-POLITICS OF THE HUMAN BODY

3. DIAGNOSING DYSCONTROL: CRITERIA OF SUSCEPTIBILITY AND CULPABILITY IN THE DSM

'Acknowledging that diagnostic categories and classification schemes are acts of the imagination rather than real things in the world enhances rather than diminishes the magnitude of the accomplishment. It is, however, the very success of these schemes in 'making sense' of things that makes it easy to mistake them for reality itself. For clinicians the problem is that the more these schemes are believed, the more their prophecies become self-fulfilling. Accounts of disease, through the expectations they arouse, influence the course of disease. There is no escaping the paradox except to recognize it as such'.

Leon Eisenberg, 'Culture and Psychiatric Diagnosis: A DSM-IV Perspective' (in Mezzich et al, 1996, pxv).

3.1 SCIENCE AND POLITICS IN THE EARLY DSM

Part I of this thesis can be seen as assessing the role of the technology as a form of anatomo-politics aimed at disciplining and normalising the individual addicted body. This chapter will examine the changing status of diagnosis in the field of addiction, following on from calls made by Jutel (2009) for sociology to consider the specific role of diagnosis in establishing a sub-disciplinary field, building on the work of Brown (1990, 1995) 20 years ago. It will begin by exploring the constructions of addiction in the early versions of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, DSM, in order to demonstrate the problems with psychiatry's allegiance to monothetic classification and the need for a sociology of diagnosis that can comprehend socio-political phenomenon. It will then examine the implications of the reconstruction of addiction as a chronic relapsing brain disease, drawing on May's (2001) work on the contemporary clinical dilemma of addiction, before the nosological metamorphoses taking place in the run up to the publication of the fifth edition of the DSM in May 2013 are critically appraised. It is argued that in trying to address what is depicted as an issue of reliability around cultural differences in substance use norms and behaviours, the DSM-V reconstructs abuse as prodomal to dependence, an early manifestation of a disease process characterised by the loss of volition of the subject. This fundamentally alters the historical distinction between substance abuse and dependence that was so crucial to its acceptance as a disease entity, bolstering its epistemological realism and deflecting questions as to its ontological status. Such diagnostic revisions are then placed in the wider context of the 'new engines of medicalisation' (Conrad, 2005), such as the impact of managed care and the rise of the patient consumer. This sets the scene for Chapter 4 where it is contended that the co-construction of the diagnostic criteria in the DSM-V and the development of vaccine treatment technology combine to further the medicalisation of addiction, by creating expectations that addiction can treated without patient participation or motivation, circumventing the clinical paradox and vastly increasing the potential for legally authorised coercive treatment. The data

analysis examines the discursive construction of addiction by key actor groups in order to guide empirically grounded interpretations of the potential benefits and drawbacks of the use of the technology in therapeutic settings. The consequences of this for decisions as to the potential use of the vaccines in voluntary and coercive settings are then appraised.

Diagnosis has had a fundamentally unstable place in the history of addiction, as can be seen in the substantial metamorphoses that have taken place in its construction in successive versions of the DSM, which is the main classification of mental disorders used in the US, and increasingly in both Western and non-Western cultures due to the standardisation of medical education and the increasing pervasiveness of its diagnostic criteria in research studies (Wykes and Callard, 2010). First published in 1952, addiction was then classified under 'sociopathic personality disturbance', subdivided into 'alcoholism' and 'drug addiction', and regarded as symptoms of an underlying personality disorder, or signs of moral weakness, with treatment directed solely at the primary disorder and almost invariably in the form of psychotherapy. It appeared alongside 'sexual deviation', which included 'pathologic behavior, such as homosexuality, transvestism, pedophilia, fetishism and sexual sadism (including rape, sexual assault, mutilation)' (APA, DSM-I, 1952, pp38-39). Originally containing no definition of mental disorder, as Cooper (2004) highlights, the inclusion of homosexuality in the DSM arose such hostility from the gay community during the 1970s that Robert Spitzer, who later became the Chairman of the DSM-III committee, proposed that a condition should only be regarded as a mental disorder if it caused distress or disability, such that homosexuality *per se* should not be regarded a mental disorder but that there should be criteria for homosexuals who experience distress concerning their sexual orientation. Homosexuality was subsequently removed from later editions of the DSM, and Sexual Orientation Disorder added. By the publication of DSM-III in 1980, Spitzer's definition of mental disorder had been added:

'Each of the mental disorders is conceptualized as a clinically significant behavioural or psychological syndrome or pattern that occurs in an individual and that is typically associated with either a painful symptom (distress) or impairment in one or more areas of functioning (disability). In addition there is an inference that there is a behavioral, psychological, or biological dysfunction, and that the disturbance is not only in the relationship between the individual and society' (DSM-III, 1980, in Cooper, 2004, p6).

The DSM-III also reflected the wider shift to a disease model of addiction and contained the new category of 'substance-use disorders', which included the separate classifications of 'substance abuse' and 'substance dependence', for alcohol and all other drugs, with the exception of nicotine which was confined to dependence (APA, DSM-III, 1980). Although dependence has in recent times come to be used as a less pejorative term for a whole cluster of behaviours previously known as 'addiction', it was initially introduced into the field in the 1960s by the WHO Expert Committee

on Drugs Liable to Produce Addiction, who used it to refer solely to the production of 'physic' dependence; 'a particular state of mind' in certain individuals, which was seen to be the common factor across the range of psychoactive substances and which may, or may not, include physical dependence, an adaptive state that manifested in withdrawal symptoms if the administration of the drug was terminated (WHO, TRS No. 312, 1965, p7). The WHO also coined the use of 'abuse', to refer to the 'consumption of a drug apart from medical need or in unnecessary quantities', clarified in 1967 as 'persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice' (WHO, TRS No. 407, 1969, p6). The distinction between dependence and abuse was not intended to denote the degree of risk to public health or the need for a particular type of drug control (as had the previous demarcation between addiction producing and merely habituating drugs), but was supposed to encapsulate the dual impact of drug use on the individual and on society. Consequently, while dependence depicted the interaction between the drug and the individual body, abuse referred to the interaction between the drug and the body politic, categorising the effects of any non-medical or recreational drug use on society.

'Its nature and significance may be considered from two points of view: one relates to the interaction between the drug and the individual, the other to the interaction between drug abuse and society. The first viewpoint is concerned with drug dependence and the interplay between the pharmacodynamic actions of the drug and the physiological and psychological status of the individual. The second is concerned with the interplay of a wide range of conditions, environmental, sociological and economic (WHO, TRS No. 312, 1965, p7).

Although their remit differed significantly, the DSM-III category of abuse echoed WHO's use of the term, with erosion of health and psychosocial function the key clinical criterion of abuse, characterised by either 'a pattern of pathological use' or 'impairment in social or occupational functioning due to substance use' that lasted for over one month (APA, DSM-III, 1980, p163). Although Spitzer's definition of mental disorder required that the patient deem their 'disability' distressing in order for it to be of concern to the medical profession, pathological use was manifested by any single symptom of a number of criteria, which shifted attention between either the subjective experience of the individual (e.g. 'inability to cut down or stop use', 'repeated efforts to control use through periods of temporary abstinence or restriction of use to certain times of the day') or culturally specific appraisals about what a normal and healthy life should look like and the way time and priorities should be organised (e.g. 'intoxication throughout the day', 'continuation of substance use despite a serious physical disorder that the individual knows is exacerbated by use of the substance')(p164). Further, impairment in social or occupational function was focused solely on external social appraisals of behaviour and its causation by drug use (e.g. 'failure to meet important obligations to friends and family', 'display of erratic and impulsive behaviour', 'inappropriate expression of aggressive feelings', 'legal difficulties because of

complications of the intoxicated state or because of criminal behavior to obtain money to purchase the substance') (p164).

However, the DSM-III did not reflect the WHO's definition of dependence as a certain state of mind, which may or may not be attached to physical dependence, but rather replaced it with Seever's abstinence syndrome, which had been developed through the early pharmacological models of the measurable effects of drug habituation in animals (Rasmussen, 2010). Dependence became diagnosed *solely* through evidence of physical dependence, manifested by either physiological tolerance or withdrawal, on the grounds that '*almost invariably* there is also a pattern of pathological use that causes impairment in social or occupational functioning' (APA, DSM-III, 1980, p165, italics added). The 'laboratory logics' of pharmacology thus worked to silence the voice of the addict in the DSM-III, by excluding psychological or subjective 'desire' and 'compulsion' for drugs in favour of objectively quantifiable measures. Although behavioural pharmacology would be displaced as the dominant form of knowledge of, and power over, addiction as the century progressed, the idea that drugs work to reinforce certain behaviours and extinguish others continues to enable and constrain the techniques, technologies and practices that are considered legitimate ways to construct addiction (Campbell, 2007).

The DSM-III did however acknowledge that in rare cases the manifestations of the disorder were limited to physiological dependence, such as when an individual became 'inadvertently' physiologically dependent on an analgesic opioid given to him by a physician for the relief of physical pain (APA, DSM-III, 1980, p165). As such, it implied that physiological dependence was not in itself to be considered especially problematic, unless it had been produced from the use of drugs outside of the medical setting, the basis of the WHO's definition of 'abuse' (WHO, TRS No. 407, 1969). However, since alcohol was known to produce physical dependence, and any use tended to occur outside of the medical setting, in order to retain the reconstruction of alcohol as both socially acceptable and at the same time, addicting to some people, for a diagnosis of alcohol dependence to be made the individual had also to manifest one symptom of abuse, clearly demonstrating the normative nature of seemingly objective pathology.

Nicotine had been absent from earlier debates on addiction, often regarded as a fairly unique member of the family of psychoactive drugs, more akin to caffeine than cocaine, since its use was not normally considered to produce socially disruptive behaviour and withdrawal from nicotine is not physically debilitating, like opiates, and it does not generally provoke profound depression, like cocaine (Acker, 2002). But as a population-focused epidemiology and the concept of risk shifted attention onto the association between smoking and lung cancer, the trajectory of nicotine's cultural acceptability began to move closer to that of illicit drugs, and further away

from alcohol, as will be discussed in more detail in Chapter 5 within the context of population based surveillance and the imperative of prevention (Berridge, 2004). With the visualisation of the opiate receptors, long postulated by behavioural pharmacologists but not shown until the mid-1970s as new technologies developed, substance abuse researchers had set to locating the distribution and density of receptors for all the major drugs of abuse in nonhuman primate and human brains. As Campbell (2007) argues, this prompted the reappraisal of all drugs in terms of their rewarding or reinforcing effects which led to the popular reconfiguration of ideas about the body and the brain and produced a 'common language' for psychiatry and the pharmaceutical industry, which brought them into alignment, rather than competition (p210). These developments also lent themselves to a broadening out of concepts of addiction which was crucial to the incipient alliance developing between tobacco and illicit drugs (Berridge, 2007). By the DSM-III nicotine had been categorised under 'dependence', however it was the only category to acquire separate clinical criteria from those common to dependence across all other substances, with nicotine dependence defined as the:

'Continuous use of tobacco for at least one month with either (1) unsuccessful attempts to stop or significantly reduce the amount of tobacco use on a permanent basis, (2) the development of Tobacco Withdrawal, or (3) the presence of a serious physical disorder (e.g., respiratory or cardiovascular disease) that the individual knows is exacerbated by tobacco use. In practice this diagnosis will be given only when either the individual is seeking professional help to stop smoking, or, *in the judgment of the diagnostician*, the use of tobacco is seriously affecting the individual's physical health' (APA, DSM-III, 1980, pp176-177, italics added).

Consequently, nicotine dependence could be diagnosed solely on the evidence of a physiological adaptation to nicotine (withdrawal), in line with all other drugs with the exception of alcohol, *or* on the basis of a pattern of pathological use, evidenced either by the subjective experience of the individual ('unsuccessful attempts to stop or significantly reduce the amount of tobacco use on a permanent basis'), or on the basis of external appraisals of their behaviour and its causation through drug use ('presence of a serious physical disorder (e.g., respiratory or cardiovascular disease) that the individual knows is exacerbated by tobacco use'). However, 'in practice', only criteria 1 and 3 were deemed salient; the manifestations of which would produce a diagnosis of 'abuse' and not 'dependence' for any other substance, even though it was the only drug not be juxtaposed next to a category of 'abuse', on the basis that 'tobacco use rarely causes any identifiable state of intoxication as does alcohol, there is no impairment in social or occupational functioning as an immediate and direct consequence of tobacco use' (APA, DSM-III, 1980, p178). In the same vein as the abuse criteria of other substances the use of the diagnostic category of abuse thus worked to enforce cultural norms, however, this cultural positioning was not related to the interaction between the drug and the body politic as for other substances, but reflected a shift

towards the prioritisation of health as *summum bonum*, rather than of instrumental value to the individual (Fitzpatrick, 2001). Defined by abuse criteria, yet labelled as dependence, the major differential diagnostic problem of nicotine dependence was reconstituted as the matter of determining 'whether or not a particular physical disorder, in an individual who is a heavy smoker, is exacerbated by tobacco use' (APA, DSM-III, 1980, p178). However, on the basis of this, the hallmark of addiction, the loss of self control, was inferred by precisely the same logic as was employed by Keller nearly two decades earlier in his defence of the disease concept of alcoholism. The criticism made by Schneider (1978) then similarly stands, and it holds that predicating this inference of loss of control in a cultural system in which the values of rationality, personal control, science and medicine are given prominence, directs the designation of disease to the affirmation of dominant cultural and institutional values.

Slow to incorporate new research and conceptual developments, the DSM-III was revised in 1987 to incorporate the work of the British psychiatrist Griffith Edwards and his American colleague Milton M. Gross (Edwards and Gross, 1976), who had developed a model of a 'dependence syndrome' for alcohol, which WHO generalised to all drugs in 1981 (Edwards *et al*, 1981). Building on the work of Jellinek and the WHO Expert Committee on Drugs Liable to Produce Addiction, Edwards and Gross (1976) had broadly described the dependence syndrome as a psychobiological process leading to impaired control over persistent, heavy drinking. As Sher and Slutske (2003) discuss, the symptoms of Edwards and Gross' dependence syndrome were composed to show the importance that alcohol consumption had taken on in the life of an alcoholic, including the centrality of drinking in the person's life relative to other life tasks and responsibilities, tolerance (larger amounts of the substance are required to achieve the same effect) and withdrawal (specific effects of cessation or reduction in intake of substance), rapid reinstatement of dependence symptoms after a period of abstinence and importantly, 'awareness of the compulsion to drink' (p201). The dependence syndrome reflected and retained Jellinek's earlier separation of alcoholism as a disease which defined by the loss of control, from that of problem drinking which was defined by social, legal, vocational or medical problems that were the direct result of alcohol consumption and were seen as distinct in both cause and effect. This 'bi-axial' concept of alcohol also reflected the distinction made by the WHO Expert Committee between dependence and abuse, with the former focused on the body of the individual, and the latter on the interaction between the drug and society (WHO, TRS No. 312, 1965). However, although Edwards and Gross (1976) assumed association between the two axes, DSM-III-R (APA, DSM-IIIR, 1987) and DSM-IV (APA, DSM-IV, 1994) made dependence take precedence hierarchically over abuse, with dependence regarded as a more severe form of substance use disorder. In the DSM-IV (APA, DSM-IV, 1994) a diagnosis of abuse requires individuals to meet one or more abuse criteria over the course of a year, and extends to all substances apart from nicotine, reflecting the continuing

perception that there are no direct social or occupational problems resulting from tobacco use. However, the criteria for dependence are now ubiquitous, with individuals required to meet three or more criteria over the course of a year to warrant a diagnosis of dependence across all substances, mirroring the earlier DSM-III dependence criteria for alcohol, and at least partially recognising Edwards and Gross' (1976) emphasis on the importance of the individual's own perception of their drug-using behaviour to the dependence syndrome (see table 7 below taken from APA, DSM-IV, 1994).

Table 7: Classification of substance abuse and dependence in DSM-IV

DSM-IV
Substance Abuse (one or more criteria for over 1 year) and never met criteria for dependence 1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household) 2. Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use) 3. Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct) 4. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights)
Substance Dependence (three criteria or more over 1 year) 1. Tolerance: a need for markedly increased amounts of the substance to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount of the substance 2. Withdrawal: the characteristic withdrawal syndrome for the substance or the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms 3. The substance is often taken in larger amounts or over a longer period than was intended 4. There is a persistent desire or unsuccessful efforts to cut down or control substance use 5. A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects 6. Important social, occupational, or recreational activities are given up or reduced because of substance use 7. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

These changes have been accompanied by considerable research on the statistical reliability of diagnostic categories, frequently using the 'test-retest' method to determine whether the same individuals meet the same diagnostic criteria at different moments of time. If individuals consistently meet the same criteria it is taken as theoretical proof of the durability of the underlying diagnostic construct. This represents what Lock (1987) termed 'monothetic classification', where the boundaries of various groupings represent attempts to carve up the 'real' world as perceived by an outside observer or analyst, in order to arrive at correct descriptions and arrange them in valid typological relations through observation, classification

and generalisation. For Rosenberg (2002), the tendency to view disease entities as ever more precise mirrors of nature able to be captured with ever increasing accuracy in concrete nosological tables, is the paradox of disease specificity, which through its pervasiveness has naturalised and legitimated cultural conceptions of difference and deviance through posing putative disease entities, but at the same time has also brought intractable social dilemmas.

Although the latest version of the DSM, (DSM-IV, APA, 1994) explicitly states there is no assumption that each category of mental disorder is a completely discrete entity with absolute boundaries dividing it from other mental disorders or no mental disorder, this is somewhat hollow given that the DSM-IV is a categorical classification that divides mental disorders into types based on defining features. As such clinicians and researchers diagnose and interpret conditions presented in the DSM as disorders that are distinct from normal functioning and from one another, even while those inside the profession acknowledge that the categories 'seem to merge imperceptibly both into one another and into normality… with no demonstrable natural boundaries or zones of rarity inbetween' (Rounsaville *et al*, 2002, p12). Although the DSM-IV included a new caveat of 'significant clinical impairment' in many sets of criterion in the attempt to distinguish between mental disorder and 'simply a problem in living', as Widiger and Mullins-Sweatt (2007) note, the evaluation of clinical significance is likely to vary in different cultures and to depend on the availability and interests of clinicians and does little to stem debate on 'where psychopathology ends and the wear and tear of everyday life begins' (p6). For Brown (1990), it is psychiatry's epistemological commitment to monothetic classification that is both the reason for its inability to account for why diagnostic categories appear and disappear over time, and the need for a sociology of diagnosis that can comprehend socio-political phenomenon.

While the dependence syndrome has consistently been shown to have high levels of reliability, with individuals diagnosed as dependent likely to show the same symptoms further down the line, the low and variable reliability of the category of substance abuse was one of the drivers for the changes to the DSM-IV (Hasin *et al*, 2006). This can be argued to reflect the professional prioritising of statistical reliability over validity; that is, whether the classification corresponds accurately to the 'real' world, because there is seen to be no reliability without validity. However, it is perfectly possible to consistently measure something that is not a good indicator of what you are intending to measure: Craniometry may have consistently measured skulls, but it did not measure intelligence, although this did not prevent it from being used to justify racial prejudice by labelling 'Blacks' and 'Indians' as separate, inferior species (Gould, 1981). Indeed, the validity of the four abuse diagnostic criteria and the category itself have continued to be subject to much criticism due to cultural and temporal specificity. Each of the current criteria can readily be understood as social consequences, which build in cultural expectations about social roles and the

societal reaction to the behaviour (see table 7 above). However, as Widiger and Mullins-Sweatt (2007) argue these do not necessarily indicate the presence of the fundamental components of mental disorder, dyscontrol and impairment, since people can freely choose to engage in harmful or impairing behaviours and the occurrence of a harmful or deviant act does not itself constitute a disease. Indeed, there is no clear line between the presence and absence of self control; although at one point people with substance dependencies were thought to have a discrete pathology that rendered them entirely incapable of any control over their drug use, now the dominant construction is that people vary in the extent to which they have inadequate control. Further, it is not clear how much volitional or regulatory control a normal, healthy person has over adaptive, healthy behaviours, since 'both normal and abnormal human functioning is, at best, the result of a complex interaction of apparent volitional choice with an array of biogenetic and environmental determinants' (Widiger and Mullins-Sweatt, 2007, p5). Rather, there is a continuum of self-control that is particularly evident in those disorders that involve behaviours that provide immediate benefits like substance related disorders are difficult to diagnose and controversial precisely because there is no distinct point at which dyscontrol occurs.

The criteria for substance abuse in DSM-IV overlap substantially with that of the category of 'harmful use' in the International Classification of Disease, ICD, an alternate classificatory system maintained by the WHO, which has historically tried to avoid variable social reactions and consequences in definitions of diseases due to its role as an international diagnostic tool, (WHO, ICD-10, 1992). However, recurrent substance-related legal problems (item 3 of the DSM-IV abuse category) were excluded from the ICD-10 on the grounds that social or legal reactions to substance use vary across times and cultures and that drug use leads to legal problems in some eras or countries, but not in others (Hasin *et al*, 2006). As Room (2007) argues, driving after drinking was reported to account for half of all the alcohol abuse cases in a US community sample, and the criteria for substance abuse are so bound to the social and political context of America that there is no reason to expect the criteria which compose it to be held together by more than the fact of at least occasional heavy use of the substance involved.

3.2 RECONSTRUCTING ABUSE AS A PRODOME OF ADDICTION: TOWARDS DSM-V

Since the DSM-IV the dominant scientific vocabulary and imagery that both shape and respond to the social experience of addiction have again shifted, as advances in neuroscience shifted pharmacology to the background. Within these discourses, addiction has been reconstructed as a

chronic relapsing brain disease that leads to compulsion to take a drug with loss of control over drug intake (Koob, 2000, Leshner, 1997, 2001, Nutt, 1997). This definition has led to the development of new and emerging suites of therapies and treatments aimed at countering the neurobiological changes in the brain, and is supported by a range of new technological innovations such as CT (Computerised Tomography), PET (Positron Emission Tomography) and other neuroimaging technology which have increasingly been used to study the effects of drugs and brain neurochemistry (cf. Lingford-Hughes *et al*, 2003; Lingford-Hughes and Nutt, 2003). These technological 'instruments of precision' have allowed neurobiological theories of addiction to become better characterised, presenting objective images of diseases which can be explained in terms of specific causal mechanisms within the sufferer's body, reminiscent of the thermometer in the early nineteenth century (Rosenberg, 2002). However, as Bowker and Starr (1999) have argued, diagnosis as classification works to separate science from politics, 'making it appear that science describes nature (and nature alone) and that politics is about social power (and social power alone)' (p46). Such technologies were initially developed to visualise the opiate receptors and trace their exact locations in the brain, and for Campbell (2007) such photoneurorealism is today's version of the old attempt to render subjective effects objective, by basing diagnoses on an understanding of the body's fundamental mechanisms and not patient reported signs and symptoms of disease. Indeed, she argues that 'behind today's neurobiological models lie the shadowy outlines of perennial beliefs about drugs and drug users that shape their innermost experiences, as well as external observations of their behaviours' (Campbell, 2010, p203). The laboratory logics of pharmacology that marginalised subjective factors are furthered by these new discourses, and the patient's narrative of the lived experience of illness becomes abstracted and stripped of its individual context; reconfigured and retold in a standardised form only as an alteration in biological structure or functioning (Kleinman, 1988).

Moreover, as May (2001) has argued, if the work of clinical medicine is to divide objective pathology (susceptibility) from subjective and experiential factors (culpability) through diagnosis, then it has been only partially successful in the case of addiction. While the neurobiology of dependence, withdrawal and abstinence can be well described, craving continues to prove difficult to define rigorously in a scientific context and although some physiological or psychogenic pathology is assumed to underlie addictive states, there simply is no test for the organicity of addiction. Tests on human subjects can indicate many of the biochemical processes involved in addiction, but these demonstrate only the effect of a psychoactive substance on cognition and behaviour, or the effect of withholding the drug from a subject who has become habituated to it. Thus while it is possible to establish the neuropharmacological effects of intoxication, toxicity or detoxification, the existence of an addictive state itself only is only evident in the explanations of the 'sufferer'. This then presents a clinical paradox; the signs and symptoms of the disease -

compulsive drug seeking and use – are seemingly the mechanistic consequence of pathological biological structures and functions over which the addict has no control. However, the clinician is powerless to affect recovery since this depends on the motivation and volition of the patient in a way that few other disorders do. The clinical construction of addiction then still embodies a set of moral questions and diagnostic signs, which has resulted in the contemporary dilemma of addiction, which remains 'a pathology of symptoms and subjective claims' in which experiential factors remain very much in the foreground (p386).

However, as Wykes and Callard (2010) have argued, even small revisions to the DSM can have unintended consequences and as such, it is worth examining the proposed revisions in detail, to determine their likely impact. The first critical change of the DSM-V Substance Use Disorders Workgroup was to reintroduce 'addiction' after its long exile from official psychiatric terminology on the basis of its pejorative and unscientific associations, and further, to extend it to include non-substance addictions, such as 'gambling disorder' and potentially 'internet addiction'. The context for this revision was seen to be problems with the long-term management of pain due to the propensity of doctors to under-prescribe opioid pain medication because of concern of producing 'addiction' (O'Brien, Volkow and Li, 2006). This is perceived to be accounted for by the confusion produced by the use of the word 'dependence' as a label for 'compulsive, out-of-control drug use'. As O'Brien, Volkow and Li (2006) note in an editorial in the *Journal of American Psychiatry:*

'The term "dependence" has traditionally been used to describe "physical dependence," which refers to the adaptations that result in withdrawal symptoms when drugs, such as alcohol and heroin, are discontinued. Physical dependence is also observed with certain psychoactive medications, such as antidepressants and beta-blockers. However, the adaptations associated with drug withdrawal are distinct from the adaptations that result in *addiction, which refers to the loss of control over the intense urges to take the drug even at the expense of adverse consequences'* (p764, italics added).

As such the Work Group has stated that: 'the word "dependence" is now limited to physiological dependence, which is a *normal* response to repeated doses of many medications… [and] *not symptoms to be counted for the diagnosis of substance use disorder when occurring in the context of appropriate medical treatment with prescribed medications'* (DSM-V, APA, 2010, italics added). Consequently, a suffix is now appended to items 4 (tolerance) and 5 (withdrawal) in the substance-use disorder: 'Note: Tolerance/ Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, ant-anxiety medications or beta-blockers' (DSM-V, APA, 2010). Here psychiatry's collective loss of memory is readily apparent, since this harks back to the DSM-III which implied that physiological dependence was not in itself to be considered problematic, unless it had been produced from the use of drugs outside of the medical setting (APA, DSM-III, 1980). However, since this included any use of alcohol a separate

set of criteria had to be formulated to retain the reconstruction of alcohol as both socially acceptable and at the same time, addicting to some people. Such distinctions were dropped from the DSM-IV as the concept of addiction was broadened out to all drugs and the dependence criteria became ubiquitous, as proponents sought to further the disease model of addiction by demonstrating that it was 'a distinct, definite physiological disease condition with definite uniform manifestations and phenomena and a definite understandable causation... [where] the signs and symptoms are as constant, uniform and recurring as those of any other disease' (Acker, 2002, p40). However DSM-V proposes to reintroduce the overtly political demarcation between culturally acceptable and unacceptable drugs, whilst seemingly retaining a universal model of addiction, by excluding tolerance and withdrawal for drugs used inside the medical profession, rather than requiring additional criteria for certain drugs used outside medical settings.

The formal recognition of the context-bound nature of physiological adaptation could have been used to finally incorporate the seminal work of Lindesmith (1938, 1940, 1968) from over 70 years ago, who argued that although opiates biochemically altered physiological states within the body which cause brute physical sensations, these arose as meaningful contents of human consciousness only to the extent that they had been symbolically interpreted; where the drug was consciously used to alleviate withdrawal distress. Or as Weinberg (1997) has argued more recently, in an attempt to overcome the dualism between cognitive and physically apprehended perceptual events that characterises Lindesmith's work, that the meanings and practical relevances that attach to drugs can be understood as acquired through the process of learning to use drugs as resources in given fields of practical action, such that the effects of their ingestion will vary in different contexts and settings. However, and crucially so, rather than including tolerance and withdrawal across all substances only as one aspect of addiction, which must be accompanied by the subjective experience of loss of control, the proposed revisions rather undertake the cultural work of enforcing norms and defining deviance since what is to be considered 'normal' or 'physiological' dependence, as opposed to pathological maladaptations, depends solely on the normative context of substance use (Rosenberg, 2002).

The second critical change made by the Workgroup was to combine abuse and dependence into a single category, bearing the same name as the previous higher level categorisation, 'substance-use disorder', SUD. Whilst still in the process of revision, this is felt to address the problem of 'diagnostic orphans', where individuals met two criteria for dependence but none for abuse, thus were left undiagnosed by DSM-IV and hence outside the official classificatory scheme (Hasin & Paykin, 1998; Pollock and Martin, 1999; Degenhardt *et al*., 2002, 2008). Despite the criticism of the abuse criteria from within the profession, items 1-3 in the new SUD are directly incorporated from items 1, 2 and 4 of the abuse criteria in DSM-IV (see table 8 below taken from APA, 2010).

Only item 3 of the DSM-IV abuse category, that of recurrent legal problems, has been dropped from the new SUD. This was reportedly on evidence that it had an extremely low prevalence relative to other criteria in relation to the diagnosis for substance abuse, and that its removal from the diagnosis 'has very little effect on the prevalence of substance use disorders while adding little information to the diagnoses in the aggregate' (APA, 2010).

Table 8: Proposed criteria for substance-use disorder in DSM-V

DSM-V
Substance-Use Disorder (two criteria or more over 1 year) 1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household) 2. Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use) 3. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights) 4. Tolerance: a need for markedly increased amounts of the substance to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount of the substance (Note: Tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, ant-anxiety medications or beta-blockers.) 5. Withdrawal: the characteristic withdrawal syndrome for the substance or the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms (Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.) 6. The substance is often taken in larger amounts or over a longer period than was intended 7. There is a persistent desire or unsuccessful efforts to cut down or control substance use 8. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects 9. Important social, occupational, or recreational activities are given up or reduced because of substance use 10. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption) 11. Craving or a strong desire or urge to use a specific substance

The proposed revisions work to decrease the overall importance of the subjective experience of addiction, whilst at first glance, appearing to enhance it. Craving, compulsion and control refer to feeling and affect states experienced by the patient, and in contrast to the other criteria, items 6 (substance taken in larger amounts or over a longer period than was intended), 7 (persistent desire or unsuccessful efforts to cut down or control substance use) and 11 (craving or a strong desire or urge to use a specific substance) of the substance-use disorder can be seen as the 'criteria of culpability'. The former two are incorporated from the dependence syndrome, with item 11 a new criterion taken from the ICD-10 (WHO, ICD-10, 1992). Indeed, the addition of item 11 strengthens the number of experiential factors which address the subjective experience of

addiction, and thus give over more ownership of the diagnosis to the patient (Bowker and Starr, 1999). However, by lowering the number of criteria necessary to warrant a SUD diagnosis, these structural revisions work to prioritise objective pathology over subjective and experiential factors. In the DSM-IV, of the 35 possible combinations of three diagnostic items, 25 would have contained either item 3 or item 4; that is 71.4% of diagnoses would have had to include reference to the subjective experience of addiction for a diagnosis to be made. In the proposed DSM-V, of the 55 possible combinations of two items, only 27 pairs include either item 6, 7 or 11, that is only 49.1% of diagnoses will have to include reference to the subjective experience of loss of autonomy for a diagnoses to be made. By seeking to abstract the patient in order to know the 'truth' of the pathology, they become an external fact to the disease they are suffering from and the experiential factors of disease are displaced (Foucault, [1973] 2003).

In trying to address what is depicted as an issue of reliability around cultural differences in norms and behaviours around substance use, the DSM-V fundamentally alters the historical distinction between substance abuse and dependence that was so crucial to its acceptance as a disease entity, bolstering its epistemological realism and deflecting questions as to its ontological status. No longer constructed as discrete entities, distinct in both cause and effect, with only dependence regarded as a disease of the will, the new single category amalgamates the criteria of both, casting abuse as a dimension of the same underlying disease and elevating abuse to the status of a prodome of dependence, an early manifestation of a disease process characterised by the loss of volition of the subject. However, it is commonly acknowledged within the psychiatric profession that meeting the criteria for abuse does not imply an individual will go on to meet the criteria for dependence. Indeed in the first longitudinal analysis of national-level data in the US it was found that of those diagnosed with alcohol abuse at baseline, only 30% went on to be diagnosed with alcohol dependence 4 years later. Of the remainder, 24% still received a diagnosis of abuse, and 46% were regarded as 'in remission', not meeting the criteria for either diagnosis (Hasin, Grant and Endicot, 1990). This has since been replicated in many other studies, including a national survey on youth, although they have all focused on alcohol and there is no comparable data for drug abuse and dependence (Hasin *et al*, 2006). Costello and Angold (2010) have examined the implicit depiction of abuse as a prodome to dependence in the current DSM-IV and stipulate that progression to the pathological end state is not a requirement for a prodome, since it is possible to have a bull's eye rash without progressing to Lyme's disease, and yet it is nevertheless a manifestation of the disease process itself. However, they argue that even if individuals meeting certain of the abuse criteria statistically have an elevated risk for later dependence, this cannot be taken as premonitory symptoms of already present alcohol addiction.

And yet this is precisely what is done in the DSM-V. What before were taken as signs and symptoms of the putative and contested entity of 'abuse', are now simply transformed to the status of signs and symptoms of the putative entity of SUD. Predominantly composed of criteria taken from the dependence syndrome, the new SUD category carries the full weight of the consequences of a dependence diagnosis on questions around individual responsibility and professional jurisdiction. By way of example, if a teenager were to be 'repeatedly' caught bunking off school, and showing signs of 'reduced' interest in extra-curricular activities such as ballet or piano lessons in favour of spending time with their peers consuming alcohol, they could be diagnosed as suffering from 'alcohol abuse' in the DSM-IV. By contrast, according to the DSM-V, the same teenager could be said to be manifesting symptoms of a disease characterised by eventual loss of volition. In the former scenario, a clinician might warn concerned parents that such behaviours may put the child at higher risk for dependence in later life; in the latter they would be warranted to advise the parents to begin the child on a course of treatment with immediate effect, to prevent the mechanistic progression of the disease process. Thus, the 'new' category of SUD works to decrease the importance of the subjective experience of addiction and simultaneously constructs occasional heavy use of a substance outside of accepted dominant social norms as prodomal to addiction, the symptom of an already present diseased will.

In large part this drive to expand the remit of the diagnostic category to those previously undiagnosed can be understood in the context of the new engines of medicalisation and the socio-political environment of American psychiatry (Conrad, 2005). Because third-party payers only reimburse treatment for patients with a DSM diagnosis, they incentivise professional diagnostic behaviour and affect the construction and designation of diagnostic categories. As Room (2007) has argued, in the context of the NHS:

'British psychiatry has been in a good position to define for itself the limits of its reach, with little to lose from turning away cases that fall outside those limits. In the absence of a national health system, the social environment of American psychiatry has been more entrepreneurial and less inclined to decide collectively that cases lie outside its competence. A health system like the American, characterized by fee-for-service and managed care, has encouraged inclusiveness in the criteria and thresholds, to make it unlikely that a clinician will have to turn away anyone appearing for treatment on the grounds that they do not qualify for the diagnosis' (Room, 1997, p203).

The structural amalgamation of the diagnostic categories of abuse and dependence lowers the bar of entry into the category by expanding the breadth and decreasing the number of diagnostic criteria that can entail a diagnosis of addiction. Until very recently the market for addiction treatments has been relatively small, considered by those inside the field as an 'orphan disease', affecting relatively small numbers of individuals and neglected by mainstream medicine (Aronson,

2006). However, more inclusive diagnostic criteria that enable patients to be eligible for reimbursement at an earlier stage in the disease will open up the addiction market by greatly widening the pool of potential consumers, as has already been seen in changes made to the criteria for Post Traumatic Stress Disorder and Major Depression with a Seasonal Pattern in the DSM-IV (Cooper, 2004). Although these revisions may be professionally legitimated by the desire to provide care for those who want it but are denied it by the political context of heath care provision in the US, the unanticipated consequences of such a revision on the multiple utilities of a diagnosis of addiction have been little examined (Jutel, 2009). Such diagnostic changes invite the drug industry to market a 'pharmacological fix' to a vastly expanded patient population, legitimated as insurance reimbursement by their status as 'disease treatment' (Rosenberg, 2002). In turn, this directs political and financial attention to individual explanations of behaviour rather than remediable social causes and social policy options for reducing the prevalence of addiction, including drug control policies (Hall, Carter and Morley, 2002).

3.3 THE NEW 'ENGINES OF MEDICALISATION'

The history of the development of immunotherapies for addiction bears testimony to the increased role of commercial and market interests in furthering the expansion of medical jurisdiction, seeking to exploit new markets through widening diagnostic criteria (Conrad, 2005). Initially developed through small 'spin-off' companies, and largely driven by a small number of key actors, the number of iterations that most of the immunotherapies have been through, and the constantly revised market entry date, bears testimony to the difficulties of attracting the large-scale pharmaceutical interest needed to push a product all the way through clinical trials. In this context, spurred on by rising political pressures to address the increasing social problem of drug use and addiction, the role of the US state, through the National Institutes of Drug Abuse, NIDA, has been crucial in bringing the vaccines into Phase II clinical trials, by the provision of both financial and logistical support to all the research groups and spin-off companies involved in the development of active and passive vaccines in the US (NIDA, 1994; interviews with UK3, US18, US19, US26, US29).

This political will to address addiction through pharmaceutical means in the context of a wider shift to a medical model of addiction, has combined with a refocusing of the pharmaceutical industry since the 1980s on vaccine technology, due in part to legislation passed in the US offering protection against liability claims and the emergence of new biotechnology-based approaches that have offered less risky ways of making vaccines. As Blume and Zanders (2006) note, these changes led to a doubling in the share of pharmaceutical industry R&D devoted to biological

products, including vaccines, between the early 1980s and the early 1990s and today the vaccine market is projected to increase at 12% per annum. Such concurrent developments contributed to building expectations about the future market potential of new treatments for addiction, and enabled commercial interests to take their place centre-stage as the driving engines of medicalisation, as they did with the development of Prozac for depression in the 1980s. On Drug Abuse Sciences, DAS, website, the spin-off company founded by Janda and colleagues at The Scripps Research Institute to take forward cocaine immunotherapies, they state that:

'The total market potential for alcohol and drug addiction therapies is a multibillion dollar opportunity. In Europe and North America alone, there are an estimated 38 million patients in need of therapy… Since addictions greatly affect normal brain function and patients' ability to comply with treatment plans and medical prescriptions, the treatment of these diseases is complicated and requires a combination of pharmacotherapies and psychosocial treatments over months or years, until a patient can recover self-control and decision-making abilities… Importantly, 80% of alcoholics and drug addicts are employed, and thus have access to health care systems through medical coverage... an estimated 10% to 15% of the overall general practitioners' and hospitals' patient base has an alcohol and/or drug addiction problem in addition to their primary medical condition. As more effective therapies become available, and government health campaigns to fight addictions broaden, DAS expects that a large fraction of this medicalized patient base will seek alcohol and drug addiction therapies. As a result, only a small fraction of the addicted population is, or would remain, out of medical reach in developed countries' (DAS, 2006).

Elizabeth Greetham, then CEO of DAS, made this even more explicit in an interview with *The Wall Street Journal* in 2001, as part of its section on 'Questioning Market Leaders For Long Term Investors' reporting that:

'Addiction, as a disease, has been treated almost exclusively as a behavioral disease or a character flaw. Over the last 10 years, however, it has become readily apparent that addiction is a disease of the brain and, therefore, does require medical treatment. DrugAbuse Sciences was founded to create and develop medical treatment for this disease... Looking at the future, our company reminds me of Eli Lilly and Prozac in the depression field. In 1984, when I wrote up Prozac for the first time on Wall Street, there was a $200 million market for depression. The market today is now $10 billion. As Prozac and other products came in, the depression market evolved and elevated depression from being a closet disease to a fully recognized and accepted disease state. Our goal is to develop that addiction market and bring addiction out of the closet by bringing effective medications to the physician and patient. Financially, we can be highly successful, but we can also make a major breakthrough for society' (Greetham, 2001).

Further, when asked the potential size of the market, Greetham referred to the 22 million alcoholics and 8 million cocaine or heroin addicts in the US and Europe according to government statistics, and continued that:

'Those are known diagnosed patients. We believe there are potentially more than double the number, if the undiagnosed patients are included. The numbers, to reiterate, are published by governments both in the U.S. and Europe. If we treat 300,000 patients for six months and charge typical daily therapy of around $4 per day, which is the usual charge for new medications today, we can generate $250 million worth of revenues to DrugAbuse Sciences. These numbers represent only 2.5 percent of the known treated market. Given the possible under-diagnosis, and since there's very little competition in this field, we believe that addiction will be a multi-billion dollar market. DAS will only have to scratch the surface to be very successful for our investment group' (TWST, 2001).

More recently, in July 2005, Cytos filed a Notice of Opposition against a European patent held by Nabi for its active nicotine vaccine, NicVAX, covering the treatment and prevention of nicotine addiction. The vigour with which Cytos and Nabi have staked out an IP position bears testament to the potential size of the profits to be made in this area, with a large treatment population willing and able to use their purchasing power in a market estimated at $1.6bn in 2009 (VisionGain, 2010). Such developments have since encouraged 'Big Pharma' to enter into the field indicating the potential lucrativeness of the market for active vaccines for nicotine addiction, as indicated by the recent partnerships struck between Cytos (NIC002) with Novartis in 2007, and Nabi (NicVAX) with Glaxo SmithKline, GSK, in 2010. In their exclusive global commercial license agreement with Novartis to develop, manufacture and commercialise the vaccine, Cytos is eligible to receive up to CHF 600 million (approx £290 million) in upfront and potential development, regulatory approval and sales milestone payments, as well as royalties on net sales if NIC002 is successfully commercialised (Cytos, 2007). However, in the hearing held by the European patent office in 2008 Nabi prevailed, and now holds issued and pending patents in the US and in many countries worldwide (Nabi, 2008). Nabi subsequently received an upfront payment of $40 million for GSK to exclusively in-license NicVAX on a worldwide basis and a license to develop next-generation nicotine vaccines using Nabi's intellectual property. Nabi is also eligible to receive up to $460 million in potential option fees and regulatory, development and sales milestones for NicVAX and follow-on nicotine vaccines (Nabi, 2010a). The willingness of such key pharmaceutical players to agree to such upfront and milestone payments signals a vote of confidence in the vaccine's mechanism of action and commercial potential.

However, to date, no large-scale commercial partners have been found for the active cocaine vaccine, or any of the passive antibody treatments. Initially developed by Fox and colleagues (Fox *et al*, 1996; Fox, 1997), at ImmuLogic Pharmaceutical Corporation, Massachusetts, the active cocaine vaccine TA-CD, and active nicotine vaccine, TA-NIC, were sold to the UK-based biotechnology company Cantab, in 1998 owing to financial difficulties (ImmuLogic, 1998). Cantab prioritised the development of the active cocaine vaccine over that for nicotine, owing to the financial and logistical support offered from NIDA to conduct the clinical trials in US. Further, with

limited liquidity the cocaine vaccine could be moved onto the market more quickly, since treatment for cocaine addiction was considered an unmet clinical need, which could be progressed through the FDA with less intensive Phase testing. This was seen to allow any problems with the vaccine to be addressed in populations who were already considered to be at high risk of morbidity and mortality, opening up the market to then progress the nicotine vaccine (interviews with UK3 and US26). Again in financial straits, in February 2001, Xenova, another UK-based biopharmaceutical company acquired Cantab and, with the support of NIDA, began Phase II clinical trials of the active cocaine vaccine in the US (Xenova, 2001, 2002). Although Xenova also pushed the nicotine vaccine forward into Phase I clinical trials in Europe, less than four years later finances had once again dried up and in September 2005 Celtic Pharma, a private equity firm focused on acquiring commercially attractive pharmaceutical products in late stage development acquired the entire share capital of Xenova (Xenova, 2005). Still with the financial support of NIDA, Celtic have taken TA-CD on into Phase II trials. However, the continued lack of large-scale interest in the active cocaine vaccine can be said to indicate the reservations held by the pharmaceutical industry towards the commercial worth of products for which the government is the sole or main purchaser, decreasing the commercial leverage of the company (Chalk, 2006).

In the context of the passive immunotherapies, there are currently 22 therapeutic monoclonal antibodies approved by the FDA, with cancer and autoimmune diseases, such as rheumatoid arthritis, the main indications, collectively constituting 78% of the total antibody sales in the US, which in 2008 generated revenues of over $15 billion, the highest earning category of all biological drugs (ACTIP, 2011, Leavy, 2010). However, initially developed to treat drug overdose, the market potential for monoclonal and catalytic immunotherapies for drug addiction can be seen to be very low due to the relatively small number of patients combined with their lack of purchasing power, acting as a big deterrent to pharmaceutical companies. There is also discussion as to whether monoclonal antibodies could be used within relapse prevention, with each immunisation potentially lasting for up to a month (Kosten and Owens, 2005). However, in contrast to the active vaccines whose technological script can be read as encouraging large-scale deployment through primary care services, monoclonal technologies restrict themselves to tertiary care settings, requiring an infusion to be delivered into the vein slowly over the course of 3-6 hours, and normally require overnight admission (Adams and Weiner, 2005). This dramatically elevates the costs associated with delivering the technology, which when combined with the high costs of producing the doses of monoclonal antibodies that are needed for these therapies is seen to be a major limiting factor, are likely to cost an order of magnitude more than the active vaccines per shot administered by analogy to the other monoclonal antibody immunotherapy products now on the market for other diseases (Kleiman, 2004).

Crucial to the future role of the passive approaches in the treatment of drug overdose will be the political decisions taken as to the appropriate levels of training necessary to administer the therapy, because due to the very short elimination half life of many drugs, especially cocaine, if emergency medical workers on board the ambulances that go the scene of an overdose are not able to administer it, it is likely the technology would be defunct, since the patient would have recovered from the crisis or died (interview with US18, US26, US30). This is similar to the debates that took place over the appropriate levels of training required to administer naloxone, an opioid antagonist that can restore breathing reflexes which are suppressed in cases of heroin and morphine overdose. In 2006, because of budget constraints, Philadelphia in the US replaced paramedics in some areas of the city with lesser-trained Emergency Medical Technicians, who were not allowed to administer naloxone at all. This caused controversy by some groups after levels of deaths from drug overdoses were seen to rise (Gussow, 2006). This was followed by campaigns in both the US and the UK over whether it was appropriate to provide naloxone on prescription and train lay people to recognise the signs of overdose and self-administer the drug. Such campaigns were at least partially successful, but provision varies substantially, and one of the key reasons that such public health programs have been able to provide naloxone prescription services without substantial public investment was that as a post-patent generic drug, it was inexpensive (Beletsky, Burris and Kral, 2009). By contrast, the high costs of therapeutic monoclonal antibody treatment was one of the leading factors in the controversy in the UK in the previous decade over the provision of the monoclonal antibody Herceptin, for certain forms of breast cancer, which initiated large-scale campaigns on the grounds that women were being denied access to a potentially life-saving treatment principally on the grounds of cost (Wilson *et al*, 2008). However, on the whole, people with drug dependencies do not form politically active support groups, and in an ideological climate where addiction is a highly stigmatised condition and drug overdose services are traditionally underfunded or unfunded, there is arguably little political will to extend such provision to highly expensive technologies, or guarantee that any such campaigns would be greeted with comparable levels of public and media support.

In *Science Progress*, Meier (2008) has argued that this public-private-sector financing model, which has funded the cocaine vaccine all the way through to the marketplace, ought to be applauded if the vaccine proves to be efficacious. However, as Meier effuses, the potential profitability of the cocaine vaccine will only be decided after the vaccine passes clinical trials and public health officials decide how to distribute the vaccine, which in turn will determine 'just how much money the private investors behind the cocaine vaccine will reap in profits' (p59):

'In the end, those decisions may well determine whether this novel approach to researching and financing this public good succeeds for all involved. And if it works well for all, then it may well spark other private-

public partnerships in search of other novel techno-chemical methods to tackle the scourge of addictive drugs in our society today' (p62).

As such the next chapter will briefly examine the dominant legal and bioethical literatures pertaining to the freedom of the addicted subject, before the discourses being constructed by key actors in the UK and the US around the voluntary and coercive use of the vaccines in therapeutic settings will be examined. The consequences of this for decisions as to the potential use of the vaccines in voluntary and coercive settings will then be appraised.

4. MAGIC BULLETS OR ONE IN THE ARMOURY? CONSTRUCTIONS OF CHOICE AND CONSTRAINT IN DRUG TREATMENT

'Over himself, over his own body and mind, the individual is sovereign.'

John Stuart Mill, 'On Liberty' ([1863] 2003, p12).

4.1. INTRODUCTION: THE HIJACKED BRAIN AND MORAL AGENCY

Chapter 3 aimed to demonstrate how the structural amalgamation of the diagnostic categories of abuse and dependence lowers the bar of entry into the category by expanding the breadth and decreasing the number of diagnostic criteria that can entail a diagnosis of addiction. Moreover, it was argued that these structural revisions work to prioritise objective pathology over subjective and experiential factors, elevating abuse to the status of a prodome of dependence, an early manifestation of a disease process ultimately characterised by the loss of volition of the subject. This was held to invite the drug industry to market a 'pharmacological fix' to a vastly expanded patient population, legitimated as insurance reimbursement by their status as 'disease treatment'. In this context immunotherapies for addiction are increasingly being put forward as a solution to the growing 'problem' of cocaine and nicotine use in US policy literatures. Because it targets an illicit drug, the use of the cocaine vaccine coercively has received much attention from bioethical scholars; however, the use of the cocaine or nicotine vaccines voluntarily by adults has been left largely untouched as ethically unproblematic. As such, this chapter will begin by exploring how knowledge interacts with politics and culture in the way societies deal with risk, through examining the impact of the construction of addiction as a chronic relapsing brain disease on juridical policies around mandated or coercive treatment in the US (Jasanoff, 1990). It is argued that the dominant legal discourses which have considered mandatory or coercive use of the cocaine vaccine have constructed the vaccine as holding the promise of resolving May's (2001) clinical paradox - finally placing the recovery of the addict in the hands of the physician, which, directed by the benevolent state, can circumvent the need for patient motivation which thus far has prevented addiction from being successfully medicalised. Although such direct forms of state intervention appear at odds with the shift to newer forms of biopolitics based on liberalism and the promotion of individual autonomy it is argued that American bioethical discourse justifies such coercive strategies and simultaneously promote individual freedom by constructing mandatory vaccination as a means to create or enable autonomy.

Drawing on the work of Gomart (2002) the underlying construction of the neo-liberal subject inherent in abstinence-oriented medical approaches and bioethical discourse is then critically highlighted, opening the door to more sociological understandings which argue that autonomous action is not a property of individuals but of complexly-ordered social relations. The importance of grounding moral debate in empirical evidence is then used to frame the rest of the chapter, which forms an empirical examination of the discourses being constructed around the vaccines by key actor groups in both the US and the UK, focusing on the voluntary use of both nicotine and cocaine vaccines, and the potential coercive use of the cocaine vaccine. It concludes by examining the impact of directing attention to the complex interplay of interactions between human and non-human actors by which autonomy is produced for questions around the clinical utility of the vaccines and its use in coercive settings. It then draws on Goffman's (1986) notion of a 'spoiled identity' to explore the effect of the convergence of concepts of addiction on the relationship between participants' self- perception of use and appraisals of the vaccines as either enabling or constraining autonomy. The complexity of drug addiction and the failure of the vaccine to be able to enforce compliance once an addictive state has been reached are then used to signal the shifting clinical gaze, away from the addicted body and towards the body politic, as the thesis turns to the techniques of governance associated with discourses of health promotion and the rise of the 'risky subject' in advanced liberal democracies (Bunton and Peterson, 1997; Nettleton, 1997; Rose, 2007).

From its very inception the US government's drug policy rhetoric and enforcement policies have conflated drug use with drug abuse. This is arguably due to the particular socio-historical context of the birth of addiction as disease in America from the moral foundations of temperance ideology, which depicted alcohol as inherently addictive due to its ability to compromise the autonomy of the subject in its immediate effects, as discussed in Chapter 1 (Levine, 1978). These origins have promulgated what Reinarman and Levine (1997) have termed 'pharmacological determinism'; the idea that consuming specific drugs inevitably leads to specific forms of behaviour, where 'malevolent molecules' are the key cause of bad behaviour. Such discourses are bolstered by the reconstruction of addiction as a chronic relapsing brain disease, which has promoted readymade analogies to other medical conditions and the ethical dilemmas faced. Although neurobiological theories of addiction have had the positive implications of increasing funding for addiction research and making more humane, less punitive responses to addiction possible, this has come at the price of simplified versions of behaviour controlled by the state of brain receptors and neurotransmitter systems. Dominant scientific perspectives now construct addiction as the flick of a metaphorical switch in the brain that occurs mechanistically as a result of chronic drug use, inevitably leading to the loss of autonomy in the subject. As O'Brien and McLellan (1996) have argued in the *Lancet*:

‘At some point after continued repetition of voluntary drug-taking, the drug "user" loses the voluntary ability to control its use. At that point, the "drug misuser" becomes "drug addicted" and there is a compulsive, often overwhelming involuntary aspect to continuing drug use and to relapse after a period of abstinence. We do not yet know the mechanisms involved in this change from drug-taking to addiction, and we are searching for pharmacological mechanisms to reverse this process’ (O’Brien and McLellan, 1996, p237).

‘Diseases of the will’ have been replaced by the mechanisms of ‘disrupted volition’, described by Nora Volkow, a neuroimager and the Director of NIDA since 2003, as the process by which ‘drugs and alcohol can disrupt volitional mechanisms by hijacking the brain mechanisms involved in seeking natural reinforcement and weakening brain mechanisms that inhibit these processes’ (Volkow and Li, 2005, p. 1429). Although, as Campbell (2010) acknowledges, today’s neuroscience and molecular genetics may be far from their historical antecedents in terms of reductionism or deterministic endeavours, the ‘hijacked brain’ metaphor has quickly become used in public discourse to legitimise claims about innate differences and irreversible alterations of brain structure and function. Now, the powerful drive to repeat seemingly irrational acts is couched in the unassailably naturalised neurobiological and behavioural theories of pleasure genes where ‘addicts are not masters of themselves but are instead in thrall to the external forces of suggestion, substance and impulse’ (Campbell, 2007, p20). This has profound implications for Western ethics, where moral agency is grounded in the individual’s capacity to choose and act freely and rationally, which demands the individual acts on the calculation of some given utility, or in accordance with the rules of a pre-existing hypothetical contract with other members of the moral community (Shildrick, 1997). On these grounds the addict fails to meet the necessary standards and is portrayed as a uniquely compromised subject, incapable of acting in their own best interests, who requires surveillance, management and control since their actions are assumed to be determined by their need for drugs (Keane, 2005). Because the view of the autonomous self-representing individual of Western moral philosophy is so fundamental to modern definitions of the self and institutionalised in an elaborate array of economic, legal and political structures, such a diagnosis carries great political import, revoking the right to non-intervention and authorising legally coerced treatment (Hall, Carter and Morley, 2004). As Keane (2005) argues, this constricted notion of ethics itself acts to exclude those defined as addicted (and therefore trapped by their bodily desires) from having their voices heard. Denial becomes a symptom of disease, where the addict’s expressed wishes and versions of reality are to be ignored in order to respect their ‘genuine’ needs and desires: ‘And the stronger the addict’s insistence that he or she does not need treatment or that the problem is other than addiction, the stronger the proof that the disease has him or her in its grip and that coercion is justified’ (Keane, 2005, p97). Consequently, coercive treatment structures become necessary not only for those who

profess themselves to be addicted, but for all those who use drugs, as was made abundantly clear in the 2003 US National Drug Control Strategy, NDCS, which announced:

'Of the estimated 3.9 million individuals who needed but did not receive treatment in 2000, fewer than 10 percent—just 381,000—reported actually thinking that they needed help... If there were ever any question about the role of coercion in getting people into treatment, these findings should answer it' (ONDCP, 2003, pp14-15).

4.2. DISRUPTED VOLITION IN THE COURTROOM

The government's authority to legally coerce treatment is derived from the state's police powers and its role as *parens patriae,* 'parent of the country', which has had its greatest application in the treatment of children, mentally ill persons, and other individuals who are regarded as legally incompetent to act on their own behalf. The role of the state's police powers to protect the public health and safety will be examined in more detail in Chapter 6, and its powers in its *parens patriae* role with regard to minors in Chapter 7; here it will focus on the latter role in regard to adults. In a liberal democracy there are seen to be no grounds for forcible medication, unless the adult is found to be so cognitively deranged as to be 'literally incapable' of deciding whether to seek medical treatment themselves, and even then, the doctrine as liberally interpreted grants power to the state only to 'decide for a man as we assume he would decide for himself if he were of sound mind' (Feinberg, 1980, p79). As described in Chapter 1, the nineteenth century attempt to construct the addict as lunatic failed, and while 'substance dependence' and 'substance abuse' are diagnostic categories within the DSM, such a diagnosis is insufficient for a *de facto* legal finding of mental incompetence. Indeed, the DSM-IV itself acknowledges the differing utilities of diagnosis (Jutel, 2009) in stating that:

'When the DSM-IV categories, criteria, and textual descriptions are employed for forensic purposes, there are significant risks that diagnostic information will be misused or misunderstood. These dangers arise because of the imperfect fit between the questions of ultimate concern to the law and the information contained in a clinical diagnosis. In most situations, the clinical diagnosis of a DSM-IV mental disorder is not sufficient to establish the existence for legal purposes of a "mental disorder," "mental disability," "mental disease," or "mental defect." In determining whether an individual meets a specified legal standard (e.g., for competence, criminal responsibility, or disability), additional information is usually required beyond that contained in the DSM-IV diagnosis.' (APA, DSM-IV, 1994, pxxiii)

Although Janssens *et al* (2004) have argued that addiction in the US is predominantly defined by a legal anthropology where the addict is regarded as an autonomous subject, since the late 1990s there has been a change in the US government's rhetoric. Earlier discourses which focused on the need to 'protect those innocent victims whom drug use and trafficking violate ...and to enforce the rule of law over the tyranny and cruelty of lawlessness' (ONDCP, 1995, p9) have been reconstituted, now portraying addicts as themselves victims, suffering from the 'disease' of drug use and desperately in need of treatment (ONDCP, 2003). Notwithstanding a clear societal preference for personal liberty in medical decision-making, coerced treatment has now become a fixture of the behavioural health field and the courts have been shown to be willing to substitute the judgement of professionals over the wishes of individuals considered to be mentally impaired, including those identified as addicts (Ridgely and Iguchi, 2004). However, there is a distinction made in legal discourses between 'court-mandated treatment' and 'legally coerced treatment'. The former does not allow the person any choice; that is the court orders that the person must receive a certain form of treatment as a condition of being paroled. In the latter, the person is given a series of 'constrained', 'alternative' or 'leveraged' choices: namely (i) the choice of whether to accept treatment or to receive the standard court penalty for their offence (e.g. imprisonment); and (ii) for those who choose treatment, a choice of treatment type that could include a specified medication, but would also allow other options (Hall, Capps and Carter, 2008, p1923).

In recent times in the US, mandated pharmacological treatment has been applied to the use of Depo-Provera, a long-acting contraceptive device containing synthetic hormones, in men convicted of sexual offences. Typically used as a female contraceptive lasting up to 3 months, when used in men it reduces the amount of testosterone by up to 75%, supposedly lowering sexual desire and thus inappropriate sexual behaviour (Spalding, 1997). Since the mid-1990s chemical castration statutes have been passed in California, Florida, Georgia, Iowa, Louisiana, Montana, and Oregon (CCLE, 2004). Further, in 2008 a US Court of Appeal upheld a district court ruling mandating involuntary long-acting antipsychotic medication as a condition of supervised release for a man diagnosed with schizoaffective disorder. Previously involuntary psychiatric medication had only been considered constitutional in prison and to restore competence to stand trial (Freeman and Frierson, 2009). To date no pharmacological addiction treatment has been mandated by the US Courts as a condition of parole; however, legally coerced drug treatment has burgeoned in recent decades, evidenced by the growing drug court movement in the US, first developed in 1989 in response to the ever-increasing number of drug cases overcrowding America's criminal courts. As of February 2011, there were 2,193 drug courts operating throughout the US, and another 208 in planning stages (NCJRS, 2011). Drug courts offer defendants the 'choice' of participating in an intensive court-monitored treatment program as an

alternative to the normal adjudication process. Individuals are eligible for the drug courts if they have been charged with a non-violent offence that is seen to be the result of drug use, *or* for simple possession of a controlled substance. Although the structure and scope of drug courts varies from one jurisdiction to another, the basic model aims to reduce recidivism and rehabilitate participants by providing various phases of treatment such as detoxification, self-help groups, drug education classes and community service. Abstinence is monitored through frequent, mandatory drug testing and offenders that do not me*et al*l the requirements of their treatment programme, or do not complete treatment, face sentencing and imprisonment. As Nolan (2001) notes, the model has received almost uniformly positive media coverage and overwhelming public support at both the national and local levels where 'judges celebrate the drug court as an exciting movement, a new way of justice, even a revolution in American jurisprudence' (p5).

The closest analogy to the potential use of the cocaine vaccine within the criminal justice system is that of long-acting formulations of naltrexone, an antagonist that blocks the brain's receptors for heroin and other opiates without producing any pleasurable effects, created by DuPont Merck Pharmaceutical Corporation in the 1980s (cf. Bonnie, 2006; Caplan, 2006; Hall, Capps and Carter, 2008). Naltrexone cannot be given until after a patient is fully detoxified from opiates otherwise it will precipitate sudden and violent withdrawal. Further, because it indiscriminately blocks the opioid receptors in the brain, people taking naltrexone are advised to carry a card or wear a bracelet at all times, advising emergency medical personnel that conventional opiate-based painkillers used to treat serious pain will have little or no effect on them (CCLE, 2004). However, antagonist medications such as naltrexone have not proved to be very successful in terms of uptake as a daily oral medication, with less than 1% of self-reported opiate addicts using it. In October 2010 however the FDA approved Alkermes depot formulation of naltrexone which lasts for up to a month, and a number of companies have developed naltrexone implants, which are surgically inserted under the skin providing a blocking effect for up to 6 months; however, none have been approved by the FDA as yet (NIDA, 2010a).

Within dominant legal, policy and bioethical discourses, the greatest advantage of active vaccines are seen to be that they obviate the need for patients to motivate themselves to stick to a treatment regimen, increasing compliance and thereby effectiveness, measured in terms of abstinence (Gorelick, 2008). Such rhetoric frequently portrays the vaccines as completely safe and effective. For example, Stevenson (2005) states that:

'Pharmaceutical researchers have developed what appears to be a completely effective, and completely safe, vaccine against cocaine (and its derivative drugs like crack)... The person experiences absolutely no effects from the cocaine. There is no high. There is no overdose. The metabolism does not accelerate. The vaccine renders cocaine both harmless and useless... The researchers insist that the vaccine's effectiveness

can only be ensured by the patient's willingness to participate in an overall treatment program (i.e., counseling) and motivation to overcome her addiction. *This is a bit of a bald assertion, of course; no one has tested the vaccine on unwilling subjects (for obvious ethical reasons), and it is not clear from a biological standpoint why the vaccine would not work the same regardless of the recipient's attitude*' (pp7-14, italics added).

Such accounts construct the vaccine as holding the promise of resolving May's (2001) clinical paradox: finally placing the recovery of the addict in the hands of the physician, which, directed by the benevolent state, can circumvent the need for patient motivation that has to date prevented addiction from being successfully medicalised. On the basis of such constructions, a number of scholars have already examined the legal context for the use of active vaccines for cocaine within the US criminal justice system, both as a mandatory condition for parole and under legal coercion, as an alternative to a custodial sentence. The consensus is generally that both mandatory and coercive treatment would, in principle, be permitted under the Constitution's Eighth Amendment or the guidelines issued by the World Health Organisation, subject to constraints of due process and the establishment of the vaccines safety and efficacy (Cohen, 1997; Hall, Carter and Morley, 2002; Hall and Carter, 2004). Further, some authors have argued that it may be defensible to extend compulsory vaccination to addicts outside the criminal justice system, on the basis of protecting the interests of both the individual and society. For example, Ridgely and Iguchi (2004) argue that:

'Experience suggests that it may be to the special interest of society to use immunotherapies particularly in vulnerable populations such as drug-abusing pregnant and parenting women, homeless addicts, and recidivist drug offenders due to the societal and economic costs of their continued addiction. Experience further suggests that some of these individuals will comply with treatment only if they are mandated to do so' (p262).

However, a number of concerns about possible unintended adverse consequences of the legally coerced use of active vaccines have been raised, namely the possibility that addicts will attempt to override the blockade by increasing the dose of drug, or that they will use other drugs that are not blocked by the treatment (cf. Hall, Carter and Morley, 2002; Hall and Carter, 2004; Hall, Capps and Carter, 2008). Further, such direct forms of state intervention appear at odds with the shift to newer forms of biopolitics based on liberalism and the promotion of individual autonomy as the dominant practice of political rule (Rose, 1999b). Indeed, the only dissenting voice in regard to the coercive use of the vaccines comes from Boire (2004), a Senior Fellow in Law and Policy at the Center for Cognitive Liberty and Ethics, CCLE, who argues that such technology 'expands the drug war battlefield from the Colombian coca farms and the Middle Eastern poppy fields to a new terrain directly inside the bodies and brains of drug users' (p217). In a report released by the CCLE in 2004, they challenge that the coercive use of the vaccinations would violate a person's

right to 'freedom of thought' since 'controlling what chemicals can or cannot reach a person's brain synapses, directly affects how that person thinks' (p36). Moreover, they argue that 'to forcibly pierce a person's body to insert a pharmacotherapy drug that is designed to patrol or police that person's body for the purpose of controlling possible brainstates, grants the state the ultimate power over the individual. Such a power is incompatible with a democracy built upon the premise of individual freedom and limited government' (CCLE, 2004, p37). However, as Raman and Tutton (2009) express:

'While biopolitical government largely works through self-governing participants (a governmentality which ''solves'' the liberal challenge), it also permits the illiberal management of unruly individuals or groups by appealing to the notion of a ''society'' that is internally complex and that may periodically require intervention by the state for its maintenance and security. In sum, ''biopolitics'' signifies from the start a conceptual complexity that is in keeping with real tensions between the simultaneous promotion of individual freedom and the justification of coercive strategies in liberal societies' (pp5-6).

The question of how this governance is justified in terms of public health benefits, by analogy to debates on universal vaccination for infectious diseases, will be returned to in Chapter 6 (cf. Cohen, 1997). However, the tension inherent in state infringement on personal autonomy in the name of the best interests of the legally competent subject is the pertinent issue here. For example, Stevenson (2005) examines the coercive use of the cocaine vaccine as a challenging test case for the model of libertarian paternalism, or 'nudge economics', as put forward by Sunstein and Thaler (2004, 2008). Nudge economics proceeds on the libertarian basis that, in general, people should be free to do as they like; in Friedman's term, they should be 'free to choose'. However, it admits paternalism by 'choice architects' such as government, to try to influence people's behaviour in order to make choosers better off '*as judged by themselves'* (Sunstein and Thaler, 2008, p5, italics in original). Policies are only acceptable insofar as they are 'liberty preserving', in that they make it easy for people to exercise their freedom by opting out of undesirable arrangements if they want to do so. One such example is the way in which food is arranged in a school canteen. If it can be so designed as to promote the consumption of healthy food, without removing the ability to consume unhealthy food, so as to 'make the students best off, all things considered', such a nudge is seen to be regarded as acceptable paternalism in a liberal society. The basis for libertarian paternalism is the view that people do not always make rational decisions, rather they often go along with the status quo or the default option, such that:

'By properly deploying both incentives and nudges, we can improve our ability to improve people's lives, and help solve many of society's major problems. And we can do so while still insisting on everyone's freedom to choose' (p9).

Stevenson (2005) considers whether it would be permissible for the state to mandate the use of the vaccine 'in the best interests of the person' in mentally competent people, where the subject class in question typically makes 'bad' ('contrary to self-interest') decisions (p61). He concludes that Sunstein/Thaler's model would allow for the mandatory use of the vaccines in parolees or probationers, since as convicts they have forfeited some of their rights to personal autonomy, which would enable policy makers 'to take more liberty with their paternalism' (p11). By comparison, in regard to welfare recipients, Stevenson argues that although there are 'utilitarian' arguments for requiring the cocaine vaccine for this group such as 'ensuring efficient use of public resources', the vaccine would likely be mandated because of 'a feeling that the beneficiaries of the public largess should be grateful enough to willingly forfeit some of their autonomy or bodily integrity and submit to the vaccination' and therefore would not be justified on the grounds of libertarian paternalism (p11). Although Stevenson recognises that the model does not consider the fact that expert decision-makers may themselves make similarly 'bad' decisions, or that their judgement may be clouded by moral judgmentalism, this is viewed simply as a 'ghost in the machine of the libertarian paternalist model' (p11). However, arguably he misses the most compelling argument that can be made for the coercive use of the vaccines within a libertarian society; *that it creates autonomy*. It is not that addicts have forfeited some of their rights to autonomy, but that addicts are seen to be incapable of making self-determining autonomous decisions about their drug use, such that it is respect for self-determination that requires mandatory treatment as a way to create or enable autonomy.

This argument is most clearly put by the bioethicist Caplan (2006) in regard to the naltrexone implant, who begins by highlighting the emphasis that has been placed in American bioethics on the values of personal autonomy and respect for patient self-determination priority over the past three decades:

'One of the great achievements that people in bioethics claim for the field is that it shifted medical practice away from a paternalistic model to one respectful of self-determination. Today, you cannot find a stronger value in the ethics of American medicine than respect for self-determination' (p117).

Caplan continues that a person has the fundamental right, well established in medical ethics and in American law, to refuse beneficial and helpful care, even if such a refusal shortens his or her own life and has detrimental consequences for others. Consequently, he argues that any proposals for mandatory or coercive treatment for drug-addicted prisoners on the basis of individual or societal benefits are unlikely to find any traction in American ethics, law, or public policy. However, he continues that 'there is another neglected but far more promising moral rationale for compelling the treatment of prisoners who are addicted' (p118).

'People who are addicted... cannot be autonomous agents precisely because they are caught up in the behavioral vice that is addiction... If a drug can break the power of addiction sufficiently to restore or reestablish personal autonomy ... then mandating its use might be justifiable. In other words you might force treatment in the name of autonomy... If naltrexone or any other drug can permit persons to make choices that are free from the compulsions or cravings that would otherwise completely control their behavior, then it would seem morally sound to permit someone who is in the throes of addiction and who cannot choose anything to have the ability to choose restored through a course of treatment' (p118).

Addiction is thus constructed as a form of coercion itself, where the person is driven by cravings and desire which absolutely determine their behaviour, a discourse which is bolstered by the reconstruction of addiction as a chronic relapsing brain disease. Abstinence-oriented medication then takes on the role of creating competency by blocking these physiological forces, such that mandatory treatment is seen as restoring autonomy and not interfering with it. Caplan concludes that the moral basis for this intervention is for the good of the patient and their autonomy, and that whether someone ought to be able to discontinue such medication at some point is an open problem, but not a key one, rather: 'the moral challenge is to open the door to mandatory treatment' (p120).

However, although bioethics origins are claimed to conform to the ideals of a pluralistic society with a need for legal policy that transcends the particularism of religion and culture, it arguably nonetheless incorporates implicit beliefs, norms and values through its discursive carrier of analytical philosophy (Mayall, 2002). The moral agent of western liberal moral philosophy is predicated on a conception of the subject as 'found', built around the 'negative' definition of freedom; 'the belief that freedom can be measured by the autonomy of the agent's actions, that is, by the absence of exterior 'obstacles' to the implementation of an original intention or plan' (Gomart, 2002, p518). In such accounts either the individual acts as a full rational agent, or the drug acts upon them and they are coerced. It is all or nothing since in the negative definition of freedom, acts cannot be shared; an act is autonomous only if it is acted alone, and agency disappears if any exterior force acts upon the individual. As Gomart (2002) notes, if the subject is constructed as *either* subjugated *or* free from constraints, it becomes impossible to conceive that the subject might benefit from pharmacological constraints through harm reduction measures. Rather, such abstinence oriented approaches are predicated on an 'apprenticeship' of freedom, which in the same vein as earlier temperance campaigns have sought to restore the capacity for reason and autonomy to prevail as the only legitimate goal of drug treatment. Where harm reduction approaches have been tolerated legal and bioethical scholars have tended to protect the underlying ideal of moral agency, justifying such measures in terms of social as opposed to individual benefits. For example, Caplan (2006) argues that methadone, an agonist drug that satisfies heroin's cravings without causing a high, and other substitution therapies do nothing for

the drug-addicted individual who has lost capacity for self-determination and only substitute a more socially acceptable form of addiction. Similarly, Cohen (2004) argues that:

'Heroin prescription may not be the ideal approach to therapy, but it is not without benefit... This modality of treatment does not change the addict's compulsion and craving but directs them into forms that are more acceptable both to the public health community and, perhaps, society as a whole' (2004, p260).

However, as López, (2004) argues, such a concept of autonomy ignores sociological critiques which argue that autonomous action is not a property of individuals but of complexly-ordered social relations. It also uncritically accepts the dominant biomedical model of addiction which constructs drug use as an invasion and unnatural, constituted as the result of a process of pollution and corruption in which foreign substances have disrupted the original balance and self-sufficiency of the body (Keane, 2005). Further, the monopolisation of debate over the use of the vaccines in adults by bioethical and legal discourses, both predicated on the same underlying conception of the individual as that which allowed the disease model of addiction to emerge, has meant that its use voluntarily by adults has been largely ignored as ethically unproblematic, even while the ability of the addict to provide informed consent to participate in clinical trials where they will be given their drug of dependence has been questioned (cf. Charland, 2002; Cohen, 2002; Foddy and Savulescu, 2006a, 2006b). However, the expected futures they express have arguably been built on constructions of the vaccines which pay little regard to the material realities of the technology and its interaction with the individual body or the complex social phenomenon of drug use. As Hall, Capps and Carter (2008) argue, the history of addiction treatment bears witness to the premature adoption of new therapies which have been widely disseminated before the necessary evidence was collected to evaluate their safety and efficacy, leading the field to discover belatedly that at best such treatments were no better than placebo's, and at worst, harmed some of their supposed beneficiaries. They prompt bioethicists to learn the lesson that they have a moral obligation to be well acquainted with the empirical evidence that is relevant to ethical issues on which they give opinions.

Consequently, the rest of this chapter will look to ground moral debate about the use of the vaccines as treatment in empirical evidence, in order to formulate more sociological analyses of their prospective use. As such, this chapter will now present an analysis of the data collected from interviews with those involved in the development, application and regulation of the vaccines, mainly in the US, but also in the UK. It will also present an analysis of the perspectives of potential user groups in the UK, drawn from the focus groups conducted with smokers, social cocaine users, drug users in treatment and parents. It will seek to explore the underlying constructions of addiction and their implications in these key actor groups in order to guide empirically grounded interpretations of the potential benefits and drawbacks of voluntary and

coercive treatment with immunotherapies, and to explore the underlying frameworks that are guiding assumptions about efficacy and usefulness.

4.3. THE 'CEILING EFFECT': CONSTRUCTIONS OF UNCERTAINTY BY KNOWLEDGE PRODUCERS

Overall, key experts involved in the development, and potential use and regulation of the of the vaccines in both the UK and the US were highly critical of discourses which constructed the vaccines as magic bullets which could enforce abstinence without patient motivation. In line with Mackenzie's (1990) 'certainty trough', those most closely involved with knowledge production about the active vaccines were the most likely to put forth 'humble' or limited claims of success, portraying the efficacy of the vaccines as highly context dependent due to the inherently variable and partial nature of the technology. Coercive use was therefore seen to be highly ineffective and potentially very harmful, likely increasing rates of overdose and prompting patients towards other drugs. Rather, vaccines were constructed as only suitable for a small subset of highly motivated patients within the context of wider treatment regimes, although this was not seen to detract from their overall worth.

The vast majority of expert participants contested the construction of the vaccines as capable of obviating the need for patient motivation by enforcing abstinence from within the body, and were highly critical of accounts which constructed the vaccines as a magic bullet since they created patient expectations that deflected attention from the need for patient motivation and willpower.

US31: 'I'm sure the initial thought was when they hear a vaccine, "Oh great it's gonna be you know a hundred percent or ninety percent effective like all other vaccines and I'm just gonna have to take a few shots and I'm gonna stop smoking." You know that's clearly not the case, that's not what happened in the trial' (former Vice-President for project & technology management for company developing nicotine vaccine).

US11: 'A lot of people interested in being involved in the vaccine trial I think in large part because many people are looking for the magic bullet and I think in some ways the vaccine was seen as maybe more of a magic bullet than some of the others people think ooh vaccine protection against flu and you should never get flu [laughs] you know if you get the flu vaccine so I think we have that thinking about the vaccine oh well if I had the vaccine I'm never going to want to smoke again and certainly that's not true' (Professor of Psychiatry involved in the clinical trials of the nicotine vaccine).

Knowledge producers involved in the development of the vaccines drew on uncertainties around the 'ceiling effect' and the inherent variability in human response to vaccination to dismiss accounts of the vaccine as a magic bullet. The 'ceiling effect' refers to the ability of active immunisation to produce sufficient titer levels, or amounts of antibodies in the blood, to sequester the drug in the bloodstream and prevent it from crossing into the brain and producing a

psychotropic experience, or 'high' normally associated with drug intake. They emphasised the scepticism with which active vaccines had initially been greeted in the field, because according to pharmacokinetics, the branch of pharmacology that explores what a drug does to the body through absorption, distribution, metabolism and excretion, the vaccine shouldn't technically 'work'. In order to completely block any drug effect by sequestering all the drug molecules in the bloodstream, there would need to be equal numbers of antibodies to drug molecules. Given the massive doses of drug that can be taken in a single drug-taking episode, and the frequency with which episodes can be repeated, calculations indicate that not all the drug molecules are sequestered in the serum, but rather the antibodies quickly become saturated, or reach a 'ceiling effect'. This is especially likely when the drug is injected or smoked because there is too little time between use by these routes and the drug entering the brain for the antibodies to work. The vaccine therefore will not block the effect of the drug entirely, but will rather only attenuate its effects, and can be surmounted if a sufficient quantity of the drug is taken. After animal models subsequently proved to meet the 'gold standard' of drug addiction research, reducing self-administration behaviour in rats, much of the literature argued for the need for reappraisal of contemporary theories on the rewarding properties of drugs. They postulated that the vaccines operate by binding to a significant number of drug molecules, reducing the bolus, or the concentration and speed with which the drug passes into the brain, thereby decreasing the reinforcing effect of the drug (cf. Gorelick, 2008).

However, at the time of the interviews, the pharmaceutical company Celtic had recently reported that Phase II clinical trials of their cocaine vaccine, TA-CD, had failed to meet the primary endpoint of a statistically significant difference in rates of abstinence between patients that had been vaccinated and the placebo group. However, they also reported that those patients that had developed the highest titer levels did have significantly more cocaine-free urine samples than low responders or the placebo group, although only 38% of the sample attained high levels, and these only lasted for 2 months (Celtic, 2006a). Over 60% of participants therefore were classed as 'non-responders' meaning that they did not develop sufficient titer levels to decrease the psychotropic effects of the drug. Currently, in order to achieve the highest levels of antibodies, patients are given a course of injections over a number of months to stimulate and maintain an immunological response for up to a year. In the dominant policy, legal and bioethical literatures this has been constructed as a temporary hitch which will be overcome as the technology develops, for example, Stevenson (2005) states that:

'As confidence builds that the vaccine is safe and that subjects can tolerate higher doses at once, the number of shots required may decrease, hopefully to one. The same principle, of course, applies to the duration of the vaccine. Clinical tests so far have used very conservative dosages as a precaution against side effects that would be overwhelming. As confidence builds regarding the permissible size of a dose, and

the ability of individual subjects to tolerate larger doses, the inoculation effect may last longer. This is speculative on my part, of course, but not unreasonable' (pp14-15).

However, the majority of expert participants involved in the development of the vaccines stressed that unlike vaccines for traditional infectious diseases, where exposure to the pathogen stimulates the production of antibodies in someone who has previously been immunised, the drug itself would not stimulate an immunological memory. Rather, the blocking effect is dependent on existing antibody levels, such that the person would require frequent booster jabs every few months to retain optimal titer levels for up to a year. For a small minority of experts involved in the animal models of the vaccines based in the field of pharmacology, this was framed as a technical problem about increasing and standardising absolute titer levels, to be addressed through the use of revised dosage amounts and schedules, or 'second generation' vaccines that use different or more adjuvants, or substances that stimulate the production of antibodies, in order to enhance the recipient's immune response. For a different minority, who were committed to the development of passive immunotherapies and can be located at the opposite end of the knowledge production spectrum, the 'ceiling effect' and titer variability were used to form a critical stance towards the lack of a clear strategic basis for the intervention. They tended to be outside of clinical or rehabilitative settings, and voiced a preference for passive approaches to drug treatment because the dose of antibody can simply be increased to match the amount of drug taken, circumventing the problem of saturation. For example, US15, a pharmacologist involved in development of monoclonal antibodies, mAbs, was highly critical of the ability of active vaccines to sequester sufficient amounts of the drug to significantly reduce the effect of the drug, when compared to other antagonists, such as naltrexone for opiates.

US15: 'Relative to naltrexone I haven't seen anything with active immunisation of nicotine or cocaine I haven't seen the kinds of shift of dose effect curves to the aspects of the drug that are associated with their abuse that make me impressed relative to what a surmountable antagonist in large amounts can do pharmacologically there's an enormous difference between them enormous' (Professor of Pharmacology involved in development of mAbs).

However, for the majority of expert participants closely involved in the development of either active or passive immunisation, mAb's high costs, short duration of action and potential to trigger allergic reactions, because of difficulties in 'humanising' mAb's obtained through mice cells to avoid the production of systemic inflammatory effects and the production of human anti-mouse antibodies, were seen to be major limiting factors to their use in drug treatment. Rather they were typically presented as more suitable for the treatment of overdose or as an adjunct to active vaccination, either sequentially as a means to provide an immediate supply of antibodies as a bridge to long term treatment, or in tandem as a means to address the variability of human response to active vaccination. However, for the vast majority of interviewees, human response

to active vaccination was constructed as inherently variable, such that the length of time which it would take to stimulate an immunological reaction to an active vaccine, the maximum titer levels achieved, and the subsequent duration of action of the vaccine, were presented as largely unknown in any given individual. An illustrative comment was that of US11, a psychiatrist involved in the clinical trials of a nicotine vaccine who stated that:

US11: 'There's a lot of variability in how people responded to vaccine so people that don't respond at all and some people that do respond really well ... [it's] really complicated because relying on an individual's immune system um and so you just never know whether a person going to have sufficient antibody levels, don't know when they're going to have it it's not as though active immunisation relying on immune system not as though you have a shot and boom you know your antibodies go up, [laughs], they go up very slowly (Professor of Psychiatry involved in the clinical trials of the nicotine vaccine).

Although this variation was used to stress the limits of vaccination in drug treatment this was not seen to detract from their overall worth for a minority of patients who responded well to vaccination. For example US31, the former Vice-President of a company developing a nicotine vaccine emphasised the clinical impact the vaccine would have even if it was only suitable for ten percent of patients:

US31: 'It's not the cure all and it's just gonna be one of many smoking cessation aids. But as I said you know because of the enormity of the problem if you have fifty million smokers and you have a drug or a cessation method that can help ten percent of them that's five million people and that's a big impact' (former Vice-President for project & technology management for company developing nicotine vaccine).

However, the vast majority of participants emphasised that even in individuals who achieved the highest titer levels, the blockade could still be overcome by increasing the dose sufficiently. However, interviewees were highly critical of accounts which framed abstinence as the only legitimate outcome of treatment, arguing rather that a reduction in drug use was therapeutically meaningful. For example, US27, a Professor in Neurobiology involved in the animal models of mAbs and active vaccines for cocaine, speaking about why the technology was not actively pursued until the 1990s, argued:

US27: 'Everybody took a look at this surmountable part of that and then they said, "Well see, it's surmountable," and they just let it go, but of course pharmacology then caught up with that later and they found that all the antagonists were surmountable as well, but then nobody went back to the immunology that was also surmountable. But it turns out that of course erm there's also at the same time, there was a change in philosophy about what to do about drug addiction and one of the philosophies, that's permeated under the surfaces that cutting down on how much a person takes is not a bad thing. Okay, erm as opposed to complete abstinence, which has been like in this country has been the kind of puritan way of treating drug addiction, but that's not worldwide, that's not the case. ..So, all of these things have led to a re-evaluation of what it means to treat addiction' (Professor in Neurobiology involved in the animal models of mAbs and active vaccines for cocaine).

Testing or 'challenging' of medications by patients to see if they could still get a drug effect was regarded as a common feature of any medication in drug treatment. The key question then

became the extent to which the normal kinetics of drug absorption needed to be disrupted by the vaccine to reduce the rewarding effects of the drug sufficiently enough to be regarded as efficacious.

UK3: 'You have to have pretty high antibody levels, but I don't think you need to reduce it all, eliminate it all, I think you just need to reduce it sufficiently and that, that's the big unknown, is how much you need to reduce it, erm, the reinforcement of the craving in order to make that difference' (former Medical Director in company developing nicotine and cocaine vaccines).

However, on the whole, this was not framed in terms of the absolute magnitude of titer levels, but was rather depicted as highly context dependent. Although the 'ceiling effect' was not seen to be a key limitation to their clinical utility where they were constructed as a tool in relapse prevention for motivated populations, there was near unanimous agreement that their use coercively would be highly ineffective. Across all expert interviewees, participants stressed the need for the active participation of the user in their own recovery, and argued that those that arrived in the clinical setting before they were 'ready' for recovery, would not progress.

UK6: 'I think by and large patients need to be a more in charge and responsible for their treatment. There are very few patients… I mean patients aren't stupid, you know and I think we have to give them responsibility for their recovery and that's always been the thing about addiction, whether it's self help such as AA or NA, CA etc, it's about taking responsibility for your recovery and part of it is coming to the doctor, but then you know I think any patient that says right, you're the doctor you know exactly what to do, doesn't want to end into a therapeutic partnership. It's just as the doctor who says right don't tell me… I know exactly what to do, I'll do the operation, I won't even tell you what it is and you'll be better, you know, you know having a passive patient is as bad as having a sort of you know, an over-active doctor in my view' (Psychiatrist and Executive member of the RCoP Faculty of Addictions).

Where patients were not motivated to comply it was seen as extremely likely that they would simply increase the dose of the drug to overcome the blockade, until they ran out of money or drug. Related to this was uncertainty as to the cardio-toxic effects of the sequestered drug molecules. Although it was portrayed as likely that sequestered drug would be less cardio-toxic than unbound drug, it was also seen to be possible that it might multiply the cardio-toxic effects of the drug, as sequestered drug would be broken down into inactive metabolites in the serum more slowly than free drug. Consequently, there was seen to be a real risk that unless the patient was fully motivated to comply, use of the vaccine could actually increase harms to the patient, by increasing the risk of overdose at lower levels than would normally apply. For example, US12, a pharmacologist and medical doctor involved in the development of a nicotine vaccine argued that:

US12: 'The thing that people worry about... is that people that are vaccinated will try to override the vaccine and take more and more and end up overdoing it. Now if they do it in a slow gradual fashion they'll titrate themselves and find they simply need a higher dose of drug in order to get an effect once their vaccinated. I don't doubt they can override it if they're really serious and they get their hands on enough, but the risk would be if someone says well I'm vaccinated and I can't get high so I'll take as

hundred times as much heroin and maybe that's too much' (Professor of Pharmacology and MD involved in animal models of nicotine vaccine).

Further, where the patient was not fully motivated, the likely outcomes were seen to be non-compliance with vaccination schedules. For example, UK3, a former Medical Director in one of the companies developing nicotine and cocaine vaccines, described earlier clinical trials with participants who had been referred into treatment from the courts in contrast to those who had been motivated to take part:

UK3: 'The cocaine trials were challenging because of poor compliance... but these people were in err, rehab effectively because erm, they would have gone to jail otherwise, they were given the choice, erm, but compliance was pretty poor I have to say and erm, you know these were people who were not the best clinical trial candidates laughs] for a lot of reasons. Erm, with nicotine though it was the opposite, err, it was very easy to find people. In fact, we were inundated with volunteers, and they were good, they were very compliant, they could see the benefits' (former Medical Director in company developing nicotine and cocaine vaccines).

There was broad agreement that if it was used involuntarily, even if the vaccine did entirely block any drug effect, patients would simply swap drugs to achieve a similar effect from another drug.

US25: 'If it was involuntary they'd simply change drug, you know a lot of you know animal research has you know shown us in the self-administration models with substitution. Okay if the drug of choice is no longer available what other drugs will readily be used in their place? And any number of stimulants will readily substitute for cocaine. Erm and you know unless they go and get immunised again, you know amphetamine and methamphetamine and you know, and there are vaccines under development for that of course, but erm, so, or the individual would spend a lot of efforts trying to surmount or overcome err whatever, although if it's extremely high antibody levels it may be difficult, but these antibody levels don't stay high forever You know what we're seeing in the human work is that they remain elevated for about, you know, twelve weeks or so and then by six months they are pretty well level. Erm, so individual you know could you know after six months very readily feel the effects of cocaine again for example if it was involuntary' (Behavioural Neurochemist and Psychopharmacologist, involved in animal models of cocaine vaccine).

Importantly, these risks were not seen to be entirely mitigated by voluntary compliance; however, initial patient motivation was seen to re-orientate efficacy away from enforcing abstinence, and towards preventing a lapse becoming a relapse.

US22: 'You know as they go into a period of remission, erm not using the drug, a classic immunisation at that point might protect them from relapse, because in relapse there might be the use you know but maybe not the super aggressive use and not getting the same effect, because you have this protective binding antibody around there could be overall a maintenance of the remitted state, you know so it would be a failed relapse as opposed to a successful relapse' (Professor of Medicine involved in the development of mAbs and catalytic antibodies).

Within this framework of harm reduction, patient motivation was not constructed as static but was rather seen to be in a state of continuous flux, where the aim of drug treatment was to enable and stabilise the motivation of the patient to progress.

US24: 'The only group I could ever envision using this for would be people in treatment. And yes their motivation, you know waxes and wanes for many of them, but erm this could help' (Professor of Clinical Neuroscience involved in clinical trials of cocaine vaccine).

Moreover, there was wide agreement across all experts that even very 'effective' vaccines in terms of response rates were only part of the answer, because the biologically reinforcing nature of the drug was only one aspect of addiction:

US11: 'In any kind of addiction more than just the effects of the drug on the brain it really is all the learning you know various stimuli that are associated with smoking behaviour relying on smoking for stress management mood regulation and so on so you know these folks need to get counselling as well giving them medication to help them quit...if you talk to any clinical researcher they will say that no one expects a pharmacologic treatment to work just by itself erm the addict you know has developed a repertoire so that you can stop the drug taking but you need to do something, you might wanna call it rehabilitation, but you have got to have substitute reinforces er you know reintegrate them back in to society particularly if the drug users start at an early age then they haven't had normal development, you know, educationally, vocationally, socially and so on' (Professor of Psychiatry involved in the clinical trials of the nicotine vaccine).

US25: 'Even very effective vaccines are only part of the answer to treating addiction because it does nothing to offset the craving that is induced by the drug, err and that's because it's simply working by preventing the rewarding effect of the drug and that's only one component of drug action. The addiction, I believe is more a cognitive thing, where just one of your memory systems, erm kind of drive the person to seek the drug and use the drug. Erm, you know that there's these memories about cue's that trigger cravings for the drugs, and a vaccine isn't going to reverse any of that' (Behavioural Neurochemist and Psychopharmacologist, involved in animal models of cocaine vaccine).

In this context the vaccines were regarded as efficacious insofar as they engaged the patient in wider treatment regimes, including both pharmacological and non-pharmacological interventions. The vaccines therefore were depicted as enabling recovery, although they were not regarded as constitutive of it.

US22: 'What we're trying to do is provide erm some support [pharmacological], you know, it won't be a substitute for the exercise of enormous willpower and the exercise of free will. But we're trying to give someone a chance to withstand the onslaught of their biology, which is a reward pathway which was designed to make you repeat when it was stimulated' (Professor of Medicine involved in development of monoclonal antibodies).

US25: 'I mean it's not gonna be a magic bullet in terms of you know just stopping addiction for anybody, but if a person is motivated err it can help them... it can reduce the amount of drug that is getting to the brain, is now gonna make it easier for other therapies, both pharmacological and behavioural to be used more effectively... And you know most drug addicts are gonna slip up after being abstinent and you know and if there's something in their system that reduces the impact of taking that first hit after not having used the drug for a while, it's gonna reduce, you know if they don't get the high euphoria that they experienced before they'd be less likely to keep going and using the drug again... So I think it's a very useful approach in that regard. In itself it's not gonna be the treatment, but it's gonna make other treatments easier and I think that's a good thing' (Behavioural Neurochemist and Psychopharmacologist, involved in animal models of cocaine vaccine).

Conversely, the efficacy of the vaccines was seen to be enhanced through their embeddedness in wider treatment contexts, for example by increasing patient motivation to comply with vaccination schedules through the potential use of incentives, to prevent the high drop-out rate

seen with other antagonists such as naltrexone. Further, wider treatment settings that addressed vocational, educational and social problems were seen to decrease the likelihood of harmful effects of vaccination, such as overdose and swapping drugs.

UK4: 'If you think about an addict who's been taking a drug to moderate their mood or behaviour for years and then suddenly you give them, you remove that drug, but you don't give them anything, like giving them an antagonist, who then suddenly has all their emotions and everything to deal with, it can be very hard. ..So, I have an issue with vaccination. I think it's going to be an interesting way forward, but I think it to medicalise it means that you've got to make sure of the psycho-social interventions are there to support these people and that's the bit that I'm not sure about' (Professor of Biological Psychiatry and Addiction).

US18: 'What do they do with the rest of their day you know um if they they don't have much in the way of a résumé for employment um so it's tough for them to find jobs and tough for them to find and in many cases the straight community they've burnt their bridges are reluctant to you know have them even come to the church and so forth it's a so its try to get communities involved in supporting them but it's not that easy' (Behavioural Neuroscientist involved in the development of active vaccines).

Overall then, voluntary vaccines were constructed as a welcome but limited addition to the current armoury of pharmacological interventions; an effective option for some people, alongside other pharmacological and non-pharmacological interventions, in the context of wider treatment regimes.

UK2: 'I think with all new treatments you know, it's the emperor's new clothes isn't it, you know, they think they've got this wonderful thing and then you know, a few years down the line people realise it's not as great as they first expected... but it would be crazy to think there'll be a magic bullet to cure all addictions, it would be another little tool in the armoury of specialists to try and, you know help someone, you know in their battle, in their lifelong battle erm, but I certainly don't think it'll be a revolution in err, in the treatment of addictions' (Psychiatrist and advisor to the ACMD).

UK6: 'This is not the magic bullet but you know, we want to have new things. You know you wouldn't get somebody saying to a psychologist oh well this psychological addiction is only a bit helpful, don't focus on it, it's, you know, it's part of what we call the armoury of things we have to use in dealing with you know, people that are often very ill, very distressed, you know, looking to us for help, and we want to enter into partnership with them, erm, and part of the partnership is to offer the best pharmacological approaches er, as well as the best psychological and social interventions. You know, there's good science er at that level, but where we found things like that helpful has been where it's been combined with a range of techniques, so you know, as long as it's kept in context, I'm very happy' (Psychiatrist and Executive member of the RCoP Faculty of Addictions).

US27: 'You gotta remember this whole approach is an adjunct. This is not a magic bullet for treatment of addiction, but I can tell you know you go out in the community and you speak to ...you'll get two or three people come up afterward and say, "You know I'm... I'm a three pack a day smoker. I have tried everything." And they'll list all the drugs and all the patches and all the stuff, and nothing works and when they hear about antibodies for nicotine, "When's it gonna be ready doc?" You know, they want that, because they can't control, they can't stop on their own. They want something to help them, and that's always given me hope, that you know maybe this can be a contribution' (Professor in Neurobiology involved in the animal models of mAbs and active vaccines for cocaine).

US24: 'I have very humble expectations for this vaccine ultimately and I do with all medication, any approaches, You know, so again my hope for this is real, but it's err, you know it's humble' (Professor of Clinical Neuroscience involved in clinical trials of cocaine vaccine).

The only exceptions to this were two interviewees drawn from NIDA, who can be seen as 'program loyalists' who showed high levels of certainty about the future success of the vaccine, and cohered much more closely to the dominant rhetoric shown in the earlier legal and bioethical discourses. For example, when questioned whether it should be used coercively US21, a member of the Pharmacotherapy Section in the Intramural Research Program of NIDA argued:

US21: 'As always we have in the addiction field the issue of patient motivation, many patients you know show denial. I mean many patients come to treatment only because of external pressures, so er that's the reason why a vaccine active immunisation might have an advantage, because it doesn't require the patient to decide you know every day, I'm in treatment, I'm gonna take this pill, they just maybe have to come in two or three times, get their vaccination and then, you know, they are protected so to speak. So, I don't know, er that's an open question we have to wait and see when we have an effective treatment' (Pharmacotherapy Section in the Intramural Research Program of NIDA).

Further, both US21 and US20, part of the Medications Development Division at NIDA, presented a view of efficacy as an absolute measure, which could be assessed in clinical trials independently of the wider context, and which subsequently could potentially be used alone, without the support of wider treatment regimes.

US20: 'Well let's worry about that when we get a vaccine that works, you know and then we'll see how well it works and then we'll decide... I mean the business of drug development... it's very methodical, it's very success driven. You've got to have the data, you've got to show that it works to continue development... You know you gotta have a successful product, you've gotta prove in clinical trials that it works' (Medications Development Division, NIDA).

US21: 'I think one could make the case that with a robust enough treatment there might be some patients who could do well with only the pharmacologic treatment, whether that be a vaccine or not, but it would probably depend on their psycho-social resources and so on' (Pharmacotherapy Section in the Intramural Research Program of NIDA).

4.4. STEP ONE: DISCOURSES OF POWERLESSNESS AND UNMANAGEABILITY IN DRUG TREATMENT

A striking finding was the overwhelmingly positive perception of UK drug users in treatment towards the vaccine for cocaine, such that many said they would be keen to be 'guinea pigs', or would 'commit crime to fund it' if it was not available on the NHS. However, situated between the two ends of knowledge production, they tended to act as 'program loyalists' according to Mackenzie's (1990) certainty trough, and did not challenge the construction of the vaccines as completely blocking drug effects or its very long-term duration, as it was presented to them through newspaper articles and other materials. As such, an interesting analogy to the potential role of the vaccine in treatment programmes was that of opiate antagonists, or 'blockers', such as naltrexone. Although the naltrexone implant is not licensed for use in the UK, a specialist GP in the district in which the rehabilitative centre was situated had been issuing them on the NHS

between 2002 and 2004, reportedly fitting more than 300, over 80 of which were referrals through the local Criminal Justice Intervention Programme. A GP may prescribe an unlicensed medication if, in their professional opinion, there is sufficient evidence of its safety and efficacy; however, in 2004 the practice was terminated by the relevant Primary Care Trust, on the basis that there was no nationally recognised sound evidence to prove its success, and therefore should only be carried out within the context of a research project (Shapiro, 2004). As these groups were conducted in 2007, there was still a strong collective memory among the residents about the effects of the implant, with a number of the residents having either personally received them, or known someone closely who had.

Most of the participants in these groups had been using heroin and crack cocaine for between 10-30 years, had numerous failed recovery attempts, and had spent extended periods of time in prison. Although curiosity, the 'buzz' and a sense of peer belonging were common reasons given for initiating drug use across focus groups with social cocaine users and drug users in treatment, adverse life events also featured as prominently in the accounts of participants in the latter group. Sexual or physical abuse in the family home featured most frequently for women, with family breakdown and bereavement the most common amongst men. In this context drug use was often constructed as a means of blocking out emotions and delaying dealing with life events they felt unable to cope with. For example, bereavement, divorce and abuse were prominent in the accounts given below:

F25: 'I'd say I just wanted to keep in with the crowd like all me mates were doing it and so to keep in with them lot and I'd say when me son died, 12 days old I hated everything, everyone, I just started using it to like suppress me feelings I suppose and then I just continued cos I felt such loneliness, depressed bored, to be honest every hit I had I was hoping I'd never wake up from you know what I mean it was always getting bigger and bigger so I hoped I'd never wake up from it' (drug user in treatment, S4/G1).

F26: 'Started using drugs because of personal family problems, step-dad used to beat me so I just wanted to block the memories out, also the company that I were keeping and I wanted to know what it were like meself to block out my feelings that I found hard to deal with such as me son's death, personal family problems, that's it' (drug user in treatment, S4/G1).

F27: 'I felt I had to kind of do it to be accepted and also which I think is one of main ones for me is er it wa the envelope that comfort blanket for me to my parents' divorce it cloaked it all out but you know put it on back burner that smashed I didn't hear arguments and if I did I didn't care you know' (drug user in treatment, S4/G1).

F28: 'Erm, well it all started, I was abused by me uncle till about 8 year old that's when I started drinkin an just had a shitty life had no love or affection from my parents' (drug user in treatment, S4/G1).

F30: 'I started takin heroin because me brother were doin it just after me Dad died and I'd just started knockin about with my brother and I just started takin it then ... kept suppressing me feelins' (drug user in treatment, S4/G1).

Participants in these groups tended to couch their narratives within a biomedical model of addiction hallmarked by the loss of volition, consciously or unconsciously drawing upon and constituting tragic narratives that both accounted for events and gave shape to them, in terms of the way in which they related to self and others (Bury, 2001). Positive talk of pleasure and enjoyment around drug use were almost entirely absent, with addiction portrayed as the reason for transgressing moral codes they would normally abide by and the subsequent loss of family, friends, accommodation and employment.

F27: 'I'd never dream of stealing off me family you know in in life on life's terms d'ya know as an addict d'ya know I I'm ashamed to say it I'm not proud to say it I have stole things from my family d'ya know and it hurts me I feel like I'm disgraceful but yet that's the addict that's the nature of the beast d'ya know it's not a right nice beast know what I mean' (drug user in treatment, S4/G1).

F33: 'Like everyone else it stripped me of everything I had I had a nice wife I had a nice house daughter and erm you go down that slippery road for a lot of years and then you start becoming aware ow slippery that road gets you get these bridges to start with you can go over regular and they all burn down one at a time and it gets to the stage you've no more bridges left and er and yer on yer knees then beggin for help' (drug user in treatment, S4/G2).

F36: 'One day it hap it er got hold of me and I were getting withdrawals and er that's definitely bin an eye opening I were that were just the start of me downfall of er everything what I had er which is a family er a wife er do ave kids in my life but I'm no longer a family man no more er I've lost all that it's took everything from me basically' (drug user in treatment, S4/G2).

The dominant rhetoric across these groups was that participants found their own drug use highly problematic and wanted to stop, but felt that it was often beyond their control. Gaining a place at a residential rehabilitation unit was presented as a key factor in most participants narratives of recovery. However, all participants in these groups were positive towards the role of medication in drug treatment, constructing both agonist and antagonist pharmacological agents as a 'crutch' which enabled them to assert their willpower, in line with the dominant harm-reduction accounts given by knowledge producers. Participant's level of knowledge about relevant medication was very high and the perceived benefits and disadvantages of different medications varied considerably. Within dominant policy, legal and bioethical literatures the main benefit of longer acting antagonist or vaccination approaches is seen to be that they increase compliance to abstinence, where non-compliance is largely constructed as morally deviant, a matter of ignoring expert advice formulated in the patient's best interests. However, in line with Conrad's (1985) patient-centred account of people's compliance with epilepsy medication, participants saw themselves as active agents in their treatment rather than passive recipients, self-regulating or varying their medication practice on grounds connected to the management of their everyday lives. Within the medical profession the side-effects of the many pharmacological medications were seen to be more than balanced against the harms of addiction; however, for drug users in treatment, medication was viewed instrumentally, and side effects were seen to be balanced against the perceived therapeutic efficacy of a drug in the achievement of specific outcomes. Many participants made a distinction between phases of addiction, and construed antagonists as

potentially helpful either in 'active' addiction, once they had recognised their use as problematic but felt unable to control it, or in the early stages of 'remission' to protect themselves from relapse after a period of abstinence. The latter was presented as both physical and psychological, with the knowledge that they had taken a blocker constructed as giving them confidence that they could remain abstinent, independent of the actual reduction it had on the effect of the drug. Consequently, antagonists were frequently seen as desirable when they knew they were going to be in what they regarded as 'high-pressure' situations, such as leaving prison or a residential rehab, or seeing using friends or relatives again after a period of absence. As F27 commented:

F27: 'At this little address at [rehab] we're sound d'ya know what I mean but it's a cold world out there an I feel I feel that d'ya know from my experience of treatment in past people going out there on their own with no sort of ah I don't know what word to use without any like naltrexone without any blocker er will find it hard y'know cos in reality life is hard it's not all a bunch of roses cos your not on drugs d'ya know what I mean and I think it's harder for addicts to settle into society than it is for y'know for Joe public, my views on it y'know' (drug user in treatment, S4/G1).

A key difference between participant's perceptions of when antagonists had been successful appeared to be the initial level of motivation and commitment to recovery that they retrospectively considered themselves to have had when they had begun to use the medication. For example, for F32, the use of the naltrexone implant had prompted them to start using crack cocaine, but they argued that it wouldn't have the same effect now:

F32: 'I had an implant me I got outta prison went and got it done same day I got out thought it wa cure all for everything [tuts] just made me smoke crack 7 days a week 24 hours a day yeah it cured me o heroin just pushed me towards crack well it wont the implant that pushed me toward crack it wa me but I just needed to ave someat d'ya know what I mean whether it wa smack or crack or both or whatever [tuts] it were just me I wont in right place at the right time wa I, to take advantage of the implant d'ya know what I mean cos it it's good it stops you taking heroin but [sighs]... Through choice now if we speak in present terms now I could take heroin if I wanted to take heroin I don't take heroin I could take crack but say if I were on naltrexone now the way my ead is now it wouldn't push me towards crack' (drug user in treatment, S4/G2).

Indeed the rhetoric that people had to reach 'rock bottom' before they were ready for recovery was a common theme among both drug users in treatment and expert interviewees involved in drug treatment, as F27 explains, drawing heavily on the AA or 'Twelve Step' paradigm:

F27: 'A lot of people believe you know people who hant been an addict well why don't you just stop, ...but it's the lifestyle that that the majority of people have to lead that takes its toll on people you know an there's gotta be a time when everyone needs to put it down … but like it says in step one you know you've got to come to realise that powerless over your addiction and life become unmanageable until that appens yer in my opinions you're not ready to get better, d'ya know' (drug user in treatment, S4/G1).

However, even where they presented themselves as fully committed when they had got the medication, many reported experiencing feelings of panic and loss very quickly afterwards, and when they found themselves within high-pressure scenarios, especially early on in the process of

recovery, the need to manage their daily existence often took precedence over longer term commitments to abstinence. Consequently, where medication was taken daily it would frequently be ceased, either temporarily or longer term, as described by F27:

F27: 'When I was taking the oral tablets I wa getting a lot of side-effects off em headaches stomach aches er and they were long-lasting ones er sickness in the morning er so really put me off taking them and again wi being an addict it the choice is yours whether you take it or not and er after a while you know addict got better of me and I stopped taking them er took me like roughly another two year to sort my life out get myself clean again' (drug user in treatment, S4/G1).

In their case, even though they experienced seemingly worse side-effects from the naltrexone implant, they regarded it positively since the long-term constraint on their ability to use had enabled them to return to the community and prevent lapses from becoming relapses when adverse life events occurred and their motivation had temporarily waned.

F27: 'I got myself into treatment and got myself clean got myself a three-month implant ...initially I were like yeah great buzzing best thing since sliced bread but then twenty minutes later when I sat and thought about it it were like getting slapped round face d'you know or fear I thought well what if it all goes wrong in treatment now I can't even run to a bag for comfort d'you know, I got passed that and er it set me up for like nine month 3 month implant helped me stay clean for 3 month it's meant to do and six month beyond that er I'd progressed quite a lot in my life you know I'd ended up getting a job a good job at that sorted things out with my ex-partner er we'd got back together like I say I had I had a good job but er I ended up using twice and I could see where it were gonna go d'ya know just using twice then feeling shit d'ya know er and then there were the guilt and all that that I felt you know lyin to my girlfriend and y'know stayin out of her way and knowin next day at work wouldn't be able to look boss straight in eye cos still smashed cos I'd been clean such a length of time and I thought sack this I'll get another one er so I went and saw Dr [name] got another one er again another 3 month implant and that set me up for best part of what, 9, I'd say about 15 month... I personally suffered with it didn't go all rosy cosy for me I got I did get infection from me first un it were like I say 3 month implant er it'd be like 8 week after I got it done got up at 6 O'clock in the morning and thought I'd go for a jog er went for a five mile run with my friend and er the scar where the implant wa which is [shows scar] er me shorts the waistband on me shorts were rubbing on it so by time we'd come back from finished the run it were itching a little bit er and later on that evening I looked down and it were like half a boiled egg sticking out of me so I had to go get it lanced, got it lanced and got a course of antibiotics er it swelled up again so I got it lanced again took a course of antibiotics and er I was right as rain y'know I had 2 smokes nine month after the implant and er y'know regardless havin two little heads growing out of me sides I won't bovvered got another knew it were helping and that wa what I needed at time think it's different for everyone y'know' (drug user in treatment, S4/G1).

However, longer term constraints did not necessarily enable recovery, where many people reported increasing dose or swapping to other drugs in high-pressure scenarios. In the most extreme case, one resident claimed they had sought to remove the implant themselves, and many participants shared similar stories of other people they knew. For example, for F34 longer acting antagonists such as the naltrexone implant were seen as inefficacious, since the knowledge of such a long term constraint over drug use pushed them towards other drugs, because it was always playing on their mind. By contrast, daily oral naltrexone was constructed as sufficiently stabilising their motivation to enable them to successfully reintegrate into the community, even though they had experienced considerable side-effects.

F34: 'I think the tablets are better cos you've got to you know you can take them, and they last 36 hours so if you miss one you still can't take heroin anyway but with the implant you've got no choice so your thinking you've got no choice and I've seen a lot of my friends just use crack instead... I came out of prison and I scored the first day and er went into ...rehab and I started taking naltrexone [oral] an I was finding some horrible side effects off it as in nightmares 6 o'clock wake up every single morning [general yeahs] no matter what time I went to sleep erm but I've done ten and an half months on em and that's the er longest clean time that I've had so far but when everyone else was spending their money on smack and crack on a Friday I'd be ironing me clothes and getting in the shower going out all around [town] villages and I enjoyed it an er honestly' (drug user in treatment, S4/G2).

Further, because side-effects were seen to be balanced against the achievement of specific outcomes, participant's assessments were not static, but subject to frequent reappraisal. For example, in retrospect, while F31 deemed the side-effects they associated with the naltrexone implant acceptable when they were early on in their recovery and felt they needed such a constraint in order to enable their life to progress, they were not seen to be acceptable now, when they considered themselves to be in remission.

F31: 'It's good for what it does it gets ya a bit of clean time I had a naltrexone implant it got me three month clean time an then I stayed clean for 7, 8 month after that but I don't think you wouldn't get me taking it again, if I wa in a bad place I'd probably get an implant but where I am today I wouldn't, ...I wanted it cutting out after I got it put in but it were good it did me good for three months well it did me good for twelve month but it were good for what I needed it for then, but just stop you from being happy I don't know what they do to your body but they do something to your body that just makes you sad all time an, I think it blocks some sort of blocks, someat anyway, you don't feel at all happy or sad your just in-between not normal just a bit down but you're not really sad you're not really happy' (drug user in treatment, S4/G2).

In line with the dominant expert position, although the vast majority of drug users in treatment constructed pharmacological medication, including (but not restricted to) antagonists, as enabling recovery, they were not regarded as constitutive of it. For example, F36 compared the vaccine to naltrexone positively, arguing that they could start 'fixing you' but were not a cure:

F36: 'Yeah definitely cos as I said with when I went onto naltrexone I had that as my crutch until I could get full trust in myself and full er full focus on on er stayin y'know ultimately stayin clean an more often than not crack has sent me back to jail heroin hant so much ever got me to jail with heroin but once crack has been involved it's more er yer more eavily into yer er yer crime it'll even push ye into doin a lot more er stupider things er you know what I mean where your ultimately then just back in jail er so if that were on offer I'd take both of em and it it at least that's a start then of of fixing you as far as yer not gonna be er actively addicted er well yer still gonna be addicted yer addicted all time but it's putting a stop to er er yer ongoing you know off and on one minute yer wantin to be clean next minute you're not' (drug user in treatment, S4/G2).

Rather, antagonist medications were seen to be capable of 'breaking the cycle' and enabling recovery, but where this did not occur within the context of wider drug treatment programmes that taught the addict how to not use drugs over a prolonged period of time, this was regarded as potentially psychologically damaging because they would always be wanting to use, but unable to do so.

F31: 'It's good for what it does it gets ya a bit of clean time I had a naltrexone implant it got me three month clean time an then I stayed clean for 7 8 month after that so it's good for stopping the heroin use
F35: Yeah
F31: It's not good for treatment though for like teaching you how to not take drugs it stops you from taking drugs
F35: Eiii
F31: It takes the choice away
F36: Yeah
F31: Which is good for some people because some people need that choice to be taken away so they can get a bit of clarity a bit of clean time under their belts, so they can learn to use learn not to use know what I mean? As a short term treatment I think it's alright but its down to choice if you wanna take drugs you'll take drugs if you don't wanna take drugs you won't take drugs, but I wouldn't want me choice permanently taken away cos like I were sayin fer a short period of time like it's alright just to give you that bit of breathing space to help you out because some people can't break the cycle but at end of day I think it it has to come down to you because if you get that an yer still wantin to use in yer head it'll be torture d'ya know what I mean it'll do more psychological damage than it will do you any good I think
F33: Cuckoos nest
F31: Yeah yer head would just be totally battered like
F35: Yeah
F31: Like when I had that naltrexone implant it were like I'd bin divorced d'ya know what I mean it wa proper heartbreakin fer three days an I wanted to stop usin but fer someat that's lifelong it'd be flippin ooh if you were still wantin to use it'd be torture, even though you dint want to use when them urges come along an you did want to use an you couldn't I think it would be like proper a proper headblag
F33: Good way o lookin at it that
F34: An I I think going through the twelve steps an the process that that should reprogramme you not to use anyway, you know, cos it does work for a lot of people
F31: It's all about slowly reprogramming rather than
F33: Keep doing it
F34: I'd rather ave me own do it off me own back rather than have someone say you can't' (drug users in treatment, S4/G2).

Antagonist medications, including the vaccines, were thus depicted as a key stepping stone for some people, but one which ultimately had to be stopped if they were to be truly recovered from addiction as argued by F27:

F27: 'I do believe they're good to give you that stepping stone especially out in society cos like as drug users you're labelled as the lepers of society aren't you d'ya know and er I felt that wi me havin this implant I moved to a new area I got a good job it give me a decent little foothold in community around me... but like I say ultimately you've gotta live without em so yeah they are good for the short term in my opinion but ultimately you can't live with it forever and you need y'know while you've got that implant in your not using simply because you can't y'know you you've got to be able to resist society y'know er as an addict in recovery not wanting to use not using just because you can't because you don't want to' (drug user in treatment, S4/G1).

Salient then was the ability to reassert 'moral virtue' over their drug use at some point in their recovery, when they felt they would have a chance of conquering their addiction without pharmacological constraints. As F31 commented, the ultimate testament to their recovery was having the ability to use and choosing not to do so:

F31: 'If I were actively using, I'd want them both, but today I'd rather have the choice, do you know what I mean I'd rather have the choice and it be my decision ... I'd rather have the choice whether I take it or not, deciding them choices makes it whether you take drugs or don't take drugs makes you stronger as a person not just do you know what I mean it builds your character' (drug user in treatment, S4/G2).

4.5. CHOOSING TO USE: CONTRASTING TALK OF DRUGS, DESIRE AND THE DECISION TO STOP

Potential users drawn from the focus groups with smokers and social drug users in the UK (including those parents who were current or past users of nicotine or illicit drugs), were the most sceptical towards the development of the vaccines, questioning the profit motives of the pharmaceutical industry and drawing on 'slippery slope' arguments to highlight concerns that they would eventually be used coercively by governments, especially in the context of illicit drugs, to prevent people from 'recreational' use. These groups can be seen to be alienated from the new technology, located at the opposite end of the knowledge production spectrum; however, unlike those committed to the development of alternative technologies, they did not challenge the construction of the vaccines as completely blocking drug effects or its very long-term duration, but were rather highly critical of the underlying biomedical model of addiction, seeing their use of nicotine or cocaine as a personal choice, which served a number of positive roles in their life. However, there were important differences between social cocaine users and smokers, and their perspectives will be examined largely separately.

The majority of social cocaine users reported taking cocaine on a weekly or monthly basis in order to enhance pleasure and enjoyment, to enable them to 'keep going for longer' in certain social settings, to think more freely, to feel a part of a group, and to escape the monotony of daily life. They viewed their use as a part of normal everyday life, managed and sensitive to external factors, such as social and geographical environment, financial costs, and health related factors and most reported extended periods of no use or reduced use due to changing life and work commitments. Overall, use was presented as a matter of rationally and reflexively re-ordering priorities at different times in their lives, for example when F19 talked about her changing patterns of drug use through pregnancy and F22 through geographical relocation:

F19: 'Obviously when I decided that I was gonna become pregnant everything stopped for me, all drugs and alcohol and cigarettes and everything and I didn't use anything while I was pregnant ... I mean I had other priorities erm I don't miss it, but if it's there you know if I go to someone's house and you know people have it then I want to join in but otherwise it doesn't bother me' (social cocaine user, S3/G1).

F22: 'I'd gone from that period [heavy use] to then moving to London and not even thinking about it it makes me feel quite sort of happy that if it's not there it's not something that I would miss but the fact that its easily accessible you know it just makes it something that I can pick or choose when I wanna and I do prefer if I'm on a big night out I would say I would always prefer to have it than not cause I'd think I wasn't got last or you know have as big a night or something like that but I don't feel anxious about it at all' (social cocaine user, S3/G2).

Over half the social cocaine users expressed they had been concerned about their own use at some point in their lives, due to health issues, reduced motivation, and its effect on their capacity

for work and other life commitments; however, these concerns were presented as a matter of recognising the role of the drug in the problem, and simply making a conscious decision to reduce or cease use, for instance when F24 talked about their health problems:

F24: 'I had concerns because I suffered from anxiety for a bit and there was a time when I started getting quite severe heart palpitations and after that I kind of cut down, I mean it was something that I noticed like a physical reaction like and even like the next day, and I thought maybe it's not worth it that's all' (social cocaine user, S3/G2).

None of the social drug users had sought professional help about their use at any point, or used any pharmacological supports and they all resisted being labelled as addicted. Perhaps unsurprisingly then, they considered the vaccine as inappropriate and unnecessary in the present; however, they also tended to dismiss any consideration of it in the future on the basis that they would never become addicted because they would always be able to stop through willpower alone should they decide their use was problematic.

F19: 'I can't foresee me ever being in that situation I think I can just take things or leave them but personally if I was in the situation where I felt like I was really addicted and couldn't do anything about it then you know I might choose to do something like that, although I always think I could personally get over it myself without that first but depends how strong willed you are doesn't it' (social cocaine user, S3/G1).

F21: 'If you feel as though you have a problem if your desperate to give up to like get on with your life sort of thing great idea yeah if it works and it doesn't have any side effects as long as it's voluntary and people want it I can see there being a market for it yes I'm sure there are people who've gone over the edge and need to you know stop erm personally though I'd hope we have got over that hump meself' (social cocaine user, S3/G1).

F20: 'I think it would be a good idea because there's certain people out there with certain personalities that probably be the best thing for them, but I don't think it's the best thing for everybody' (social cocaine user, S3/G1).

Such accounts can be seen to constitute 'heroic' core narratives, in contrast to those of tragedy employed by drug users in treatment, which help to maintain a social distance between acceptable or responsible drug use and addiction as the loss of moral agency (Bury, 2001). However, they also reflected an underlying normative framework that contested a homogenised biomedical view of addiction, where biological reward was regarded as sufficient to maintain drug using behaviours. Although participants regarded vaccines as potentially helpful to some people, they were seen as highly limited if they detracted attention from psychological and sociological aspects of drug use, since drug use was about the 'high' and not the drug itself, such that people would simply swap drugs if their underlying issues were not addressed. For example:

F22: 'If you're actually on that much of a mission to get high that you actually need to have a drug to stop you getting high then you will just find something else... it's about the high it's not about the drug itself it's about how it physically makes you feel someone feels they need that so much then they will replace it with something else because inside them that's what they need' (social cocaine user, S3/G2).

F20: 'I really can't see it stopping Ok well it stops the receptors of the drug giving you the high on your brain but I think a lot of people that have got an addictive personality are gonna be like
F21: Go find drain cleaner or something like that
F20: They'll do anything to get the high basically whether it'll be cocaine or something else, getting that feeling whether your addicted to cocaine or heroin or whatever if someone just gives you an injection and says right you're not going to be addicted to that anymore mentally I'd be like well OK I'll get addicted to something else you know I want that same feeling' (social cocaine users, S3/G1).

Similarly then to the perspectives of knowledge producers and drug users in treatment, these participants presented the use of cocaine vaccines as inefficacious and potentially harmful if used outside of comprehensive treatment programmes as indicated by F24 and F23 below:

F24: 'I don't really see it would necessarily solve many problems like it may be cutting off one thing to them but it's not addressing the behavioural aspects of it it's not addressing the they could find something else or you know it's all those things they would associate with that lifestyle not just the drug use for one specific drug' (social cocaine user, S3/G2).

F23: 'The vaccines are fine so long as there's other you know they're still gonna need to spend on you know helping the mental side of it or cause you know a lot of people who are addicted aren't just addicted like haven't just become addicted to that drug it's generally cause something's not quite right in their life or there's this something's gone off balance and they look for a solace in something else because it makes them happy or it makes them feel normal' (social cocaine user, S3/G2).

The majority also raised concerns about the long-term side-effects of the vaccines and a significant number were sceptical of the motives of the pharmaceutical industry and the government in developing the vaccines, drawing on 'slippery slope' arguments to highlight concerns that they would eventually be used coercively to prevent all drug use, magnifying the concerns outlined below:

F23: 'And obviously the physical effects of like when you were saying like that they can't feel euphoria or what have you there must be some sort of other side effects of these vaccines like that would have you know in terms of people's personalities are they gonna get dumbed down you don't know' (social cocaine user, S3/G2).

By comparison, the majority of smokers reported smoking between 6-30 cigarettes a day to enhance pleasure and enjoyment in certain social settings, for relaxation and 'me-time', and as a tool for stress management and weight control. However, although the majority considered their use as sensitive to external factors such as social context to a certain extent, only a minority of smokers presented their use as a matter of rationally and reflexively re-ordering priorities throughout their lives. For example, F13 considered themselves to be a 'social smoker', who had only smoked occasionally since they had met a non-smoking partner:

F13: 'I met my boyfriend and he didn't smoke so I just kind of I just felt like I didn't want to smoke cause he didn't and then I just kinda so that's how I kind of stopped and then I found myself just having the occasional one so... I don't smoke on a daily basis but I don't think that I'd ever want to completely give it up because I do still enjoy it like in those social situations and like to I do enjoy it sometimes so I don't think that I'd want to completely give it up' (smoker, S2/G1).

However, overall, patterns of use tended to be presented as less flexible, and most did not report periods of non-use of longer than a few hours when awake and the vast majority reported one or more failed quit attempts and applied the label of addict to themselves. Similarly to the dominant rhetoric in the groups with social cocaine users, some smokers offered heroic narratives of recovery which constructed all pharmacological intervention as supplanting rather than enabling willpower, through replacing a moral journey of recovery with a quick pharmaceutical 'fix' and only suitable for 'others' who were not able to moderate or cease their use by willpower alone, such as seen in the talk of F1:

F1: 'If you've got a strong mind I think you can overcome the sense of addiction and you know it depends what kind of person you are... I mean I was able to about the fourth time round just stop out of willpower but you know I'm kind of a really strong minded person and not that many people have got that you know I'm not gonna do it I'm not gonna do it' (parent and ex-smoker, S1/G1).

However, most smokers had used a variety of nicotine replacement therapies, NRT's, agonist pharmacological supports that relieve craving and withdrawal symptoms, which are seen to be the 'gold standard' in smoking cessation treatment within the medical profession because they have virtually no side effects. However, for many smokers, seemingly minor side-effects had led them to quickly cease using them and return to smoking:

F12: 'I tried the tabs as well and they did help but then I ended up with a huge blister under my tongue cause I'd been sucking them so hard
F10: Yeah I had a blister under my tongue too
F13: And I got allergic to the stick on ones
F9: Yeah the patches I had a reaction to them when I tried them' (smokers, S2/G1).

F17: 'I've used everything apart from inhaler you had that inhaler didn't you
F14: Oh I hate that inhaler
F15: Yeah the taste of it's horrible and it don't seem, it takes a tiny little bit of the edge off but it's not enough nowhere near enough' (smokers, S2/G2).

However, in contrast to drug users in treatment who drew on a biomedical model of addiction as the loss of autonomy, although the majority of smokers expressed feeling that they *should* stop smoking, due to financial costs, the disapproval of non-smoking partners or friends and future health concerns, they nonetheless expressed a strong desire to continue smoking because they enjoyed it. Varying medication practices in the micro-management of daily life then did not occur within the context of a long term commitment to abstinence as with drug users in treatment, but against the backdrop of an overt ambivalence towards denying oneself a key pleasure through abstinence, clearly seen in the talk below:

F10: 'I don't want to stop smoking because I enjoy it I feel more like I have to give up smoking because of the expense because of the health things but if it wasn't for those negative things I love smoking I really enjoy it I really really enjoy it' (smoker, S2/G1).

F12: 'I feel I have to because I don't like that it ages you and I don't like the expense and bad for your health and I'm not as fit as I was for those reasons but I do enjoy it and I can't I don't imagine going out would be as enjoyable without a cigarette even though you have to sit outside I just don't see it as it's like bread and butter to me a fag and beer so yeah I feel that my life would be slightly lacking' (smoker, S2/G1).

F15: 'If it weren't for the possible health implications and the cost I'd probably have no concerns about smoking at all they're the two things really that affect me if it didn't cost as much as it did and I wasn't in the possibility of writing myself off then I wouldn't feel guilty whatsoever about smoking really or if I didn't have [a child] I don't think I would either cause then it'd be on my back really and there'd be no-one else to consider in that situation' (smoker, S2/ G2).

F16: 'If someone said you're never gonna have any implications I'd smoke for the rest of me life I wouldn't have any problems with it at all' (smoker, S2/ G2).

Smokers' then did not construct addiction as the loss of autonomy, but rather appeared to use the category to refer to the impact of smoking on financial constraints in the present and possible negative health outcomes in the future. Indeed, only one current smoker expressed their own use explicitly in terms of loss of autonomy, and here it was portrayed as a dual edged sword:

F9: 'It's a pleasant part of my life because I've been smoking for so long and you know it's my friend I like it I like doing it obviously the downside is expensive harmful potentially and addictive you know because it's the downside of the habit that it also ties you, you have to have a cigarette and if you don't then you do silly things to get one so it's kind of the two things are the same but form different perspectives of the addiction side either a pleasant habit or an addiction depending… I do like it I cannot conceive of a life without it but I would like to be able to conceive of a life without it not necessarily because of the expense or the harm but because I hate feeling chained to it' (smoker, S2/G1).

Stopping smoking then was largely constructed as a temporal and moral journey whereby a long-term commitment to abstinence was built up over a number of quit attempts, which enabled the smoker to generate a sense of achievement:

F14: 'Yeah but you're more likely to feel better about stopping like if I stopped smoking tomorrow and never smoked again I'd go through the journey of stopping smoking the cravings and everything like that and probably feel a hell of a lot better when I've stopped and if I do want a cigarette I'd be like well I've done all this and I've gone through all this why do I want a cigarette whereas if I'd got a jab and didn't want a cigarette ever again it wouldn't
F17: You wouldn't feel like you benefited and done it yourself
F14: Yeah like the achievement' (smokers, S2/G2).

When considering longer acting treatments such as vaccines, for the vast majority of smokers, the loss of the choice to enjoy smoking through the perceived immediacy of the blockade and its duration was regarded highly negatively, as indicated in the talk below:

F9: 'It's that element of choice with craving isn't it like you saying to yourself well I could have one if I wanted I could ask F10 and he'll give me one but your choosing not to so you don't feel deprived in a way I suppose because you could if you wanted to
F13: I think it'd be harder if it was like oh you can't have one if I was told I could never have one again
F9: Yeah
F10: Oh I couldn't handle that

F13: No I like having the choice I like knowing I don't think I could ever give it up completely I like knowing that I can have one if I want one
F9: Yeah I think that's really important cause you know if the child having a tantrum doesn't come out does it if someone says no you can't have a cigarette then it's argggggg I'm gonna going to thwart you
F10: If it's longer term you make a choice to have that vaccine which you may well have made an informed decision but you may well want to start smoking again after that you may find that in certain situations you miss that you miss socialising with that group but tough you're immune you've made that decision now whereas nicotine replacement therapy you can just stop you don't have to continue
F9: I hate the feeling of that personal choice being taken away from you in whatever shape or form Ok it's been your choice like F10 says but then
F13: What if you change your mind
F9: Yeah exactly you change your mind or some really stressful situation comes along and you think I can't get through this without my fags' (smokers, S2/G1).

F1: 'Mmm see I still think of myself as a smoker because the minute that goes I'm never gonna be a non-smoker and that's my the psychology of how I how you stop like you said you have to allow yourself to have the choice
F3: Mmm
F1: And you know we have the choice now if someone offers me a cigarette I can say yes or
F3: See that's a really interesting idea you have to allow yourself the choice so if you're having these drugs which could make you feel almost panic' (parents, S1/G1).

Similar then to the discourses of experts and drug users in treatment, smokers' motivation to quit was portrayed as in a state of flux. However, whereas the majority of drug users in treatment viewed a long-acting pharmacological block as enabling them to achieve their long-term aims in certain circumstances, the ambivalence of most smokers' long-term commitment to abstinence can be seen to shape their interpretation of the same modality as primarily a negative constraint on their autonomy to choose to smoke in the present. As the groups with social cocaine users, participants were strongly critical of pharmacological determinism, and viewed the efficacy of the vaccines as highly limited as they only addressed the nicotine use itself and did not take into account the wider role that smoking played in the person's life, for example, F12 referred to smoking as 'kind of breathing' indicating its importance in their life. However, rather than swapping drugs, the dominant conception was that smokers would simply smoke more, or swap to brands of cigarettes containing higher levels of nicotine in order to get an effect if vaccines were given without wider support mechanisms:

F10: 'You'd have to smoke Marlboro red to get an effect' (smoker, S2/G1).

F16: 'You have full strength cigs, smooths then ultra lights and menthol and lot of people I mean I work on cigarette counter so you know lot of people want this particular cig we don't have it in stock so they go oh give us the smooths come back the week after go I smoked twice as many cause each cig contains half the nicotine and half the tar and half the is it monoxide or someat so they're not getting so they have to smoke two to get same as one
F15: Drag on em harder as well
F16: I mean I smoke smooths where I can and I've given cigs to my mates and they've snapped the filter so they can take it all back and it just defeats the object really so I think with that you'll just see the same thing more smokes more cigs to get the same buzz or whatever
F15: Or people what smoke roll ups or such cause they tend to be stronger don't they so you probably would wouldn't you' (smokers, S2/G2).

Consequently, as was common across all the other groups, nicotine vaccines were only considered to be beneficial if they were administered in the context of wider treatment programmes which also took psychological and sociological aspects into account.

F15: 'I think that it could be helpful but not as something which you just take it and you just quit you need a lot of support or it can be something which when you quit to help you not start smoking again and same with the cocaine but it's never gonna work on its own otherwise you gonna have a hell of a lot of social issues a lot of psychological issues and general day to day problems which won't just go away you need more to it than just the vaccination itself' (smoker, S2/G2).

Again, the majority of smokers also raised concerns about the long-term side-effects and also perceived vaccines as 'unnatural', as indicated below:

F15: 'I'd wanna wait and see what happened cause its someat that the nervous system isn't really something that you wanna play around with and I'd wanna wait and see maybe wait 10 15 years and see what first generation think and see if anything goes wrong cause it's something that seems like it's quite a new thing that they're doing and you don't know what else it's gonna effect and you don't know you could take it and it then means your bodies attacking something it shouldn't be erm in future or if you need to take a drug for something else and your body attacks whatever that is you don't want that so it's someat what I would want to wait and see what happened before I took it myself' (smoker, S2/G2).

The notable exception in these groups was F2, a member of one of the focus groups with parents, but also an ex-smoker, who said that she had smoked during pregnancy and had found quitting impossible until she had taken varenicline (Champix), a partial agonist which alleviates nicotine withdrawal symptoms and blocks the effects of nicotine from cigarettes if the user starts smoking again. She was much more positive towards the use of medication in general and the potential use of the vaccine, presenting pharmacological constraints as enabling willpower but not supplanting it, in line with dominant accounts by knowledge producers and drug users in treatment programmes.

F2: 'I wish I'd never started smoking I wish I'd never never ever didn't love it as much as I do now... tried to stop smoking so many times and then Champix actually made it possible gave the power basically to be able to do it and long term stop not that it's not still difficult every day' (parent, S1/G1).

4.6. DISCUSSION: NOTIONS OF EFFICACY AND UTILITY

The empirical evidence suggests that in this context both knowledge producers in the UK and the US and illicit drug users in treatment facilities in the UK are highly positive towards the development and potential use of the vaccines voluntarily, where vaccines were constructed as enabling autonomy and stabilising motivation. In line with dominant legal and bioethical

discourses such as that by Caplan (2006), participants in this group drew on biomedical models of addiction which construct addiction as a form of coercion which determines behaviour. Similarly then, abstinence-oriented medication took on the role of creating competency by blocking these physiological forces. However, in direct contrast to these dominant accounts, such constructions did not reflect an underlying libertarian definition of agency based on the dualism of autonomy and subjugation. This was crucial since knowledge producers presented the efficacy of the vaccines as inherently variable and partial, only attenuating and not blocking the rewarding effects of the drug and only lasting for periods of months not years. Vaccines were thus only portrayed as suitable for a small subset of highly motivated patients within the context of wider treatment regimes, which would address psychological, sociological and environmental factors of drug use. Recursively these were seen to increase the efficacy of the vaccines through maintaining patients in booster programmes and decreasing the potential of the vaccines to cause harm. Through directing attention to the complex interplay of interactions between human and non-human actors by which autonomy is produced, such accounts depict the human subject as constructed, where varying constraints, including agonists, in the context of wider treatment regimes is seen to provide the chance to enable the addict to behave differently (Gomart, 2002). They were thus highly critical of accounts which portrayed the vaccines as magic bullets which could enforce abstinence without patient motivation, with coercive use therefore seen to be highly ineffective and potentially very harmful, likely increasing rates of overdose and prompting patients towards other drugs. Interestingly then, although the vaccines were perceived as having limited efficacy in clinical trials, they were portrayed as having a potentially major clinical utility, for the small subset of highly motivated patients that responded to treatment if they were embedded in wider treatment contexts. Overall then vaccines were considered to be 'one in the armoury'; a useful adjunct to other approaches, which could enable autonomy and stabilise motivation, but did not constitute recovery.

Although illicit drug users in treatment can be considered 'program loyalists' according to Mackenzie's (1990) certainty trough, discussion and comparison to other antagonist and agonist medication suggests that participants differed in which constraints they found most helpful, and that these varied over the course of their treatment journeys. The vast majority related tragic core narratives of spoiled identities through drug use, predicated on a biomedical model of addiction as the loss of autonomy, and were likely to perceive vaccines positively as enabling autonomy and restoring the capacity for self-governance. They can be seen to willingly enter into medicalisation in order to account for events and give shape to them in terms of the way in which they relate to self and others (Bury, 2001). However, they also reflect the availability of scientific scripts as the dominant cultural lexicons available to people with which to fashion experience and interpret their innermost sensations (Campbell, 2007). Initial patient motivation was presented

as a key factor in recovery narratives, where hitting rock bottom was regarded as essential to establishing a long-term commitment to abstinence. Drawing on past experiences with naltrexone, drug users in treatment indicated that where antagonists were used before this point, increasing of dose and swapping of drugs were common means of circumventing the blockade. Where they could not be easily circumvented, they could be psychologically and physically damaging. However, even where they had perceived themselves as fully committed, non-compliance was common, but their discourses challenged dominant constructions of non-compliance as deviant behaviour, presenting themselves as active agents in their treatment, self-regulating or varying their medication practice on grounds connected to the management of their daily existence (Conrad, 1985). The understanding that side effects (including abstinence itself) are evaluated against the achievement of specific outcomes demonstrates the context-bound nature of efficacy and highlights the need for vaccines to be embedded in wider treatment contexts if they are to have clinical utility. Further, medications that were regarded as enabling autonomy in active addiction were often regarded as constraining autonomy in inactive addictive, precluding their ability to demonstrate 'moral virtue' over their drug use. This was only seen to be possible where the addict acted 'alone', without any medication, and was portrayed as the ultimate testament to recovery, reflecting the cultural power of the conception of the neo-liberal individual.

By contrast, social cocaine users and current smokers (including parents where they were a current/ past drug user or smoker) in the UK formed a second group, and were more critical towards the development and potential use of the vaccines. Overall, social cocaine users presented their use as a rational part of normal everyday life, sensitive to external factors, and contested a homogenised biomedical view of addiction, where biological reward was regarded as sufficient to maintain drug using behaviours. Vaccines were generally considered a positive addition for 'others' who could not reflexively manage their drug use amidst changing life conditions, but emphasised their limitations and potentially harmful effects if used outside of comprehensive treatment programmes which did not treat the underlying psychological and sociological problems. Similarly, the majority of smokers portrayed the vaccines as inappropriate for personal use. Across this second grouping then participants tended to present heroic core narratives of drug use as natural and positive aspects of being human, and were likely to perceive vaccines negatively as constraining autonomy and supplanting motivation. Such accounts formed sites of resistance to the dominant clinical gaze, which enabled participants to maintain a social distance between acceptable or responsible drug use and addiction as the loss of moral agency. However, arguably they also promote alternate 'technologies of the self', or ways of knowing and understanding the self, and ways of acting on these selves through self-discipline, as will be explored in more depth in Part II (Turner, 1997). They also reflect a wider cultural alienation from

pharmacological determinism, which portrays chronicity as a feature of the brain on drugs, rather than of the social worlds in which people learn to use drugs in chronic ways (Campbell, 2007).

However, it is perhaps surprising that smokers fitted largely into the second grouping, constructing themselves as autonomous agents whilst presenting their patterns of use as relatively inflexible, having numerous failed quit attempts and accepting the label of addict as applied to themselves. Given the discourses of F2, a parent and ex-smoker who presented pharmacological constraints as enabling in line with the dominant accounts given by knowledge producers and drug users in treatment, it is perhaps likely that should groups have been conducted specifically with ex-smokers, there would have been more substantial overlap. However, it perhaps also reflects the nature of the substance under consideration and the sets and settings of drug use. Tragic narratives constructed around drug use included clear notions of 'hitting rock bottom' as key to the formation of a long-term commitment to abstinence, which is supported by the findings of MacIntosh and McKeganey (2001) who have drawn on Goffman's (1986) work on the 'spoiled identity' to explain successful recovery attempts from unsuccessful ones. This in turn likely reflects the dominance of AA or 12-step programmes in illicit drug treatment and the nature of addictive illicit drug use. As Tournier (1979) has argued, AA aims to provide a therapeutic milieu within which persons with spoiled identities can re-establish social ties with others similarly stigmatised. At the foundation of the AA message is complete disillusionment with life, since it is from this 'low bottom' that addicts are seen to be able to escape their predicament, by abandoning their illusions of control and accepting the label of addict. However, as Tournier notes, while this disavowal of control may be helpful to someone that is alienated from family, peers or community and is using alcohol or drugs as a means of coping with isolation and with feelings of loneliness, it has a tendency to homogenise drugs and drug users and its universal utility is questionable.

Although the reappraisal of all drugs in terms of their rewarding or reinforcing effects has led to a broadening out of concepts of addiction and an increasing convergence between tobacco and illicit drugs, as seen in Chapter 3 nicotine has never entered the category of abuse in the DSM because it does not cause an identifiable state of intoxication and there is no impairment in social or occupational functioning as an immediate and direct consequence of tobacco use. Rather, the concept of nicotine addiction was argued to reflect a shift towards the valorisation of health in certain cultures, whereby a loss of autonomy was inferred by the presence of a physical disorder which was seen to be exacerbated by tobacco use (APA, DSM-III, 1980). However, it was clear that smokers tended to accept the diagnostic category of addict not on the basis of the presence of a physical disorder, but on the grounds of present financial constraints and potential physical disorders in the future. Consequently, long-term commitment to abstinence can be seen to be

more difficult to establish, unless financial or health implications threaten identity in the present, such as was the case for F2 when she had continued to smoke during pregnancy. Therefore, the majority of smokers in these groups negative appraisal of a long-term constraint on their ability to use can be understood in terms of the new temporal dimension that can be seen in constructs of nicotine addiction, which requires the individual to balance potential negative future health against actual positive pleasures in the present, as will be examined in more fully in the next chapter.

In conclusion, the vast majority of all knowledge producers and potential users drawn from across the focus groups cohered around a view of the vaccines as but one in the armoury, which would only prove to be beneficial if they were embedded within wider treatment contexts that could address psychological, sociological and environmental factors of chronic drug use or smoking. Paradoxically however, it is the complexity of the social phenomenon of drug use and addiction and the inability of the vaccine to be able to enforce compliance once an addictive state has been reached, that has prompted certain policy and scientific discourses to shift the gaze away from the addicted body and towards the body politic, as Lingford-Hughes and Nutt (2004) make clear by analogy to the treatment outcomes with other antagonist pharmacological approaches:

'They have not proved particularly successful in practice because they are not reinforcing: they give no pleasure. Indeed, they may be aversive if they displace residual agonist, such as heroin, from the brain and precipitate withdrawal. For these reasons, drug addicts are generally reluctant to use antagonist treatments unless required to do so by law or as a requirement from a professional body to continue in work. There is no reason to suppose that the antibody vaccination approach will not have similarly low take up... Perhaps an alternative strategy would be to produce an enduring blockade before first exposure as a preventative measure, such as is done with vaccination against measles and other infectious diseases. This would, of course, be ethically controversial, although given the fact that cocaine dependence is more damaging to many individuals than measles, it is an option that should be debated' (p11194).

Indeed, a report by the US National Research Council Board on Behavioral, Cognitive, and Sensory Sciences (Harwood and Myers, 2004) has argued that the most practical use for these vaccine products will be in children and adolescents. As such, this thesis will now turn to the biopolitics of the population, and the particular techniques of governance associated with discourses of health promotion and the rise of the 'risky subject' in advanced liberal democracies (Bunton and Peterson, 1997; Nettleton, 1997; Rose, 2006).

PART II: PROPHYLACTIC VACCINATION OR A BIOPOLITICS OF THE POPULATION

5. PRIVATE CHOICES AND PUBLIC HEALTH PROBLEMS: THE RISE OF ADDICTION AND THE POLITICS OF PREVENTION

'The health of the people is really the foundation upon which all their happiness and all their powers as a State depend.'

Benjamin Disraeli, 'Speech before the House of Commons, July 24th 1877' (in Johnson, 1963, p42).

5.1. THE EPIDEMIOLOGICAL TRANSITION AND THE RISE OF LIFESTYLE MEDICINE

Part I of this thesis assessed the potential role of the technology as a form of anatomo-politics aimed at disciplining and normalising the individual addicted body. Following on from this, Part II will focus on the ways in which the state has sought knowledge and power over the social body, looking at the role of prophylactic, or preventative vaccination as a form of biopolitics of the population. It seeks to explore the tensions between older forms of biopolitics which acted on the whole population and the shift to newer forms of public health which characterise advanced liberal democracies, that seek to govern populations through the control of risk. This chapter will briefly review the key public health literature to highlight the extension of the clinical gaze into the everyday lives of the population by charting the rise of epidemiology and the shift away from a focus on the individual addict onto the problems associated with drug use and addiction on an aggregate level, focusing on developments from the 1950s (Bunton 1997; Miller and Rose, 2008; Nettleton, 1997; Rose, 1999a, 1999b). It aims to demonstrate the increasing collision of policy approaches to smoking and illicit drugs, through examining how public health's increasing reliance on biomedicine and its evolving focus on environmental individualism has embedded addiction within a paradigm of infectious disease in dominant discourses. It will also explore the ways in which technologies of the self have increasingly been articulated in somatic terms, where certain lifestyle factors have come to be understood as themselves disease entities by virtue of their irrationality in a culture which increasingly prioritises health as the key manifestation of the modern self-reflexive, autonomous agent. It is argued that by reclassifying curative intervention and 'magic bullet' treatment technology as public health prevention tactics, the state is directed to exert its police powers to protect the public health and safety, and parental desire to protect their children is activated. This framework will then guide the subsequent empirical examination of the discourses of key actor groups. Chapter 6 will explore the role of the state's police powers to protect the public health and safety, through the techniques and practices of control and

discipline inherent in older forms of biopolitics aimed at the whole population through the potential strategy of universal or mass childhood immunisation of addiction. It will begin by locating the technology in the broader historical and cultural context of vaccination and the relationship between the state and its citizens, before providing a critical overview of the construction of the new technology as a protective vaccine in the dominant discourses of industry, policy and bioethics. The data analysis will then explore the underlying constructions of addiction and their implications in key actor groups, in order to guide empirically grounded interpretations of the potential benefits and drawbacks of widespread preventative vaccination against addiction. Chapter 7 will extend the discussion of the role of the state in neoliberal biopolitics by focusing attention on new forms of indirect regulation, surveillance and control. In particular it will examine the discursive construction of childhood and the relationship between the state, parent and child, before seeking to deconstruct the popular public deficit model of understanding by empirically exploring the factors underlying parental decision making about vaccines for addiction for children. By shifting the focus to technologies of the self, or the ways in which technologies of domination are internalised and reproduced by individuals in the context of their parental role as guardians of their children's future health and happiness, it will examine the willingness or resistance of parents to further the medicalisation of addiction by seeking or accepting vaccination against addiction for their child.

In both the UK and the US in the last years of the nineteenth century, public health and medicine had been viewed as overlapping areas of interest and activity. Developing from 'social medicine' with its roots in nineteenth century concerns with health and social reform, advocates regarded medicine as playing a political role in the creation of egalitarian societies in a period of social activism and reform, marked by tensions between personal liberty and state intervention, which saw the application of scientific methods to government, industry, finance, medicine, schooling, theology, education, and the family (Rodgers, 1998). Early paradigms of public health stressed the need to develop sociological enquiry into the conditions that maximised health and prevented disease, rather than focus exclusively on clinical medicine. Importantly, while medicine is often assumed to consider its remit downstream, late on in the process of pathogenesis, public health was historically focused on ameliorating the social and environmental conditions producing disease. In the twentieth century public health became concerned with integrating the social role of medicine into the training of physicians through the creation of a new academic discipline of social medicine, which would provide medicine with the clinical skills to analyse the social causes of illness and health in the same way that the alliance between medicine and the laboratory sciences had provided new insights into the chemical and physical bases of disease (Porter, 2006). However, as the twentieth century progressed, their changing boundaries led to a relationship marked by antipathy and hostility. For Brandt and Gardner (2000), public health came to be

identified with prevention and a focus on populations, together with interest-oriented policing and politics, while medicine became associated with the cure and treatment of individuals, within an objectivist and reductionist technocratic science.

Rogers (1998) sees the pre-war era as a period of trans-European, trans-Atlantic, social experimentation with programs meant to soften and delimit the effects of intensive industrialisation and urbanisation, as the 'progressive architects of social politics... searched for a middle course between the rocks of cutthroat economic individualism and the shoals of an all-coercive statism' (Rogers, 1998, p29). But as Europeans and Americans borrowed, imitated and modified social programmes, existing local and political circumstances actively shaped their implementation, and the strategies sought to stabilise society by modifying the play of market forces and softening the social and economic inequities of the market took on different forms (Karger and Stoesz, 2010). Intertwined with international debates about socialised medicine and the eradication of health and socio-economic inequalities, the relationship between public health and social medicine took varied paths during the interwar years and by the end of the Second World War its institutionalisation differed widely in different national contexts. Porter (2006) describes how in Latin America, social medicine focused on the social structural determinants of health, such as economic inequality, with an aim of political and social transformation, whereas public health continued to prioritise the practical implementation of public policy.

In the US, Colgrove (2006a) argues that for most of the twentieth century the public health profession was institutionally weak compared to organised medicine, and that it struggled to advance a community focused mission in a civic culture that privileged individualism, the free market and limited government. As Brandt and Gardner (2000) demonstrate, as the medical profession became more homogenous and powerful, it increasingly viewed public health interventions as a potential infringement on the doctor–patient relationship, with early twentieth century calls by US state public health institutions for the reporting of communicable diseases, such as tuberculosis and syphilis, regarded by physicians as dissuading patients from seeking care. Further, proposals for neighbourhood public health interventions that could combine public health interventions with clinical care were regarded as threatening to the economic well being of the rising medical profession, because of concerns about free care to potential paying patients. These historical conditions powerfully influenced the orientation of medical training and practice, away from the community and the social forces arguably important in the aetiology of disease. While medical education became increasingly uniform, public health remained heterogeneous, committed to research into the social, environmental and biological determinants of health and disease in populations, but also increasingly responsible for training frontline health workers to staff the bureaucratic structures of state and federal public health agencies. Similarly in the UK,

the tension between the relation with medical services and the community role of public health was played out between general practitioners, GPs, and public-health doctors for control of the same territory in the years between World Wars I and II (Berridge, 2000). On both sides of the Atlantic while debates as to whether public health and medicine should be provided in a single unified system continued in the 1930s and 1940s, in the post-war years the growth in the biomedical research enterprise reinforced the paradigm that illness was to be fought at the physiological rather than the societal level, and further eclipsed the perspective offered by the public health profession (Colgrove, 2007, p5).

Brandt and Gardner (2000) identify the key tension that separated public health and medicine in the Anglo-American context as the emergence of the biomedical model of disease that became dominant in the first half of the twentieth century, which transformed research and practice in both medicine and public health. Where public health had focused attention on the complex social conditions that produce disease, involving interests, politics, and behaviours that resisted clear, objective solutions, the biomedical paradigm uncoupled disease from its social roots, removing socioeconomic status, ethnicity, race and culture, personal psychology, and gender from disease causation, replacing them with scientific objectivity and technique:

'[T]he biomedical paradigm brought to medicine an instrumental elegance focused at the cellular level and based on a sophisticated laboratory science. The timely and effective delivery of new and effective treatments for specific diseases became the new paradigm of clinical medicine… Medicine could not solve the problems of poverty, illiteracy, and inequity—but it could, at least potentially, cure the diseases that these social forces produced... The validity of the biomedical paradigm came to be deeply embedded in both professional and popular culture. This reflected a particularly American fascination with scientific and technical remedies for complex social problems as an approach to reform. The reductionism of the medical model, its insistence on mechanism and a universal pathophysiology, directly contradicted long-standing assumptions in public health about the significance of the social environment and behavior in the production of disease' (p711).

Although public health never completely abandoned its commitments to environment, behaviour, prevention, and the social determinants of disease, it nonetheless became increasingly accommodationist to the authority of biomedicine (Brandt and Gardner, 2000). Drawing on early work undertaken by statisticians in the US life insurance industry in the 1920s, behavioural analysis of individual risk factors began to replace traditional political/ economic explanations of central public health concerns such as infant mortality, where the established structural explanation of the relationship between poverty and infant mortality was challenged by new behavioural arguments about mother's obesity as the major determinant. As Porter (2006) argues, the previous focus of public health on social structure gave way to an interest in social behaviour, and the rise of

'lifestyle medicine', and a model of public health prevention that primarily focused on changing individual behaviour rather than addressing the social structural determinants of health and disease. This new argument claimed that lifestyles, such as unhealthy behaviours like excessive food consumption and lack of exercise, created major risks rather than life conditions such as economic inequality.

In large part this shift from an environmental to an individual focus of public health in Britain and the US following the Second World War stemmed from the epidemiological transition; the change in patterns of mortality and morbidity brought about from the decline of infectious and deficiency diseases and the rise in chronic non-communicable diseases. As Brandt and Gardner (2000) discuss, historians, epidemiologists, and demographers have frequently debated the causes and implications of this transition, since the underlying question is which interventions had been most effective in changing patterns of morbidity, mortality, and longevity during the course of the 20th century. The physician and demographic historian Thomas McKeown famously argued that the decline in mortality from infectious disease was due primarily to an improvement in economic conditions, brought about by the Industrial Revolution, which provided the basis for rising standards of living and, most importantly, enhanced nutritional status that bolstered resistance to disease, and not from targeted public health or biomedical interventions (Colgrove, 2002). However, after the epidemiological transition, the extent of chronic, mostly non-infectious diseases brought the singling out of 'risk factors' even more to the fore, as seen in the multitude of mass media messages that aim to change individual behaviour, rather than circumstances which have a major influence on the health of populations, such as wealth distribution, loss of work, or quality of dwellings, which, as Perdiguero *et al* (2001) argue, seem to be excluded from scientific, professional literature, 'because they are factors linked to the economic and socio-political sphere of society, independent from the will of individuals' (p669). They emphasise that focusing on individual behaviours ignores the fact that such 'lifestyle behaviours' (commonly referring to six concrete problems - tobacco, physical exercise, social integration, alcohol, drugs and nutrition) are systematic expressions of ways of life and models of production and consumption of differentiated social groups, and that they cannot simply be reduced to the will and responsibility of the individual to modify an 'unhealthy' behaviour and adopt 'healthy' life habits.

The new focus on chronic disease at the national level, concerned with the concept of 'risk' and behavioural determinants of health at the individual level, was epitomised by the emergence of smoking as central issue for post-war public health from the 1950s (Berridge and Loughlin, 2005). The publication of Doll and Hill's (1950) seminal article on '*Smoking and carcinoma of the lung*', which demonstrated a clear statistical association between smoking and incidences of lung cancer

was key in establishing epidemiology as a discipline, providing it with a new legitimacy as the scientific key to revealing the aetiology of disease. When it was brought into the wider public domain through the 1962 report of the UK Royal College of Physicians, RCoP, a new medico-public health coalition had formed around the smoking issue which marked the decline of the environment as a public health issue. Whilst the RCoP committee's initial remit had been on smoking and air pollution, it was soon refocused on individual issues, after discussions at a high level Cabinet committee in 1957 found the connection with smoking and lung cancer potentially less embarrassing than air pollution, which had been dealt with by the 1956 Clean Air Act. References that up to 30% of lung cancer deaths might be attributable to atmospheric pollution were dropped from the final report, in favour of a greater emphasis on cigarette smoking which stressed the role of individual prevention and responsibility for health, rather than the need for government intervention (Berridge and Loughlin, 2005). This reflected a declining emphasis on environmentalism in public health in the UK both within and outside government, replaced by a new paradigm based on the methodologically individualistic tools of epidemiology aimed at preventing chronic disease through the education of individual behaviour. While the 1957 Cabinet committee on smoking had questioned whether government could legitimately intervene in an area which was a question of individual responsibility, since public health intervention was seen in terms of vaccination campaigns and not intrusion into individual habits, by the 1970s this reluctance had gone, to be replaced by a focus on population levels of risk and the need for individual prevention, through the concept of the `risk avoiding individual' (Berridge, 1999, p1186). This new coalition of the 1960s and 1970s would subsequently provide the basis for more general public health and prevention policies across the Anglo-American context, with campaigns targeting lifestyle behaviours for the prevention of heart disease, various forms of cancer, liver disease, digestive disorders, venereal disease and obesity, in turn giving authority to the new concepts of personal prevention and the focus on the relationship between individual lifestyle and population based levels of risk (Porter, 2006).

5.2. EXTENDING THE CLINICAL GAZE: A VISIBLE EPIDEMIC

Within this changing context of a public health that primarily focused on changing individual behaviour rather than addressing the social structural determinants of health and disease, the 1960s brought a renewed flux of policy changes around drug addiction in the UK, at least partly derived from a rise in the number of drug addicts, and a descent down the social and age scales. This was made visible by the 'addicts index', a record kept by the Home Office since 1934, based on information derived from police inspections of pharmacists' records and reports from doctors,

which made it possible to observe the pattern of heroin addiction on a broader scale (Berridge, 1997). Bing Spear, Chief Inspector of the Home Office Drugs Branch, made use of the index in a study published in 1969, but dealing with the spread of heroin addiction some years earlier, and took an implicitly epidemiological approach by detailing how addiction spread on the basis of contact with an addict, framed in terms of 'an infective agent arriving in ideal conditions for the spread of contagion' (Mold, 2007, p279). For many observers the rise in reported cases of addiction and its spread among a specific group of users seemed to constitute an 'epidemic' of heroin use, in contrast with the handful of isolated cases of addiction seen in the past, which led the psychiatrist Thomas Bewley to write in the Lancet in 1965 that, 'there is at present a small epidemic of heroin and cocaine addiction with case-to –case spread' and alcohol specialist Max Glatt, to announce in the same journal that 'every addict is a potential source of infection' (both in Mold, 2007, p279).

In 1958 amidst these concerns the UK government appointed an Interdepartmental Committee on Drug Addiction (chaired by Lord Brain) to review the arrangements which had been in place since the Rolleston Committee had been set up in 1924 to advise the Home Office on the place of maintenance prescribing in the treatment of addiction. The Rolleston Committee had found that addicts were few in number, mainly middle classed, middle-aged and had usually become addicted to opiate drugs following treatment for another condition. Composed entirely of medical men the report reflected the pre-eminent views of the medical profession: that opiate addiction was a disease requiring treatment, and that while the ideal treatment was gradual withdrawal of drug dependence within an institution, long-term prescription of an opiate drug by a general practitioner was a legitimate part of this treatment (Mold, 2007). Lart (1992) places this in the context of Foucault's ([1973] 2003) work on the 'medical gaze' of the nineteenth century, where medical practice functioned through the physical examination of the body, with careful recording of signs and symptoms, diagnosis and prognosis, observations, course and outcome of disease and finally dissection of the body after death. This mode of production of medical knowledge led to a reductionist conception of disease, understood as deviation from a construction of 'normality' based on anatomo-physiological knowledge of large numbers of people within hospitals. The Rolleston report encapsulated this individualised conception of illness, with disease located in the individual body, and the sick individual enclosed within an institution, such that its treatment was seen to be a private issue between doctor and patient. The Brain report initially concluded that such arrangements were still appropriate, but was publicly criticised for failing to recognise the extent of the problem, and the change in population of addicts and the non-therapeutic origin of their addiction, raising fears that the new addicts composed a deviant subculture that could pose a danger to the physical and model health of society (Mold, 2007).

In the same year the United Nations held the Single Convention on Narcotic Drugs, which consolidated and broadened previous drug treaties, forming the bedrock for the global penal response to drug use, and formally introduced the four-schedule scheme, which has since become the basis of US and UK drug classification. The Brain Committee was hastily reconvened, and subsequently proposed a modified medical model of control, but with tighter restrictions, including compulsory treatment, dedicated specialist psychiatric clinics, and a system of 'notification of addicts' (Berridge and Bourne, 2005). While the medical model of control was maintained, it became incorporated within a framework of public health/ epidemiology which stressed not just the consequences of addiction for the individual but for society as a whole. The report justified the public health strategy of notification thus:

'We recommend that all addicts… should be formally 'notified' to a central authority and this authority should keep an up-to-date list of such addicts with relevant particulars. The term 'notification' is used in the Public Health Act, which lays upon doctors the duty to notify patients who are suffering from certain infectious diseases. We think the analogy to addiction is apt for addiction is after all a socially infectious condition and its notification may offer a means for epidemiological assessment and control. We use the term deliberately to reflect certain principles which we regard as important, viz. that the addict is a sick person and that addiction is a disease which (if allowed to spread unchecked), will become a menace to the community' (Point 18, The Second Brain Report of the Interdepartmental Committee on Drugs, 1965).

The crucial role of epidemiology in establishing a causal link between smoking and lung cancer in the 1950s was now central to the debate about illicit drug use a decade later; but whereas epidemiology had linked smoking to a chronic disease, in the latter case it was used to describe the spread of drug use itself (Mold, 2007). As Bessant (2008) notes, metaphors play a variety of intellectual, emotional, creative and illustrative functions. The metaphors we use to describe a condition influence actions to be taken, by rendering certain solutions more amenable than others. In this context the ready use of the 'drug epidemic' metaphor constructs and shapes people's understanding in terms of something that is 'infectious' or 'contagious':

'It implies that 'normal' people can 'catch it' if they associate with or get too close to the infected groups. Understood as an 'epidemic', drug use and associated pathologies (crime) become a clear and dangerous threat to 'community health' and in urgent need of 'treatment' if they are not to become widespread. Like medical epidemics, drug use as an epidemic implies there are 'experts' who can 'treat' the problem with appropriate technical solutions' (Bessant, 2008, p201).

As Berridge (1997) outlines, the change in the number and type of clients prompted doctors to operate a harsher and more restrictive approach, and the committee's conclusions provided a model which combined a more penal medical approach with elements of public health control. Notification and compulsory treatment of sick individuals had first been introduced in 1889 to

deal with infectious diseases such as smallpox, typhus, typhoid and diphtheria. In the early twentieth century special clinics were introduced to treat diseases that spread by social contact, such as tuberculosis and venereal disease, and the response offered to heroin addiction in the 1960s clearly drew on this public health legacy, and also reflected a change in the doctor-state relationship in the drugs arena, in which medicine and law remained allies. The government adopted all the recommendations of the Brain Committee, except for compulsory treatment, and in 1968 opened dedicated drug dependence units, DDUs, in a number of London Teaching Hospitals. In order to prevent the spread of addiction to other patients the DDUs were often based in remote parts of the hospital building, with clinics held in the evenings to stop addicts mixing with 'ordinary' patients, and references to the DDUs as 'containment units' underscored their public health function. They served a dual purpose; to control the heroin epidemic by prescribing opiate drugs to addicts to decrease their need to sell drugs to others (thereby creating more addicts) to fund their own habit, and to treat addicts by gradually reducing opiate substitutions until the addict had withdrawn from the drug. The second Brain report had placed severe restrictions on general practitioner prescribing and put forth psychiatry as the particular legitimate area of medical expertise, based around the long-held notion that addiction was a disease of the mind, rather than of the will or the body, and it was psychiatrists, many of whom were already involved in treating alcoholics, who took on the treatment of heroin addicts in the DDUs (Mold, 2007). However Mold (2007) holds that the understanding of addiction as a mental disorder did not necessarily conflict with the idea that this was also a socially infectious condition, with psychiatrists such as Bewley asserting that although addiction was spread by contact, the individual's psychiatric make up predisposed them to addiction by making them susceptible to the 'infection' of addiction, reflecting the broader shift to a model of public health increasingly oriented towards a biomedical paradigm focused on the characteristics of the individual consumer.

By contrast, the public health metaphor was present in the US from as early as the 1930s. As Acker (2002) notes, when the Public Health Service, PHS, Federal Narcotic Farm in Lexington, Kentucky was dedicated in a ceremony on May 25th 1935, Surgeon General Hugh S. Cumming, the main speaker, and commissioner of the Public Health Service, described addiction in public health terms, as if it were a contagious disease. As the target of the illicit market in opiates, addicts were portrayed as a source of contagion, endangering their fellow citizens as addiction spread through contact between addicts and other people. Therefore, segregating addicts from society 'with the object of medical treatment' was seen to protect the public as well as helping the addict (p160). Cumming compared the treatment of addicts to the treatment of the insane; whereas in past, less enlightened periods, simple confinement of the insane had prevailed, medical progress had now provided humane, therapeutic regimens for those suffering from mental illness and would do so

similarly for addiction. Whereas the change in the number and type of clients in the UK had prompted doctors to operate a harsher and more restrictive approach in the 1960s, the perceived threat of addiction for society as a whole had prompted the shift towards a more penal medical approach within a public health framework in the US much earlier. American attitudes towards opiate addiction in the nineteenth century were initially empathic in the same vein as the temperance supporters' views towards alcoholism, primarily because of their medical use and medical connotations; opiate addiction was not considered a major social problem and there was little public moral devaluation of addicts (Conrad and Schneider, 1992). However, as Levine (1978) argues, as the original moral entrepreneurs of addiction as disease lost interest in furthering the concept of alcoholism towards the end of the nineteenth century, the concept of addiction did not disappear from American life, as increasingly during the nineteenth century opium came to be regarded as inherently addictive. The perceived ability of narcotics to rob the opiate addict of free will changed the popular stereotype of the addict to an individual who 'lacked both proper inhibitions and the stimuli of individual responsibility' (Morgan in Conrad and Schneider, 1992, p119).

Although, as Conrad and Schneider (1992) argue, initially there was not the same public support for banning opium as existed in the later stages of the Temperance movement, as opium addiction became increasingly intertwined in public consciousness with opium-smoking dens and Chinese immigrants, anti-Chinese sentiment in the US became intimately tied to a fledgling anti-opium sentiment. As the progressive era unfolded, governmental regulation of industry and commerce increased, and attention shifted away from the subjectivity of the individual to the inherent dangers of opiates on society, with both alcohol and opiates seen to demand state intervention in the interests of protecting society. The US model for drug prohibition legislation, encapsulated by the 1914 Harrison Act, which provided the federal government with the power to regulate the possession, use, and sale of narcotic drugs, has since dominated the international control system and helped to determine systems of domestic regulation across the Western world (Davenport-Hines, 2001). By the time of World War I, drug addiction in the US was viewed as both a waste of people's lives and a threat to the national war effort, and between 1915 and 1922 in a series of decisions the Supreme Court effectively demedicalised addiction and upheld a criminal definition, through prohibiting opiate maintenance which led to thousands of physicians being arrested on narcotics charges and having their licenses revoked for prescribing opiates, effectively creating a new 'criminal class' of addicts who turned to illegal networks to procure their drugs (Conrad and Schneider, 1992). Thus in the US the rising visibility of drug addiction came through the provisions of the Harrison Act, as addicts became the largest class of offenders in prisons, leading to the establishment of the Federal Narcotics Farms by the Justice Department

as essentially separate prisons run by the PHS, providing segregation and limited medical treatment.

The US Narcotic Farms reflect a deep tension between 'old' and 'new' modes of biopolitics in the management of drug addicts and demonstrate the continuing role of the state as a central biopolitical actor through the exclusion of people from the realm of the law (Gottweis, 2005). 'Narco', as it was known locally, was based on a model of exclusion, where addicts were cast out and disqualified from juridical and political inclusion in order to preserve the purity of the community, in a similar way to the exclusion of lepers in the Middle Ages (Foucault, 1999). By comparison, the UK approach to the containment of addicts through the DDUs can be seen as akin to the new practices of inclusion and quarantine that Foucault (1999) argues were established through the treatment of plague victims. Even though addicts were confined to certain territories which were marked out and closed off from the main hospital buildings, similarly to the practices of *quadrillage*, the meticulous spatial planning by which towns were divided up during the plague, it was not about driving out individuals but rather of establishing and fixing them, of assigning them places by which an ever finer approximation of discipline could be generated, as power becomes continuous and diffuse throughout the community, subjecting individuals to ever more constant and insistent observation. For Lart (1992) this change to newer modes of biopolitics reflects the career of drug use as a disease entity in private and public health, which in turn reflects the wider context of medical perception and knowledge. As the health challenges of the early twentieth century changed from cholera and typhoid, which were seen as diseases relating to people's interaction with the environment, to diseases such as tuberculosis and venereal disease, which were seen as diseases of contact, of relationships between people, inpatient care in the hospital or sanatorium, gave way to the 'Dispensary'; ambulatory care for patients in the community, which provided screening, contact tracing, and the observation and monitoring of the course of the disease within the community. For Lart, the Dispensary made possible: 'the extension of the medical gaze, out of the hospitals and away from the individual body into the community. Instead of being located within and coterminous with the individual body, disease was located in the spaces between people, in the interstices of relationships, in the social body itself' (np).

The shift in focus from sick populations enclosed within the hospital, to the unenclosed, general, 'normal' population through contact tracing and notification of disease made the patterns of relationships between people visible, and the institutional arrangements for dealing with venereal disease brought even more personal and private relations and contacts under scrutiny and surveillance. In the new way of seeing illness it was not enclosed within an individual body in an institution, but visible between bodies in the community. The surveillance of whole populations

through the growth of the survey and the technical tools of screening, and the discovery that physical signs (such as hypertension) or psychological states (such as depression) that had been regarded as abnormal and hence signs of illness were in fact present in large numbers of the 'normal' population, worked to dissolve the perception of health which was predicated on a global division between two types or groups of population, the normal and the abnormal, or the healthy and the sick (Lart, 1992). Rather, as the clinical gaze extended to the whole of society a series of fine and constantly observed differences between individuals who were ill and those who were not became apparent, and addiction became perceived as a socially infectious disease and a threat to the social body that could dissolve the divisions between the ill, the potentially ill and the healthy, a threat that needed to be controlled by the action of government and the involvement of a wider range of welfare services (Foucault, 1999). However, it was not until the 1970s that the biopolitical model of control through exclusion would dissipate in the US, as the Narcotic Farms were closed down amidst changes in drug policy and scandal over its drug program, which recruited hundreds of prisoners to volunteer as human guinea pigs (Campbell, Olsen and Walden, 2008). As the centralised form of institutional care was supplanted by a national network of local treatment centres that included voluntary organisations, researchers and policy makers, a similar biopolitical model of inclusion as that achieved in the UK would become diffuse through America, as the clinical gaze further penetrated into the everyday lives of citizens, including their emotional states, the nature of their interpersonal relationships, the management of stress and other 'lifestyle' choices' (Lupton, 1997).

5.3. ENVIRONMENTAL INDIVIDUALISM AND COERCIVE PERMISSIVENESS

Changes in policy and the scientific climate during the late 1970s led to the re-emergence of concerns about the environment and epidemic disease in both the US and the UK and by the 1980s there was a 'new' public health, which placed less focus on purely curative medical approaches and the ascendency of individual behavioural determinants seminal to health in post war years. The shift back towards social and environmental determinants of health was demonstrated by the WHO Ottawa Charter of 1986 and the WHO healthy cities programme, which began to run in Europe in 1987, both of which promoted a holistic view of health as the result of much more than medical care and the need for healthy public policy rather than just encouraging individual behavioural change (Berridge and Loughlin, 2005). However, although this 'new environmentalism' within public health may have moved away from the single focus on individual responsibility of the 1970s, it was an 'environmental individualism', which situated the individual in the domestic or work environment, that the late twentieth century public health and

its alliances with technology and biomedicine would embody (Berridge, 2003). For Berridge (1999), in Britain this was encapsulated by the emergence of passive smoking as a 'scientific fact' in the 1980s, which she relates to the changing objectives of the post-war public health coalition, founded on the concepts of epidemiology. Following a broadly constructionist perspective, Berridge analyses the expansion of risk exemplified in passive smoking through its interaction with politics and culture, where scientific facts and the role of expertise in promoting them are locked into mutually reinforcing relationships, with facts developed and expressed in the context of professional interests, available technology, power relations and resource allocation.

The major focus of the anti-smoking case in the UK was on stopping smoking, but in the 1960s risk reduction, or 'product modification' was a key scientific and policy strategy. However, during the course of the 1970s the prominence of groups such as Action on Smoking and Health, ASH, primarily a government funded pressure group, combined with a changing culture of smoking, which politicians have seen as an important factor preventing stringent anti-smoking policies in the 1960s. While years after the publication of the seminal Doll/ Hill article, Bradford Hill still kept a full box of cigarettes in his room at the London School of Hygiene and Tropical Medicine, on the basis 'it would be ill mannered not to offer visitors a cigarette', the relative marginalisation of tobacco, and its 'de-normalisation' in post-war years led to its gradual exclusion from 'polite society' (Berridge, 2003, p82). The issue of social acceptability was also seen as a key factor by the tobacco industry, with an industry spokesperson in 1979 declaring 'the social acceptability issue will be the central battleground on which our case in the long run will be won or lost' (Berridge, 1999, p1188).

However, while the public health constituency was shifting towards a more aggressive stance on the pollution of public spaces, environmental smoke was still regarded as a less relevant, moral issue, compared to the hard scientific link between smoking and cancer, and organisations such as ASH and the public health coalition sought a campaign based on the issue of rights rather than that of science: 'It was attempting to turn the industry-promoted smokers' rights and individual freedom arguments on their heads by arguing, in the classic way, that one person's freedom to smoke compromised another's freedom not to have to inhale' (Berridge, 1999, pp1188-1189). But with the publication of papers such as that by Hirayama (1981) showing the non-smoking wives of heavy smokers as having a higher risk of lung cancer, and the quantification of risk afforded by other epidemiological studies, the risk came to be seen as applied to the general population rather than just the individual smoker, through exposure to tobacco smoke by 'passive' or 'involuntary' smoking. Berridge (1999) draws an analogy to illicit drug policy, which changed to a more restrictive emphasis in the UK in the late 1960s when epidemiological evidence indicated that addiction was a 'socially infectious disease' which might affect the whole

population. This concept revived notions of infectious disease, the classic concern of 'traditional' public health, and gave scientific urgency to a case for greater control of smokers. Mold (2007) also highlights the parallels between the response to passive smoking since the 1980s and the earlier reaction to heroin addiction, with both seeing a reconceptualisation of an individual's behaviour as being dangerous to all, and not just to the smoker or to the heroin user. With smoking, this was the risk of developing lung cancer after being exposed to someone else's cigarette smoke, with heroin, it was the threat that addiction posed to social and moral health; for both there was a wider belief that their use had consequences for public health. Elsewhere, Berridge (2007) raises the case of AIDS, which became a high-level political issue once the risk was perceived to be to all, and makes a connection between passive smoking and AIDS, seeing the two as linked in the new public health discourse of 'environmentalism and infection,' and arguing that they demonstrated both the reappearance of environmental concerns and a new alliance between public health and biomedicine, moving away from the reliance on epidemiology.

The British approach to control of public space was initially generally permissive and voluntaristic compared to the US, where the passing of the 'Minnesota Clean Indoor Air Act' in 1975 set the precedent for anti-smoking legislation in other states. This act required that institutions and companies allot space for smokers and non-smokers inside their facilities and was the first step for the movement toward a separation between smokers and non-smokers in the United States (Wolfson, 2001). The UK 1990 Environmental Protection Bill to control smoking in public spaces was defeated, and the emphasis on individual enterprise and subsequently governmental advice and guidance rather than legal control as was the case in the US, was reflective of the 'systematic gradualism' approach characteristic of the slow and accommodating advance of UK policy makers and researchers in smoking policy and health campaigns. However, as the 1980s progressed, politicians changed their mind about speaking directly to the public on health matters, and their early worries about the 'nanny state' expressed in the 1957 Cabinet Committee gave way to 'coercive permissiveness', a desire to inculcate new norms of behaviour and regulate individual health behaviour, demonstrated through mass media and centralised health campaigns directed at the whole population (Berridge, 2007).

These debates brought into play tensions over the relationships between public health and industrial interests, but as Berridge (1999) has noted, it was the threat to *others* posed by passive smoking, particularly to so-called 'innocent victims' such as women and children, which widened the debate and provided a more powerful engine for driving policy. Further, although there has been a substantial reduction in the proportion of smokers in the UK and the US since the 1962 RCoP report and the 1964 Surgeon General's report, this decline has not taken place evenly throughout society, with those situated in the lower socio-economic classes much more likely to

smoke. As smoking became increasingly concentrated in marginalised groups, groups that were more readily conceived of as being 'deviant' it became easier to mount a consistent attack on the habit. Similarly, when young recreational heroin addicts became visible in the 1960s they were frequently demonised and were subjected to greater forms of control than their middle-aged, middle-class counter-parts of the 1920s (Mold, 2007). This shift has made more restrictive measures feasible, seen most recently in the passing of a Bill in February 2006 to ban smoking in enclosed public spaces in England, including public houses, bars and restaurants (DH, 2006). Similar developments can be traced in the recent wars on 'Big Food' since the 1990s, where reformers have rejected behavioural aetiological explanations of obesity and have focused instead on an environmental explanation of the role of corporate capitalism in the production of diseases, arguing for government intervention to control and prevent obesity through taxation of high-calorie foods of low nutritional value, the banning of junk food sales from schools, and compulsory public disclosure of calorific and chemical constituents of nutritional products, including on restaurant menus (Porter, 2006). By the 1990s passive smoking had been transformed from a moral issue revolving around the nuisance of smoking, to one of the rights of the non-smoker, and then into a medical and scientific one. Public health again incorporated an environmental dimension, but one where self-regulation and individual morality were still central, and alcohol, drugs and smoking all shared the same emphasis on the environment at the local level and on individual action, where:

'[P]assive smoking and the policies it helped initiate essentially combined the individualism of the 1970s public health paradigm with the environmentalism of the 'new public health', with its resonance with the image of nineteenth century public health. It was environmental individualism, an alliance of individual and environmental approaches, just as the science itself married different technical approaches into a reformulation of the original epidemiological case' (Berridge, 1999, p1192).

Berridge (2003) argues that the lifestyle agenda of the 1970s, modified by the environmentalism individualism of the passive smoking case, took a new turn in the 1990s, through the 'rise of addiction' for smoking, resulting in increasingly medicalised public health policy. While not entirely absent, during the 1970s the concept of dependence was not central to the debate around smoking, as it was in the drugs field, with smoking still regarded as 'habit forming' in contrast to the addictions of drinking alcohol and drug taking. The popular idea of cigarettes as 'enslaving' was seen as incompatible with the key public health emphasis on self-determination and individual responsibility, but from the late 1980s and early 1990s the addictive properties of tobacco received more attention, re-categorising the 'voluntary' nature of smoking, and the risk that was denoted it (Berridge and Loughlin, 2005). For Berridge (2003): 'The notion of 'involuntary smoking', first developed through passive smoking in the early 1980s, was modified. The lack of volition was now on the part of the individual smoker' (p79). However, as Berridge

(1999) notes, there were cross-national differences in the way these issues were dealt with at the policy level. The passive smoking issue combined with the concept of nicotine addiction and consequent drug regulation through the Food and Drug Administration, FDA, reconstructing a 'substance' as a 'drug' in the US. In Britain, the issue of addiction and the role of nicotine brought an emphasis on risk reduction, on the possibilities of treatment and medico-pharmaceutical interventions such as nicotine replacement therapy. Berridge argue that nicotine was poised for a closer relationship with the licit 'medicine' concept, as tobacco and its substitutes had been in the Medicines Act negotiations of the 1970s, and British policy, as with passive smoking, retained a duality and a contrast with the US reminiscent of divergent paths round drug control in the 1920s.

Since the reconstruction of nicotine as an addictive drug, it has increasingly been placed alongside alcohol and drugs, under the category of 'psychoactive substances', with resulting transference of concepts and initiatives from one substance to others. As Mold (2007) notes, the way the responses to smoking and drug taking have collided is reflective of the way the diseases surrounding these behaviours are being conceptualised: 'smokers, like drug users, have increasingly been regarded as having a disease (addiction) that poses a danger to all. This kind of behaviour is no longer simply seen to lead to disease, as was the case with smoking and lung cancer in the 1950s; rather, the behaviour has come to be regarded as a disease in itself' (p280). A disease that is simultaneously a socially infectious condition and an individualised pathology; spread by social contact to individuals who are genetically predisposed to the infection of addiction. However, in a cyclical fashion, in the twenty first century, a similar reconstruction can be seen in the case of drug addiction in US policy, where drug use is being increasingly framed as a disease in itself through the use of the infectious disease metaphor. In 2003, section II of the NDCS opened with a historical anecdote about how Dr Snow stopped London's 1854 cholera plague when he realised that the infection was being spread via contaminated water, explicitly drawing on an infectious disease metaphor to promote the need to 'block the vectors that spread contagion [to] fight a modern epidemic – the spread of drug use and addiction', expressively targeting 'drug users' as the primary 'vectors of contagion' (ONDCP, 2003, p17). Similarly, Alan Leshner, previously the Director of NIDA, has frequently promulgated a public health model of addiction to construct either the 'abuser' or the 'addict' as the 'host':

'Understanding the health aspects of addiction is in no way incompatible with the need to control the supply of drugs. In fact, a public health approach to stemming an epidemic or spread of a disease always focuses comprehensively on the agent, the vector, and the host. In the case of drugs of abuse, the agent is the drug, the host is the abuser or addict, and the vector for transmitting the illness is clearly the drug suppliers and dealers that keep the agent flowing so readily. Prevention and treatment are the strategies to help protect the host. But just as we must deal with the flies and mosquitoes that spread infectious diseases, we must directly address all the vectors in the drug-supply system' (Leshner, 2001, np).

5.4. THIRD WAVE PHARMACEUTICAL PUBLIC HEALTH AND TECHNOLOGIES OF THE SELF

The shifts in public health paradigms can be understood in the context of the major changes in the structure of the economy and government since the 1980s, which has been defined by the 'rolling back of the state' through the marketisation, privatisation and deregulation of public services. As Turner (1997) argues, amidst the burden of dependency with ageing populations in Western societies, the notion of citizen rights to health and social welfare that emerged in the progressive era has been increasingly questioned by the liberal ideology of individual obligation to become more self-regulating and self-forming by saving and creating personal bases of security.

The notion of generalised risk in the environment has led to greater surveillance and control through the promotion of preventative medicine, which has led to new forms of biopolitics which place more emphasis on the risk avoiding individual (Lupton, 1995). This can be understood as the rise of surveillance medicine, the shift from an emphasis on technologies of domination to that of technologies of the self, where the individual is not just subjected to the technologies of medical surveillance, but is expected to engage in the practice of self-surveillance (Armstrong, 1995). As Rose (1999b) argues, whereas the original biopolitics thesis implied a separation between those who calculated and exercised power and those who were its subjects, in the new biopolitics power is democratised and coercion is reshaped as the exercise of freedom. In advanced liberal democracies authorities have come to understand the task of ruling politically as requiring them to act upon the conduct of the individuals and populations who are their subjects in an indirect manner through the promotion of subjectivities, the construction of pleasure and ambitions, and the activation of guilt, anxiety, envy and disappointment. Through the extension of the political apparatuses of health into the everyday lives of the population via a complex network of forces and images, the health-related aspirations and conduct of individuals have been shaped and the self-government of the autonomous individual has been connected up with the imperatives of good government (Rose, 1999a). As Nettleton (1997) notes, governmentality then relates to the deployment of 'technologies of the self' in the conduct of social policies. As indicated earlier however, not all choices are regarded as wise or to be encouraged, and as Bunton (1997) highlights, in these new regimes, '"risk-takers" become demonised as the new "sinners" of a secular discourse which has replaced religious belief systems, such as those who smoke in public, drink and drive, or practice unsafe sex' (p229). For Higgs (1998), compliance then is achieved through directing 'free will' through both coercive and non-coercive strategies, which the state and other institutions urge on individuals for their own benefit, and is thereby crucially reliant upon systems of expert knowledge which constitute and define the objects of their knowledge, mediate between individuals and authority and measure progress.

These changes have marked implications on notions of subjectivity, since as Turner (1997) notes, if health began as a form of policing which was specifically concerned with the quality of the labour force, then it has come to take on a life of its own as it has become the main means by which we understand ourselves. As Rose (2001) argues, contemporary biopolitics has come to invoke moral responsibility, since it is also 'ethopolitics', that is, it is 'the politics of life itself and how it should be lived' (p18). The increasing salience of health to the aspirations and ethics of the West that has promoted such cultures to define problems and their solutions in terms of health and illness, posed as treatable bodily malfunctions, has also led to profound transformations of personhood. For Rose (2003) increasingly, the sense of 'self' in psychological terms which developed across the twentieth century, has come to be displaced by a 'somatic individuality', where there is a tendency to define one's individuality in bodily terms and to understand that body largely in terms of contemporary biomedicine. The somatic individual codes their hopes and fears in terms of this biomedical body and the continuous reform or improvement of self, performed through acting on this body, becomes the life's work of the contemporary biological citizen. But the somatic individual is in turn a key actor, and biological conceptions of self do not lead to passivity, but are bound up with the more general norms of advanced liberal societies of the enterprising, self-actualising, responsible individual, such that every citizen is an active partner in the drive for health, and one who must accept responsibility for securing their own well-being (Rose, 2003). In this way the rationality of neo-liberalism produces an 'entrepreneurial self', endowed with the ability to manage their own risks and risk behaviours, where health promotion is a strategy that engenders risk minimisation by attention to lifestyle and the privatisation of risk (Petersen, 1997). Contemporary biopolitics then is also risk politics, where the enterprising self must deploy risk strategies which involve calculations about probable futures in the present, and interventions into the present to control that probable future. As Nettleton (1997) notes, such monitoring is not confined to the objective environment or the 'body object' but is also directed at the subjective level of consciousness, such that risk is determined not only by one's personal circumstances, but also by one's personal capacities:

'Each individual thus acquires a personal preventative capacity *vis-a-vis* the event of his or her illness, a preventative capacity structured around the possibility of self-transformation and, before that, of self-knowledge. If the regulation of life-stye, the modification of risky behaviour and the transformation of unhealthy attitudes prove impossible through sheer strength of will, this constitutes, at least in part, a *failure of the self to take care of itself* – a form of irrationality, or simply a lack of skilfulness... The mastery of the self is thus a prerequisite for health; the lack of self-mastery, accordingly, is a 'disease' prior to the actual physical complaint, whose symptoms are detectable as behavioural, psychological and cognitive patterns' (Greco, 1993, in Nettleton, 1997, p214).

As Rose (2003) argues, to these new neurochemical selves, psycho-pharmacological drugs are central, both to the ways in which our conduct is determined to be problematic and governed by others, but also by ourselves. While Rose uses the mediating examples of depression and Attention Deficit Hyperactivity Disorder, the same burgeoning of psycho-pharmacological treatments can clearly be seen in the treatment of drug addiction. As Campbell (2010) notes, the history of addiction research indicates that early twentieth century 'neurophysiology' has long been subsumed to the project of achieving good self-governance: 'personal responsibility, impulse control and appropriate consumption of the 'right' drugs (today, drugs that ward off the effects of the 'wrong' drugs)' (p93). In the context of advanced liberalism then, immunotherpaies for addiction can be seen as extending contemporary biopolitical regimes by increasing the range of options open to active self-caring healthcare consumers, capable of selectively consuming health products and reading their own health messages in order to actively manage their present and future risks, as was seen in the dominant commercial discourses in Chapter 3 (Bunton, 1997).

However, in the context of third wave 'pharmaceutical public health', which has forged alliances with new scientific fields and the pharmaceutical industry, increasingly drawing on drug and vaccine responses to public health issues to reclassify curative intervention and 'magic bullet' treatment technology as public health prevention tactics, they can also be seen as a product of older modes of biopolitics, which cast the state as the central actor coercively taking charge of the biological existence of the individual in the name of the benefit of each and all (Berridge, 2003; Rose, 1999a). The technological script of the vaccines directs their use as a preventative measure, and in embedding a ubiquitous concept of addiction in the language of infectious disease, direct the state to exert its police powers to protect the public health and safety, and the guilt of the parent is activated to act in the present to prevent future harm to their child (Verbeek, 2006). Immunotherapies for addiction then can be seen to combine 'old' and 'new' modes of biopolitics in a flexible way, representing neither the abdication of sovereign power nor a simple continuation of the well-known biopolitical strategies (Gottweis, 2005). As such, the next Chapter will focus on the role of the state in facilitating or mandating mass childhood immunisation, MCI, by exploring the key socio-political differences in the history of MCI in the UK and the US, before going on to examine the construction of potential target populations for vaccines for addiction in patents. It will then take a critical look at the way in which the infectious disease metaphor is being utilised in key bioethical and policy literatures before exploring the underlying constructions of addiction and their implications for key actor groups, in order to guide empirically grounded interpretations of the potential benefits and drawbacks of mass childhood vaccination against addiction. Chapter 7 will then move the analytical themes away from the state to examine in more depth the shift to newer biopolitical regimes and the place of vaccines for addiction in the remit of legitimate parental medical decision making on behalf of their children.

6. WHERE STATE POWER PENETRATES THE SKIN: THE BIOPOLITICS OF MASS CHILDHOOD IMMUNISATION

'There are many drugs that, when taken into the body, will produce in some persons a reaction that is satisfying or attractive to them and will persuade them to continue the use of a drug even to the point of abuse or dependence. If such a drug abuse or dependence is likely to be, or is known to be, only sporadic or infrequent in the population, if there is little danger of its spread to others, and if its adverse effects are likely to be, or are known to be, limited to the individual user, there is no public health problem. On the other hand, if the drug of dependence is associated with behavioral or other responses that adversely affect the user's interpersonal relations or cause physical, social, or economic consequences to others as well as to himself, and if the problem is actually widespread in the population or has a significant potential for becoming widespread, then a public health problem does exist.

World Health Organization, 'Report on the 16th session of the Expert Committee on Drug Dependence' (1969, pp6-7).

6.1. INTRODUCTION: INDIVIDUAL RIGHTS AND THE COMMON GOOD

Chapter 5 aimed to demonstrate how public health's increasing reliance on biomedicine and its evolving focus on environmental individualism has embedded addiction within a paradigm of infectious disease, reclassifying curative intervention and 'magic bullet' treatment technology as public health prevention tactics (Berridge, 2003). This Chapter will extend the analysis to focus more specifically on the biopolitical tensions inherent in the potential deployment of immunotherapies for addiction in mass childhood vaccination, MCI, where the state is the central actor, coercively taking charge of the biological existence of the individual in the name of the benefit of each and all (Rose, 1999a). It begins by exploring the role of the state's police powers to protect the public health and safety by locating the new technology in the broader socio-political context of vaccination and its representations of the relationship between state and citizen. It will then critically examine the construction of prophylactic MCI in the dominant discourses of industry, policy and bioethics. Crucially, the way in which the infectious disease metaphor is being utilised in key bioethical and policy literatures will then be highlighted. The discourses of key actor groups will then be examined, to explore the underlying constructions of addiction and their implications, in order to guide empirically grounded interpretations of the potential benefits and drawbacks of mass childhood immunisation against addiction.

Although national Prohibition in the US may be one of the best known examples of the role of social and ideological forces in shaping public health policy, questions as to the legitimate role of the state in promoting health and preventing disease have deep historical roots on both sides of

the Atlantic. Indeed, the story of the regulation, surveillance and control of bodies by the state, or by others with the permission or encouragement of the state, has been indelibly marked by controversies over the extent to which the protection of the public's welfare has served as a pretext for the erosion of fundamental rights (Bayer and Colgrove, 2002). Within this framework, vaccination cultures involving new technologies and organisational principles, collective decisions, and collective health care arrangements can be seen as an aspect of a wider process of state formation, originating in the fear of contagious disease and epidemics on the part of the middle classes (Streefland *et al*, 1999). As Herd (1992) argues, the socio-cultural context has been crucial in shaping scientific and public health research, in defining the level of concern and the conceptual approaches to public health problems, and the state response to epidemics differs widely between the US and the UK.

Exploring the tensions between personal liberty and public health in the progressive era in the US, Willrich (2008) argues that while the rubric of public health law covered an extraordinary array of government activities, from yellow-fever quarantines, to pure milk standards, 'the most salient public health struggle of the era arose at precisely the point where state power penetrated the skin' (p76). Colgrove (2005) describes the opposition to vaccination from its introduction in the beginning of the nineteenth century as founded on claims it was dangerous and that to compel it through law was an unacceptable invasion of personal liberty, based on fears that scientific advances were being put to coercive uses and that the institutions of the state and civil society were increasingly expanding into the previously private realm of decision-making, especially child rearing. In the 1980s the question of how far a democratic society should go in forcing its members to be protected against disease focused around fluoridation of water supplies to prevent dental cavities (Martin and Groth, 1991). However, in the last two decades the issue has tended to be raised anew in relation to immunisation against infectious diseases. State imposed quarantine and forced vaccination has since balanced strategies of mandatory vaccination with education and persuasion, weighing in on the side of mandatory vaccination as a precondition for attending public school in the US, but with the important clause that parents can claim exemption on the grounds on religious and philosophical objections, intended to mitigate concern about governmental intrusion on individual decision making (Colgrove, 2006b).

As Bayer and Colgrove (2002) discuss, in the US context, the events of 9/11 resulted in a renewed debate over the core values of public health, as proposals were made to enact emergency health powers that would radically enhance the power of the state. The Model State Emergency Health Powers Act (MSEHPA), written by request of the Centers for Disease Control and Prevention and made public in October 2001 gave state governors the authority to declare a public health emergency, if necessary, without consulting public health officials where there was 'substantial

risk of a significant number of human fatalities or incidents of permanent or long term disability' (p1811). Health-care providers, medical examiners, and pharmacists would be required to report to public health authorities within 24 hours the name and other identifying information of individuals with conditions that could be related to bioterrorism or other fatal or dangerous infectious agents. The public health authority would be granted the right to compel individuals to undergo medical examination, testing, and vaccination or treatment, and those that refused would be subject to isolation or quarantine. If health-care providers refused to intervene they would be subject to criminal prosecution: 'in all, the act was a stark expression of the view that a public health emergency might necessitate the abrogation of privacy rights, the imposition of medical interventions, and the deprivation of freedom itself' (p1811). The proposed act was heavily attacked by proponents of civil rights and liberties, and as individual state legislatures worked to update their public health legal infrastructure, many adopted either a revised version or even more scaled-back versions. However, uneasy though the tensions between public health and civil liberties in the US may be, by July 2002 emergency health powers legislation had been passed in 19 states and introduced in 17 others.

By comparison, as Salmon *et al* (2006) observe, the UK has a history of struggle with compulsory vaccination, with the Vaccination Act of 1853, which required smallpox vaccination in England and Wales, galvanising the anti-vaccination movement, which was joined not only by those against vaccination, but also by opponents to intrusion by governments on personal autonomy. In 1907, the Act was amended to remove the administrative barriers thereby allowing parents to claim exemption on the grounds of conscientious objection, resulting in a substantial reduction in the number of vaccinated children. By 1946 the UK had repealed vaccination requirements altogether because nearly half of parents in many areas were claiming conscientious exemptions. However, Nicholson (1996) has argued that public health authorities in the UK are now moving towards compulsory vaccination. He outlines the change in the 1990s offering GPs financial incentives to achieve high coverage for childhood immunisations; if they immunize more than 90% of the children on their list who become eligible each year, they receive a bonus as well as a fee for each immunisation. Nicholson notes that as on average each GP had only thirty children become eligible each year, a refusal of vaccination by just three or four families carried considerable financial implications, resulting not only in pressure at the local level, but also in families being told to find a different GP. In 2004, decreases in vaccine coverage for measles, mumps, and rubella, MMR, that resulted from the widespread concern about associations between MMR and autism led the British Medical Association to revisit the issue of compulsory vaccination. However, they concluded that compulsory vaccination was not appropriate for the UK and supported a 2003 Scottish Executive Report, which concluded that 'such a policy

[compulsory vaccination] ... runs counter to the... core principle that vaccines should be administered on a voluntary basis' (in Salmon *et al*, 2006, p438).

However, previously such debates around vaccination have been confined to infectious disease, where crucially vaccination protected not only the individual but the community from a biologically contagious virus, and it is this scientific fact that has so far carried the ethical and political logic of compulsory or coercive vaccination (Willrich, 2008). In this context the development of a vaccine against the human papilloma virus, HPV, which prevents infection from some species of HPV associated with the development of cervical cancer and genital warts, reignited the debate on the balance between individual rights and the common good. However, it also reshaped it as the first vaccine where voluntary behaviour became the source of disease risk because the biggest risk factors of contracting HPV are the lower the age at which sexual activity is initiated and the higher the number of sexual partners, leading to religious objection that it would promote 'promiscuous' sexual behaviour. Because school vaccination requirements in the US are determined by individual states, there is much variation in state legislations, but where states grant regulatory bodies the power to require vaccines, they must decide whether to require coverage by insurance plans and address funding issues, including for Medicaid and youth who are uninsured. In June 2006 the US national Advisory Committee on Immunization Practices recommended the HPV vaccine for routine use and the US Centers for Disease Control and Prevention, announced it would be made available through the federal 'Vaccines for Children' program. Previously, only Virginia and the District of Columbia have moved toward requiring sixth-grade girls (11-12) to get vaccinated, but both allow parents to opt out of the 'requirement' for any reason, amid funding concerns, and parental objections about safety and the promotion of promiscuity (Markowitz *et al,* 2007). In the UK, the HPV vaccine has now been added to the NHS Schedule of Immunisations, for all 12-13 year old girls, but as with other vaccines in the UK, it is not compulsory.

Although issues of religion and adolescent sexuality have dominated the HPV discussion, the broader debates around the introduction of the HPV vaccine will likely reoccur if vaccines for addiction are put forward for mass childhood vaccination programmes, since both shift the source of disease risk from passive exposure to biological pathogens in the environment to the voluntary action of individuals. Crucially, in advanced Western liberal democracies, parents (or legal guardians), are presumed to act in the best interests of their children which infers upon them the right to make decisions for their children, including medical ones, as will be examined in more depth in Chapter 7. Although minors have a right to be protected against vaccine preventable illnesses, and society has an interest in safeguarding the welfare of children who may be harmed by the choices of their parents or guardians, the state can interfere only in the most compelling of

circumstances (Blume, 2006). Thus although requiring vaccination by law achieves more widespread protection than policies of persuasion and education, it is a critical question whether achieving a higher level of coverage justifies the infringement on parental autonomy that compulsory vaccination is argued to entail (Colgrove, 2006a). Epidemiological and ethical analyses about disease risk then become key to political calculations about the justification of the extension of the state into the private realm of the family and parental autonomy over the welfare of their children.

As discussed in Chapter 4, it is in its role as a tool in relapse prevention in adult males and non-pregnant females who are being treated for drug dependence or drug overdose that immunotherapies have negotiated the byways of the key regulatory agencies, such as the US Food and Drug Administration, FDA. Thus far the only study (Bagasra *et al*., 1992) to investigate their use as a means to prevent addiction in animal models was inconclusive, and the methods used in the study are in dispute (Gallacher, 1994). However, a report by the US National Research Council Board on Behavioral, Cognitive, and Sensory Sciences (Harwood and Myers, 2004) has argued that the most practical use for these vaccine products will be in children and adolescents. As discussed at the end of Part I of this thesis, one of the primary justifications given for this is their likely inefficacy in the populations for which they were developed, due to their status as antagonist treatments that provide no pleasure or reinforcing effects to the addict, which history shows tends to lead to their early discontinuation, unless the individual is required to use them by law or from a professional body to continue in work (cf. Lingford-Hughes and Nutt, 2004). By contrast, their use prophylactically before first exposure is seen to be potentially more effective, since the technology is aimed only at preventing the initial experience of the psychotropic effects of drugs, rather than tackling the neuroadaptations of 'disrupted volition' which compromise the ability of the already addicted subject to comply with medication regimes. As such, this chapter will now turn to the construction of prophylactic vaccination in commercial literatures by which potential populations of consumers are being defined, and then to bioethical and policy discourses in which MCI for addiction is being justified.

6.2. PATENTING PROPHYLAXIS AND THE JUSTIFICATION FOR MCI

All the companies developing active vaccines have filed patents for their use both as a treatment agent and for prophylaxis. In constructing the vaccines as preventative medication, they portray drug use as adversely affecting either the user's interpersonal relations or the cause of physical, social, or economic consequences to others. Through analogy to infectious disease, they also portray such use as either actually widespread in the population, or as having significant potential

for becoming widespread, thereby reconstructing addiction, and especially smoking, as a critical public health problem in line with the definition used by the WHO in 1969, as seen in the opening quote to this chapter (WHO, TRS No. 407, 1969). For example, the early forerunner ImmuLogic, then developing TA-NIC, an active nicotine vaccine and TA-CD, an active cocaine vaccine, was issued a US patent in March 1999 covering the methods common to both products, which stated:

'The prevalence of drug use and abuse worldwide, especially in the United States, has reached epidemic levels. There are a plethora of drugs, both legal and illegal, the abuse of which have become serious public policy issues affecting all strata of society with its obvious medical and social consequences. ... Two especially problematic drugs of addiction are cocaine and nicotine... The cumulative effects of cocaine-associated violent crime, loss in individual productivity, illness, and death is an international problem... Since nicotine is legally and widely available there is relatively low pressure against its use, unlike cocaine... The high rate of recidivism in smokers who try to quit is indicative of the strong effect of nicotine dependence... The drug-conjugates of the present invention, as well as the compositions of the present invention, may also be used as a prophylactic. That is, the drug-conjugates or compositions may be administered to a mammal prior to any exposure to the drug to generate anti-drug antibodies. The generated anti-drug antibodies would be present in the mammal to bind to any drug introduced subsequent to the administration of the conjugate or composition, and therefore minimize or prevent the chance of becoming addicted to the drug' (Swain *et al*, 1999, Column 1).

In Feb 2003 Nabi, the developers of the nicotine vaccine NicVAX, were awarded a US Patent (No. 6518031) for its application titled, 'Hapten-carrier conjugates for treating and preventing nicotine addiction'. The patent states:

'Smoking is a prevalent problem in the United States and worldwide... Nicotine use is widespread due to the easy availability of cigarettes, cigars, pipes and smokeless tobacco. According to the US Department of Health and Human Services, cigarette smoking is the single leading cause of preventable death in the US. Exposure to second hand smoke also has been reported to have serious detrimental effects, including exacerbation of asthma... The present invention envisages preventing or treating nicotine addiction by administering a nicotine-carrier conjugate in a pharmaceutically-acceptable formulation... For preventing nicotine addiction, patients at risk for developing nicotine addiction, such as teenagers, are treated with a conjugate according to the invention' (Ennifar, S. *et al*, 2003, Columns 1-2).

The press release issued by Nabi's partner, Glaxo SmithKline, in November 2009 proclaimed 'Smoking is a global epidemic... recognised by the UK Royal College of Physicians as being on par, from an addictive standpoint, with heroin and cocaine' (GSK, 2009). On Nabi's NicVAX website, even though it is marketed as a smoking cessation therapy, the statistics point to the potential size of the market, noting that worldwide '1 in 5 teens, between the ages of 13 and 15, smoke' and that in the US 'approximately 48.5 million adults and 3.1 million high school students smoke'

(Nabi, 2010b). Similarly, the widespread nature of smoking is again targeted on the website of Celtic Pharma, the private equity company that acquired the worldwide rights to TA-NIC and TA-CD in 2005. Here, the market for its cocaine vaccine is defined as patients that 'attend in-patient programs and out-patient clinics seeking treatment for cocaine addiction'; however, with regard to the market for the nicotine vaccine it makes direct reference to teenagers:

'According to the US Centers for Disease Control and Prevention, approximately 45 million adults and 6 million teenagers in the US smoke, triggering an estimated $75.5 billion in excess medical costs and another $81.9 billion in mortality-related productivity losses each year. Despite widespread knowledge of tobacco's dangerous health effects, smoking continues to pose a serious public health threat, and there is a clear and large unmet demand for more effective anti-smoking products' (Celtic, 2011).

Again, in 2005, Cytos, the main competitor to Nabi, received a US patent for its active nicotine vaccine, Nic002, by embedding prophylaxis in the context of the widespread nature of smoking and its costs to society:

'Addictive drug abuse disorders carry with them a number of specific, well recognized sequelae that have both societal and economic consequences. These include death, disease, violence, crime, loss of employment, reduced productivity, relationship and familial breakdown, and the spread of HIV and other sexually transmitted diseases... Smoking is not only dangerous to individuals, it also results in staggering societal costs. The estimated smoking-attributable cost for medical care in 1993 was more than $50 billion and the cost of lost productivity and forfeited earnings due to smoking-related disability was estimated at $47 billion per year. Thus, the total economic cost associated with nicotine addiction is greater than the combined costs for all other types of addictive drugs... Novel approaches to the treatment and prevention of addiction, to nicotine and to other drugs, are clearly needed... the invention is useful for the prevention or treatment of diseases, disorders or conditions which include, but are not limited to, poisoning by toxins, disregulation of hormone levels, drug intoxication, or drug addiction and the like' (Bachmann and Maurer, 2005, Columns 1-2).

In reconstructing addiction as a critical public health problem and thereby directing state attention to the possibility of MCI, the potential market for active vaccines is wildly inflated, as can be seen in the rhetoric of Independent Pharmaceutica's website, which states that:

'In developed countries, approximately 85 million children each year are exposed to second-hand smoke in the home. In developing countries, approximately 625 million children are exposed. Currently, the death and disease caused by tobacco use results in an annual global loss of 200 billion US dollars. With new and improved products the smoking control market is anticipated to become a rapidly growing market' (Independent Pharma, 2010).

However, such rhetoric also arguably tips the balance between individual rights to civil liberties and the justification for state intervention through MCI in order to protect the public good heavily towards the latter, and is not confined to commercial discourse but has also become increasingly entrenched in bioethics and policy. With dual expertise in medicine and law, Peter J. Cohen joined NIDA's Medications Development Division to evaluate the medical, ethical and legal issues surrounding the use of the vaccines in 1996, and was the first to consider the potential legal and ethical implications of the prophylactic use of the cocaine vaccines which NIDA were supporting financially and ideologically. In his article, Cohen (1997) drew on a public health model of addiction to argue that addiction was a disease, and that it could usefully be regarded as an infectious agent. He claimed that: 'although the pathogenesis of addiction is neither bacterial nor viral, the ability of a vaccine to modify its devastating effects could be examined in terms of an infectious disease model. Since legal scholars and judges often engage in generous simile and symbolism, it would not be surprising if future judicial opinions were written *as if* addiction had an infectious nature' (p172, italics authors own). He bases his argument on the significant analogies between addiction and infectious disease: 1) the interaction of the individual with society as a whole in both addiction and infectious disease, such that it is possible to compare 'tranmissibility' of addiction with that of an infectious disease; 2) the individual infected with a bacterium or virus may be a temporary 'host' for the infectious organism, as it moves from one susceptible person to another, and while the mechanism is different , an: 'addicted 'host' often sustains his or her disease by selling drugs to or sharing them with others, an act which spreads the affliction to the many' (p172).

Cohen (1997) argues that complete acceptance of the analogy between addiction and infectious disease is not absolutely necessary in order to consider the ethical and legal implications of the vaccines, since the most important consideration: 'is that of *treatment* and not *mechanism of treatment*. Cocaine addiction remains an overwhelmingly important *public health* concern as such its treatment and prevention must be subject to the same approach as any other illness within the public health domain' (p172, italics authors own). Drawing on this public health model of addiction, Cohen considers the mandatory vaccination of 'targeted' populations outside of the criminal justice system and concludes they would be fraught with potential for prejudice, and as a result would face severe Constitutional challenge; however he argues that 'paradoxically, these problems would be obviated if society adopted the obvious and inevitable policy of mandatory universal vaccination' (p171). While he acknowledges that many people would object to the state intruding into the private sphere, and that balancing the benefits and disadvantages would require debate, he concludes that: 'hopefully the decisions will be made by an informed and compassionate society with a firm knowledge of the disease nature of addiction' (p174). In so doing, Cohen invokes the standard biomedical model of disease as morally neutral and the

character of medicine as value-free, which has been questioned consistently throughout this thesis (Mishler, 1981). Further, Cohen's analogy reflects the pharmacological determinism inherent in much drug policy rhetoric in the US, as outlined in Chapter 4, since the act of consumption is portrayed as inevitably leading to addiction, ignoring the sets and settings of the context in which the drug is used (Becker, 1973; Reinarman and Levine, 1997). Arguably in this context such rhetoric is furthered, since the previously voluntary act of initiation itself is replaced by a generalised risk in the environmental, whereby the disease of addiction passively spreads from one 'susceptible' person to another. This is reflected in much of the bioethical literature which considers potentially targeting specific individuals or populations, either by examining genetic markers for a predisposition to addiction, or by socio-economic factors, thus indicating those most likely to use drugs (cf. Hall, 2005; Harwood and Myers, 2004; Miller and Klanica, 2004).

The Center for Cognitive Liberty and Ethics, CCLE, (2004) have noted the reconstruction of addiction as an infectious disease in official US policy, and expressed deep concern that such constructions, alongside the moniker of 'vaccines' given to the active immunotherapies, dovetailed with a future move to make the use of pharmacotherapy drugs compulsory, at least for some segments of the population. One of these segments was people who rely heavily on public benefits, which include public school children. Their main concern was that 'many parents would undoubtedly protest against any effort to include pharmacotherapy 'vaccines' in the childhood vaccine program because drug use is not an infectious disease; however, government rhetoric is already laying the groundwork for responding to such parental objections' (p23). Indeed, as already discussed, because bioethicists generally hold the values of patient autonomy and informed consent to be pre-eminent, there is a tendency for them to be sceptical about compulsory vaccination laws, as was evident in the HPV debate, where it was argued that because HPV is not casually transmissible coercive laws may be considered unacceptably paternalistic (Colgrove, 2006b).

Consequently, the existence of a compelling rationale for requiring MCI for addiction then is predicated on the success of this analogy to infectious disease whereby the use of biological metaphors for the aetiology of the spread of addiction promotes and persuades of a certain conduct by suggesting a generalised risk in the environment whereby individual rights are weighed against the protection of the public health through a social form of herd immunity. Implicit in such discourses is the empirical assumption that vaccinations for addiction *could* adequately prevent the spread of the 'disease', and the normative claim that they *ought* to be used for such a purpose, based largely on consequentialist and utilitarian modes of ethical reasoning wherein the neo-liberalised individual has a less significant stake. However, as Wilsdon and Willis (2004) argue, the

tendency for possibility to be conflated with desirability in the arguments used to support a new technology, result in a circularity whereby assumptions about the economic and social benefits of innovation become implicitly built into the loop and shielded from genuine debate. Consequently, social and ethical issues are often in no real sense addressed, and when faced with new situations policy makers tend to turn to frames of reference inherited from different situations, without an adequate exploration of the underlying similarities to justify the transposing of one norm to another (Hoffman *et al*, 2006). As such, this chapter will now present an analysis of the data collected from interviews with those involved in the development, application and regulation of the vaccines, mainly in the US, but also in the UK. It will also present an analysis of the perspectives of lay participants drawn from the focus groups conducted in the UK with smokers, social cocaine users and parents.[3] It will seek to explore the underlying constructions of addiction and their implications in these key actor groups in order to guide empirically grounded interpretations of the potential benefits and drawbacks of widespread preventative vaccination against addiction and the extent to which expert and lay frameworks of evaluation differ. Again, it also provides an opportunity to examine how wider publics respond to, or challenge, the dominant clinical gaze, both as active participants in the medicalisation of addiction and as sites of potential resistance and to assess the consequences of this for decisions as to the potential use of the vaccines in MCI programmes in the UK.

6.3. EXPERT ASSESSMENTS OF THE RELATIVE RISK BALANCE OF VACCINATION

Overall, there was a striking ambivalence or aversion to MCI, with the majority of expert and lay participants expressing deep concern about the widespread preventative use of the vaccines; however there were notable differences in the underlying frameworks guiding participant's assessments, and they will be considered separately. Again, following Mackenzie's (1990) 'certainty trough', as seen in Chapter 4, those most closely involved with knowledge production were the most likely to emphasise that unlike vaccines for traditional infectious diseases, where exposure to the pathogen stimulates the production of antibodies in someone who has previously been immunised, the drug itself would not stimulate an immunological memory. Rather, the blocking effect is dependent on existing antibody levels, such that the person would require frequent booster jabs every few months to retain optimal titer levels for up to a year. On this

[3] NB. The focus groups conducted with drug users in treatment are not included in this chapter because MCI was not discussed in any depth as due to time constraints it was decided to focus on their personal experiences with drug use and treatment, and their perspectives towards vaccinating their own children.

basis the majority of interviewees doubted the practical value of prophylactic use of vaccines for either cocaine or nicotine and the quote given below by US18, a behavioural neuroscientist involved the development active vaccines, was a typical response:

US18: 'If you take a five year old and you immunise them against cocaine and ten years later when they're fifteen they take cocaine, cocaine will not cause the antibody titers to go up, they would have to be immunised again and again and again because they fall off after a period of two to three months after immunisation. So you know from a practical viewpoint that limits this approach in terms of prevention' (Behavioural Neuroscientist involved in the development of active vaccines).

The traditional cornerstone in the assessment of new vaccine technology is the balancing of the risks and benefits of the vaccine relative to the disease in question (Malone and Hinman, 2007), and those that rejected the likely efficacy of MCI tended to highlight individual autonomy in drug use and make explicit or implicit normative challenges to the metaphor of contagion and the related conceptions of risk which have come to be associated with the dominant disease model of addiction. These interviewees often elaborated their position by drawing parallels with the HPV vaccine, as targeting a risky behaviour an individual enters into through choice, rather than for a biological pathogen one is involuntarily exposed to in the environment. For example, UK4, a Professor of Biological Psychiatry and Addiction argued:

UK4: 'Well I think it's the first one that's been given to prevent something that may not happen if you didn't engage in risky behaviour. I think that's why it's so different, isn't it? I suppose it's not your fault if you get measles, mumps or rubella' (Professor of Biological Psychiatry and Addiction).

Central to this underlying assessment of the risk-benefit balance was the rejection of the analogy to infectious disease based on the moral agency of the drug-using individual. Since personal choices could reduce the risk of the disease to zero, the risks of vaccination to the individual were generally seen to outweigh the benefits.

US22: 'Personal choices could completely preclude your need for this thing. So you're presuming a fall from upright behaviour, to use a monistic term, and then you're trying to buttress that and are you actually encouraging it in a strange way and you're accepting there will be on average drug use and so we're going to build in for someone using drugs? I'm just thinking, I was never very concerned about the prophylactic administration in those who had not demonstrated a propensity for the drug, there are complications with aspirin, if I told you, you had to take an aspirin a day to be protected from cocaine, okay, a certain number of people will have stomach bleeds you know but one has to be reasonable about this, well now we're talking about giving people injections of artificial enzymes or constant injections of carrier bound hapten, it just didn't it never seemed plausible' (Professor of Medicine involved in the development of mAbs and catalytic antibodies).

US14: 'I don't think that anyone is seriously considering active immunisation of large populations of people, even those at high risk, for prevention. I think this is a treatment program for established addicts… there will always be some significant risk associated with making someone actively immune to cocaine and your fiddling with a vital function for human well being so you don't want to put someone at risk unless you know that the benefit far outweighs the risk associated with its administration um we're not at the stage where we can predict that someone's going to become a cocaine addict even under circumstances where they might be environmentally at great risk so I think anyone at least anyone that I've talked to would be err risk adverse at present with respect to an

approach towards prevention' (Senior Research Scientist in Pharmacology involved in animal trials of active and passive immunotherapies for cocaine).
US26: 'Nothing is without risk and every vaccine has some side effects associated with it and so if your going in as a treatment agent for a cocaine addict and you've got some nasty side effect that shows up that's OK because if it's effective that's a trade off your willing to make. But if you're going in to healthy adolescents to prevent them from smoking boy you're going to have to be really squeaky clean um and you probably are I mean people have looked pretty carefully to make sure you're not inducing antibodies that cross react but with prophylactic vaccine where you're talking about immunising millions of people and you know well, we'd have all these what if's - what if somebody gets in a car accident and their blood brain barrier is compromised and then these antibodies get into the brain what are they going to bind to and you just never know and so there's all those things that you don't know until you've immunised a million people' (VP Biotech Company developing active immunotherapies for nicotine and cocaine).

Furthermore, whereas conventional risk-benefit assessment includes herd immunity, where the risk to the individual is balanced by the protection to the community, as US18, a policy-maker and research scientist involved in the early development of the vaccines argued:

US18: 'The argument for using vaccines for children as a requirement for them getting into school is not for the individual's health but rather for the good of the community because if they're not vaccinated and they get the disease they can spread it to others so we can argue that it's for the greater good. But in the case of a child trying cocaine it's a little less compelling that they're going to be you know suddenly giving cocaine addiction to everybody else it's not the same kind of proposition' (Behavioural Neuroscientist involved in the development of active vaccines).

By drawing attention to the role of choice in drug use, interviewees also highlighted the interplay of the technical problems inherent in prophylactic vaccination due to unanticipated consequences arising from the freedom of the individual, illustrated by US29, a Professor of Psychiatry involved in the clinical trials of the cocaine vaccine in the US who argued:

US29: 'I mean prophylactic vaccination, it's unfortunately not like smallpox or something else in that people don't want to get smallpox but people want to get high' (Professor of Psychiatry involved in the clinical trials of active cocaine vaccine).

The potential unanticipated consequences of widespread prophylactic vaccination put forward by participants were manifold. The most commonly cited related to the partial nature of the technology such that the vaccine would only attenuate and not block drug effects entirely, and could thus be circumvented by increasing the dose of a drug in order to achieve the desired effect, thereby increasing the harmful side effects such as cardio-vascular toxicity and also raising the financial cost of drug use. The possibility of children swapping to other (perhaps stronger) drugs they have not been vaccinated against was also frequently raised as increasing the risk to the individual. Another common and persistent theme throughout the interviews was the perception that MCI would promote the development of new and stronger versions of drugs on the black market as dealers sought new markets, which would have negative effects on society. Consequently, widespread vaccination programmes for children tended to be constructed as

potentially harmful for both the individual child and society, and as largely cost-ineffective measures against drug use and addiction for the state.

UK9: 'Even if there were vaccines for tobacco and cocaine for children that leaves an awful lot of other substances people can abuse... From a policy perspective, any vaccination programme, depending on the cost of the product could be an extremely expensive way of looking at an issue that could actually be more effectively, cost effectively dealt with by other known methods' (Professor of Health Sciences and member of WHO Expert Committee on Drug Dependence).

The majority of expert interviewees were also very critical of the possibility of targeting prevention to high-risk groups, before they had begun to show signs of problematic use. Although the role of genetic make-up in predisposition to addiction was not dismissed by all participants, most rejected the theoretical or practical usefulness of using biological markers for addiction to target prophylactic vaccination, rather than to help define populations that may respond well to vaccination in terms of titer levels once an addictive state had been reached. Further, the use of socio-economic factors to target vaccination was seen as opening up a 'Pandora's box' of issues around stigmatisation, with labelling seen as placing a great psychological burden upon the individual. However, many were largely in favour of some forms of limited targeted prevention, but only where adolescents were already using a drug problematically and they assented to treatment, although here most participants emphasised it should be classed as treatment and not prevention, even if the child were not formally diagnosed as 'addicted'.

UK10: 'That's going to open up a Pandora's Box isn't it? It's going to lead to all kinds of problems and ethical issues of how do you classify people - do you pick on lower socio-economic status families who are more likely to go and use hard drugs? Are you likely to pick on people with family histories who have got a family history of drug misuse, or psychiatric problems, or alcoholism? I mean it's, it's a can of worms basically' (Specialist registrar in psychiatry and executive member of the Royal College of Psychiatry).

However, a substantial minority of expert participants directly involved with the development of the nicotine vaccines in the US were strongly in favour of MCI for nicotine and analysis of the data suggests that underlying these technical barriers to vaccination there was a clear difference between the two groups in the underlying conception of addiction which guided their perceptions. For these interviewees, widespread vaccination at birth was constructed as the ultimate aim of the technology, with targeted vaccination through either genetic or socio-economic factors regarded as a 'conservative' or 'risk-adverse' approach.

US11: 'I probably would do mass vaccinations but maybe there might be a time targeting kids who are high risk who start to experiment, that would be a real conservative way to approach the situation' (Professor of Psychiatry involved in clinical trials for nicotine vaccine).

US12: 'I think it's probably premature to think about using vaccines like that but that really is the goal it really is the goal… so I think the sequence I could envision, if they're effective, is using them for

treatment and then if they're effective, if they're safe, moving to early intervention moving to occasional smoking, finding people who are on the early part of their trajectory and then just moving back and back and back until you're getting people before the start on the basis of behavioural or genetic risks whatever works' (Professor of Pharmacology and Medicine involved in development of active nicotine vaccine).
US13: 'I think as our understanding of genetics and how genetics relates to addiction and the different relationships between how the genes define you and how your environment defines you, I think as we get more and more of an understanding of those issues the identification of high risk individuals will become much easier and then I think it is a good idea to try vaccinate those people or those adolescents if they are, if there's evidence that they've been doing it, or even before. I think the cost of drug addiction to society is so great that it's worth doing whatever we can' (Research Scientist involved in animal models of active and passive nicotine vaccination).

For participants advocating the widespread use of the nicotine vaccine, nicotine tended to be singled out as more addictive than cocaine and distinctively harmful among all drugs, both to the individual and society, as typified in the quote below:

UK8: 'Nicotine clearly I think there would be less of a possibly contentious issue there because for example, nicotine is not an illegal drug, it's much more widely used, there's stronger consensus on its harms, and there is no obvious safe use of tobacco' (Member of the Advisory Council on the Misuse of Drugs).

While the use of cocaine was seen to be a moral choice, where a child may actively choose to initiate cocaine use, knowing the dangers, for a variety of different reasons, talk of pleasure was almost entirely absent from talk of smoking. In the absence of any 'reason' to smoke, the only explanation for the continuation of the child to do so, knowing the potential harmful effects to their health, is seen to be because they are already 'addicted', such that questions around the moral choice of the child to choose to smoke are deflected. These frameworks drew heavily on pharmacological determinism, where the presence of nicotine addiction tended to be conflated with any use of nicotine, since it was regarded as leading inevitably to dependency. In the context of the high incidence of smoking within the general population, the child is constructed as passive in the face of the generalised 'risk' in the environment, as UK3, a former Medical Director of a Biotech Company developing both nicotine and cocaine immunotherapies argued:

UK3: 'Cocaine vaccines I don't think we're ever going to be used as a preventative vaccine because the incidence was too low. And I think the ethical issues associated with vaccinating teenagers on the off chance that they would become addicted to cocaine was just - I don't think you could justify that. Now there may be an argument for saying you can identify potential high risk children who may go into experimenting with cocaine where you could use it preventatively, but that aside, our view was, this was going to be therapy, not prevention... One thing I was very keen on, but I think it's still some way off, is using the nicotine vaccine for prophylaxis, for prevention of children becoming addicted in the first place. And I think in some ways, if you can get through the ethical issues, I think it's probably got a better chance of working. I mean my theory, for what it's worth is that children all experiment with cigarettes and they probably think it's pretty filthy but they become addicted. Now, if they hadn't become addicted, I don't see that it's any different from trying a food you don't like. You know you try it you don't like, you don't have it again. I mean, there's nothing nice about smoking, it's just the addiction that makes you do it again' (former Medical Director of a Biotech Company developing both nicotine and cocaine immunotherapies).

Accordingly, while cocaine is seen to be unsuitable to MCI because only a small amount of children will choose to put themselves at risk by using cocaine, the failure of the smoker to adhere to neo-liberal norms of self-care lends itself more readily to discourses of passivity and infectivity. Further, the limited duration of the vaccine was used to justify any potential infringements on the individual liberty, since the vaccinations could be stopped at adulthood, with the likely depletion of antibodies within a year, such that nicotine vaccination was constructed as 'keeping options open' for the child, rather than foreclosing them:

US13: 'When they are 18 if they wanted to make that decision to smoke we would hope that by that time they would be mature enough to make the correct decision, but if not then the vaccination could be terminated and then in the course of 6 months to a year their antibodies concentrations would fall off enough that they wouldn't have any effect of the vaccine if they did choose to smoke' (Research Scientist involved in animal models of active and passive nicotine vaccination).

Consequently, vaccines were portrayed as protecting the child, either through adolescence or from birth, by protecting the neurochemistry of the developing brain, such that at the age of majority they would have the necessary competencies to act autonomously to make the 'right' decision.

US12: 'I think the potential for doing some good is always greater with prevention there's a growing consensus that being addicted, using a drug for a period of time, rewires the brain so somebody who is a smoker who quits is not the same as somebody who has never smoked and we know this, this is not great news because smoker who quits has a very great chance of relapse whereas the non-smoker has a much lesser risk of starting but it's not a simple behavioural thing it's hard wiring the neurochemistry of the brain has been altered, which doesn't mean that they can't quit it just means you got a very different job seems to me there's a real premium in interrupting the trajectory before those neuro-patterns get established before the new synapses are there and everything's been changed the earlier the better so I like the idea of early intervention' (Professor of Pharmacology and Medicine involved in development of active nicotine vaccine).

Because all smoking behaviour was regarded as indicative of addictive disease, the prevention of smoking was constructed as equivalent to the prevention of any other infectious disease. Smoking becomes the inevitable outcome of a susceptible individual in a high-risk environment, which deflects questions over the right of the individual child to make the choice to smoke. In this context, the tobacco industry takes on the active role, aggressively dispersing biological pathogens rather than consumer choices, and the hallmark of addiction, involuntariness, becomes applied to the very act of initiation of smoking. Rather than smoking being seen as a 'bad' choice, it is constructed as a 'non-choice'; the inevitable outcome of a genetically or behaviourally susceptible individual to environmental exposure. As such vaccination was constructed as 'keeping options open' rather than foreclosing them, which was put forward forcibly by one researcher directly involved in the development of active nicotine vaccines:

US12: 'When somebody talks about the right to a smoking future you're kind of making the assumption that smoking is a choice, you know the tobacco field has pretty much figured that one out already, people don't really make a choice, people do make a choice to have one cigarette, they don't really make choice to become addicted erm … and so do you affect the social environment and the odds of making a certain choice maybe temporarily the ability to be able to make a choice for somebody? Well

sure but the lack of a policy the lack of a vaccine the lack of an intervention is also a very active choice where your saying we're going to leave advertising unopposed you know, so the idea that not offering a vaccine is doing nothing is absurd not offering a vaccine is seen as supporting tobacco use by not opposing advertising' (Professor of Pharmacology and Medicine involved in development of active nicotine vaccine).

This talk worked to shift the risk-benefit balance in favour of vaccination, since the risk of nicotine addiction was effectively brought forward and equated to the risk of exposure, such that US12 continued to argue that the perception that addiction medication should be risk free was crazy, since smoking had such a high mortality rate, without making a distinction between the use of medication in the differing contexts of treatment and prevention.

US12: 'The idea that an addiction treatment should be risk free is kind of crazy, we don't demand that of medicines that are treating other diseases … People who are in the field seem to be reluctant to use or to prescribe medications that have some risk because they're comparing it in their mind to nicotine replacement which has close to none, which is bizarre because smoking has a fifty percent mortality it's just not today' (Professor of Pharmacology and MD involved in animal models of nicotine vaccine).

In summary, such third wave public health constructions present the nicotine user as a passive victim, and direct the eyes of the state onto the vulnerable host, at risk from environmental exposure. Thus the moral decision to experiment with nicotine becomes already constrained, marked by the hallmark of addictive disease, and in need of treatment. Consequently, by drawing on metaphors of infectivity and passivity these discourses justify MCI for nicotine within a neo-liberal society as beneficial to both society and the individual, by preventing a constraint on autonomy, not as infringing on freedom of choice.

6.4. LAY DISCOURSES OF DIFFERENCE AND DIVERSITY

The vast majority of participants drawn from the focus groups with smokers, social drug users and parents in the UK rejected MCI and did not see any difference between the issues raised by nicotine or cocaine, regarding their (il)licit status as an artificial distinction that was subject to change over time, and which were equally the product of personal choice. These groups can be seen to be alienated from the new technology, located at the opposite end of the knowledge production spectrum, unlikely to challenge the construction of the vaccines as completely blocking drug effects or its very long-term duration, but highly critical of the underlying biomedical model of addiction and drug use. The dominant lay challenge to widespread vaccination overlapped substantially with expert perspectives, questioning its potential efficacy through explicitly or implicitly rejecting the passivity of the infectious disease analogy by highlighting the freedom of the individual to choose to use drugs or smoke. However, in contrast

to expert interviewees, these focus group participants were more likely to couch their perspectives in terms of personal rights and freedoms than relative risk benefits.

F5: 'It's your choice to take them [drugs] even if there's an argument that it's not a choice when you've got hooked on it, unlike measles or whatever never choose to have that' (parent, S1/G2).
F21: 'It'll be a choice of theirs whether they take drugs or not, it's not their choice if they get measles or something is it I mean it just happens to them' (social cocaine user, S3/G1).

F10: 'Well no-one would choose to have measles and mumps and some sort of infection and disease would they really?
F13: Yeah I think it's a different sort of, well they're preventing them getting an illness which I don't think they would choose to have, but the addiction or stop them smoking it's like-
F12: It's like preventing them from having a lifestyle choice rather than an illness which I think is very different' (smokers, S2/G1).

Similarly, lay participants were quick to point to the inefficacy of widespread vaccination due to the unanticipated consequences arising from the ability of the child to circumvent the vaccine by swapping to other drugs they have not been vaccinated against, including alcohol. Again, the likely development of new and stronger versions of drugs on the black market as dealers sought new revenues was also a recurring theme, which was seen to increase the harms to both the individual and society.

F1: 'People are always gonna find another outlet to go crazy by you know if you take this away I think it'll just result in a different kind of substance abuse and then they'll look for a cure for that one-
F3: Unless you can blanket stop any of these drugs be addictive do you not think if you remove those enjoyments from a young adult they're just gonna think well I can drink so I'll just drink yet more' (parents, S1/G1).

F15: 'It's going to push people to try and find even worse drugs as well cause the ones at the moment yeah there are big issues around them, but what happens when people push to find something else to get a buzz avoiding that drug and it's something which is deadly serious and it's something widespread and it's even more addictive and there's no vaccine for it and you don't want to push society to that point really' (smoker, S2/G2).

F12: 'You can totally imagine it – people, the drug dens, coming up with more sneaky ways, more potentially dangerous ways of getting stuff that won't be affected and you can totally imagine that would happen I can totally see it
F10: Yeah cause there's money to be made there so someone's going to
F12: Some kind of really weird concoctions of things that you could die on first taking' (smokers, S2/G1).

The vast majority of lay participants were also very critical of the possibility of targeting prevention to high-risk groups, before they had begun to show signs of problematic use. Although they tended not to contest the possibility of genetic markers for pre-disposition to addiction, most were critical of the practical use of such markers, drawing attention to the choice to initiate drug use and smoking and the salience of nurture over nature in defining that choice. In line with experts, many were largely in favour of some forms of limited targeted prevention, but only where adolescents were already using a drug problematically and they assented to treatment. In contrast however, a substantial minority of participants across these groups, mainly

located in the groups with smokers and social cocaine users, questioned the underlying premise of vaccination for addiction: that the eradication of addiction itself was necessarily desirable. Here, participants directly challenged the conceptual link maintained in the dominant biomedical model of addiction between difference and dysfunction that is disvalued, constructing instead positive accounts of the abnormal state of addiction (Caplan, 1992).

F11: 'I think it's interesting why necessarily addiction should be viewed as something wrong … you know maybe to be human is to be addictive … I think addiction is important for a human being you know for what is a human being and through having an addiction you might learn a lot of things which are important
F12: I also agree with that I think people who overcome an addiction erm you know it can be an amazing kind of development it can make someone so much more strong you know have resilience and all sorts of amazing qualities and if you never even had the addiction to begin with you might not ever even discover you might end up a lot blander as a person because of it' (smokers, S2/G1).

F23: 'There's some brilliant people that have got over addictions and are helping other people you know and have made their lives worthwhile because they were an addict and now they're not' (social cocaine user, S3/G2).

Furthermore, the vast majority of participants from across these groups were quick to identify the vaccines modality as working only indirectly on addiction, through preventing the experience of drug use, and were highly critical both of the pharmacological determinism inherent in dominant accounts and of the marginalisation of the social value of drug use and smoking. Indeed, many lay participants argued that the use of drugs in certain contexts was positive, and that social mores were in constant flux and that it was wrong to impose current morals on future generations.

F18: 'One of the positive things about drugs is that it totally like opens your eyes to sort of like I dunno you have different perceptions of certain sorts of things after you've taken drugs and so it is quite a positive thing obviously not to get addicted to them but to try them in the first place and I think you get a certain set of parents who would be like oh no and would give them the vaccine straight away and then you know those children are never going to get to try that' (social cocaine user, S3/G1).

F1: 'And you know it's kind of saying well all these things are really bad things and they're not always really bad things, everything in moderation is okay' (parent, S1/G1).

F10: 'What would worry me is, it's awful to remove that choice from someone, but you're putting today's society's kind of moral values
F9 and F11: Yeah yeah
F10: So you might be vaccinating children against, I don't know homosexuality, because a lot of people see that as being wrong, so you know it could open potential for a lot' (smokers, S2/G1).

Furthermore, even where the actual use of drugs was not constructed as positive, the importance of the *choice* to use drugs in differentiating society was frequently invoked. For example, many people made reference to a 'boring society', where universal vaccination against addiction would make 'everybody the same':

F15: 'That sounds like it would be in a day and age where you would have a curfew where everyone would have to be in bed by 9 o'clock and you have to get up at this time in a morning and everyone has to do their washing on this day and stuff and it's too much of a nanny state and its taking away your

human rights. Fair enough you have things which prevent, you know what I mean, the drugs which are illegal are illegal because they are dangerous they're life inhibiting and stuff and like you know what I mean you're not allowed to go stab someone because that's morally wrong but smoking is not really morally wrong it's a personal choice, it's a personal decision' (smoker, S2/G2).
F12: 'Well then you're getting into the whole designer babies I mean it's all that kind of thing creating the ideal human to the point where we all become like robots and
F11: Yes but what is this ideal
F12: Well I don't know but that we all end up just the same little good citizen robots
F10: All get married at 20 all have children at 22 set order you know
F12: Never do anything wrong never have anything bad happen
F10: Work 9 till 5 every day
F13: I think it's scary that notion of perfect you know who's judging what standards are you judging it by why should it be so desirable to be so healthy you live to be hundred and twenty five you know' (smokers, S2/G1).

6.5. DISCUSSION: SMOKING AND THE 'LAW OF 1970'

While for a minority of expert participants vaccines for nicotine were constructed as equivalent to the prevention of any other infectious disease, the empirical evidence suggests that in this context the vast majority of both expert knowledge producers in the UK and the US and lay participants in the UK were highly critical towards the potential use of vaccines for cocaine or nicotine in MCI. The construction of epidemiological models which located risk in the generalised environment, and the child as passive were heavily contested, and by emphasising the liberty of the child in initiating drug use, participants expressed profound doubt over the likely effectiveness of the new technology. The expert aversion model tended to draw on the role of individual choice to highlight the imbalance of vaccination in terms of the risk-benefit ratio of MCI, since personal choices could effectively reduce individual risk to zero, and a 'social' form of herd immunity was seen as insufficient grounds for prioritising the common good over individual rights. Both experts and lay participants equally explicitly constructed the drug user as a moral agent in order to contest the efficacy of MCI by highlighting the likelihood of unanticipated consequences, such as children circumventing the vaccine by swapping to other drugs (including alcohol) they had not been vaccinated against and the development of new and stronger versions of drugs on the black market as dealers sought new revenues. In the focus groups with smokers, social drug users and parents, participants were also quick to interrogate the major premise, or general truth on which arguments for widespread vaccination were based (Becker, 1998); that drug use and addiction are states we would necessarily want to prevent. The prevention of addiction is not distinct to the prevention of drug use, given the *modus operandi* of the vaccines which materially conflates the two; 'treating' the former by divorcing drug use from its associated psychotropic effects. Lay participants also made frequent reference to positive discourses of pleasure and heterogeneity, where the use of drugs was constructed as an important factor in differentiating society and allowing the expression of individuality. They also challenged the conceptual link between difference and dysfunction that is disvalued (Caplan, 1992), constructing

positive accounts of the abnormal state of addiction. Similar to the findings of Marris *et al* (2001) in conducting focus groups with publics across Europe on agricultural biotechnologies (GMOs), participants here took uncertainty for granted and did not expect zero risk, but because they often assumed that there would be unanticipated consequences in the long term, they demanded that the reasons for proceeding with the innovation be good ones. Thus questions such as 'What are they doing this for?' 'What is the need?', 'What is their purpose?' were posed because they wanted to have the means to assess whether or not the intended purpose was important enough to justify exposing ourselves to these uncertainties, especially where the potential long-term consequences were seen to be irreversible and potentially serious. Following this, rather than speaking of public perceptions of risk versus benefits towards vaccines for addiction, it may be more accurate to understand public evaluation about their development in terms of uncertainty versus need or purpose, which in this case was clearly questioned.

However, there was a substantial minority of expert participants directly involved with the development of the nicotine vaccines in the US who were strongly in favour of MCI for nicotine, constructing widespread use at birth as the ultimate aim of the technology. In these discourses the nicotine user was portrayed as a passive victim of nicotine addiction, and consequently vaccination was seen as akin to preventing a constraint on autonomy, not as infringing upon freedom of choice, similar in kind to the infectious disease narrative put forward by Cohen (1997). Here environmental exposure is seen as sufficient to put all children potentially at risk, even where not all children will become 'infected' with the disease (use a drug), or show symptoms of its presence (addictive behaviours). This downplayed conceptions of agency, both in the choice to initiate use, and in the ability to maintain moderate use without demonstrating addictive behaviours, tipping the risk-balance ratio in favour of state intervention in order to protect the public safety. The prioritising of nicotine vaccines over cocaine vaccines as likely entities of mass immunisation campaigns may seem an interesting contradiction given their respective licit and illicit status. However, drawing on the literatures covered in the preceding chapter and the shift to risk avoidance strategies involving calculations about probable futures in the present, and interventions into the present to control that probable future, such a finding is perhaps not that surprising.

Nicotine is distinctive among psychoactive drugs in that its health consequences are in the distant future, compared to alcohol and opiates which are likely to provoke acute negative effects far earlier in a user's career, such as accidental injury resulting from intoxication and local injuries related to drug administration, such as abscesses at injection sites or perforated septa from snorting, as well as with some drugs, serious health consequences associated with withdrawal. Thus, it is a future-oriented kind of person who is likely to make the individual choice to give up a

profoundly pleasurable habit, smoking, as a hedge against the likelihood of debilitating disease in the later stages of life (Acker, 2002). As Keane (2002) argues, 'healthism' has led to the conception that there is only one way to live a meaningful happy and productive life, such that pleasure and enjoyment in the present have been largely excluded from discourses around smoking, except in the disembodied forms of 'psychoactive euphoriant effects' in the brain (p122). Smoking is therefore seen as an irrational behaviour that serves no useful purpose and can only be explained in terms of pathology; 'if the smoker is not suffering from disorder why do they continue a dangerous habit which they do not really enjoy?' (Keane, 2005, p93). As the meaning of smoking has been reduced to enslavement to a chemical and categorised as addiction, the smoker has been discursively produced as a pathological identity, and their disordered inner has become seen as the proper object of rehabilitative self discipline. The construction of smoking as a symptom of affliction, rather than a cultural practice or individual choice, transforms the political landscape of tobacco use, as arguments based on rights and freedoms are disarmed in the face of biology and the absence of choice it implies. However, one of the conditions of this benevolence is the embracing of an identity based on pathology, where smokers are seen to fundamentally differ from non-smokers on the physiological level, with smoking genes which control susceptibility. All smokers have then become regarded as passive, whether first or second hand inhalers, while the tobacco industry has taken on the active role of agent of disease and death (Keane, 2002).

As the earlier temperance belief that the drug itself was inherently addictive came to be applied to heroin and cocaine in the early twentieth century (Levine, 1978), arguably it has now begun to shift again. As cocaine in being reconstructed as both socially acceptable and at the same time, addicting to some people, as seen in Chapter 4, nicotine is acquiring the status of the 'most addictive drug', inherently addictive and the biggest threat to the public health. Extending the earlier discussion of Gomart (2002), the construction of smoking in this context can be seen as a perfectly causal object, moving on its own impetus to infect the whole of society. As in the 'law of 1970' in France, which established the penal measures against drug use and traffic, where an essentialist definition of a drug is taken it becomes crucial for the state to intervene:

'Either the drug acted, and all succumbed; or the State blocked the circulation of the drug to preserve the autonomy of the citizens. This definition of the drug – which fits the dualism of the liberal definition of freedom – then justified a political statement about the subject in society... The threat that the perfectly causal drug posed to the collective justified the subordination of the individual's good to that of society as a whole' (p524).

However, whereas in the law of 1970, responsibility for the repressive policies it permitted were not seen to lie with the legislators but with the addict who had abdicated their right to liberty and the protections reserved for autonomous citizens by trying to reach 'artificial paradises', in the

context of smoking, the repression of the state is seen to be much less overt. These discourses can be seen to extend the response to passive smoking since the 1980s (Mold, 2007). This passivity, when combined with the perceived virulence of nicotine (largely through its licit status), poses smoking as a far greater threat to the health of the nation than cocaine, where pleasure and enjoyment still separate the user from the addict in common perception. While drug addiction is seen to pose a *moral* threat to both the individual and society, the harms posed by smoking are seen to be uniquely restricted to the *health* of the individual and society, arguably allowing the infectious disease metaphor to take greater hold. Thus although state intervention through vaccination to control cocaine use is seen to act as an infringement on autonomy, intervention to prevent nicotine addiction is portrayed solely in the supposedly morally neutral terms of protecting the public health, where smoking is seen as a non-choice, the result of passive exposure to overwhelming environmental pathogens, and not as an expression of moral agency.

However, overall, perceptions of the state acting as the prime mover in mandating or facilitating MCI were strongly criticised and the perspectives of key knowledge producers and lay groups presented here suggests that the move to establish MCI for addiction would raise broad questions about the acceptability of mandatory public health measures in the US, and the role of political advocacy in determining how preventive health measures are implemented in both the UK and the US. Indeed, the likelihood of such an Orwellian future seems unlikely in an age where governments have acknowledged that they are more likely to achieve their aims through 'nudges' (Sunstein and Thaler, 2008) and the indirect promotion of parental responsibility than through such overt subjugation of freedom (Rose, 1999b). In contrast to the concerns of the Center for Cognitive Liberty and Ethics, CCLE, (2004) noted in the last chapter that the US state was actively manoeuvring to make the use of pharmacotherapy drugs compulsory for public school children, in opposition to parental desires, given the biopolitical context of 'healthism' in neo-liberal democracies it is arguably more likely that such a move would be promoted and facilitated by parents. Indeed, it has been the opinion of all the state-commissioned inquiries in the US (Harwood and Myers, 2004), Australia (Hall and Carter, 2002, Hall, Carter and Morley, 2002) and the UK (Ashcroft, Campbell and Capps, 2005) that the decision to vaccinate against drug addiction will not come directly through the state, but rather through parents wanting to take responsibility for their children's health and lobbying for state provision of immunotherapies for addiction. Consequently, bioethicists have tended to focus on whether parents have the right to vaccinate their children against addiction. Prophylaxis then also raises important questions around the scope of parental autonomy, and the ways in which technologies of domination are internalised and reproduced by individuals in the context of their parental role as guardians of their children's future health and happiness. As such, Chapter 7 will now turn to the empirical examination of discourses presented by both expert and lay participants, in their role as parents, and their

willingness or resistance to further the medicalisation of addiction by seeking or accepting vaccination against addiction for their child.

7. DRUG USE AND DOMAINS OF DISCRETION: THE PHYSICAL AND TEMPORAL EXTENSION OF PARENTAL POWER

'Virtues are as dangerous as vices in so far as one lets them rule over one as authorities and laws from without and does not first produce them out of oneself, as one should do, as one's most personal self-defense and necessity, as conditions of precisely our own existence and growth.'

Friedrich Nietzsche, 'The Will to Power, Book II' (1967, no. 326, p178).

7.1. INTRODUCTION: PARENTAL ACCEPTANCE AND RESISTANCE OF VACCINATION

Chapter 6 focused on the biopolitical tensions inherent in the potential deployment of immunotherapies for addiction in mass childhood vaccination, MCI, which cast the state as the central actor in the wider context of a new public health which is decentralised and tends to act only indirectly to promote population health by activating individuals to manage their own risks and risk behaviours. As such, this chapter will focus attention on new forms of indirect regulation, surveillance and control which characterise newer biopolitical regimes and the place of vaccines for addiction in the remit of legitimate parental medical decision making on behalf of their children. It will briefly cover the key literature on parental resistance to vaccination and the role of herd immunity in the wider context of the ideological conflict between individual rights and expert articulations of the common good (Blume, 2006). The discursive construction of childhood in dominant bioethical and legal discourses surrounding the legitimate scope of parental autonomy over their children will subsequently be examined. Drawing on Feinberg's (1980) work on the child's right to an 'open future', Hasman and Holm's (2004) article on the right of the child to a smoking future will then be critically appraised. The chapter will seek to deconstruct the popular public deficit model of understanding by empirically exploring the factors underlying parental decision making about vaccines for addiction for children, and place their arguments in the context of the material limits of the vaccines. Although there is considerable overlap between the main empirical themes of these two chapters, they were separated in order to explore in more depth the ways in which technologies of domination are internalised and reproduced by individuals in the context of their parental role as guardians of their children's future health and happiness, seeking to further the 'best interests' of the individual child, rather than the health of the population. Consequently, it will explore parents' willingness or resistance to further the medicalisation of addiction by seeking or accepting vaccination against addiction for their own child. As such, this chapter will specifically examine the focus groups conducted with participants recruited as parents with children under 2 years old, although it will also draw on data from the

groups conducted with social cocaine users, cocaine users in treatment and smokers, where they also considered the option of vaccination in relation to their own children. It will draw on 'expert' discourses, where interview participants discussed their perceptions towards vaccinating their own/ others children specifically in regard to the best interests of the individual child.

This shift away from older notions of state mandated vaccination, towards politics of education and persuasion, can be viewed in light of Rose's (1999b) notion of biopolitics, whereby the task of ruling politically is achieved through the promotion of subjectivities, the construction of pleasure and ambitions, and the activation of guilt, anxiety, envy and disappointment. The modern private family does not need to be governed through mechanisms of social control imposed under threat by courts, since it has taken upon itself responsibility for the duties of socialization. Rather, new relational technologies of the family are installed within us, which include the constant scrutiny of the effect of the actions of the parent upon the health, adjustment, development and intellect of their children (Rose, 1999b). In this context, the addition of any new vaccine that a state adds to its list of requirements or recommendations is judged in the context of both the existing regimen of vaccines that children currently receive and with regard to the possibility that additional mandates may inflame grassroots opposition (Colgrove, 2006b). However, as concerns about vaccine safety have grown in the previous three decades, through the global debate on the pertussis (whooping cough) vaccine in the 70s and the more recent controversy in the UK about the safety of the measles, mumps, and rubella (MMR) vaccine, more and more parents in the industrialised world are choosing not to have their children vaccinated, posing a problem to public health officials (Blume, 2006). Parental resistance to vaccination is typically framed within a deficit model of understanding, where opposition is interpreted as irrational and stemming from a misunderstanding of risk, met with by efforts from public health policy makers to plug the information gap. However, as Hobson-West (2003) has argued, the notion that parental objection to vaccination is based on a misunderstanding of risk assumes that risks can be objectively determined and interpreted, which is contested by theories of social construction which would hold that alternative socio-cultural meanings are possible. Interpreting public concerns towards vaccination in terms of risk de-politicises the debate and deflects attention from the role of resistance as a critique towards the assumptions on which vaccination policy is based, such as the relationship between the individual and community, citizen and state, and health and disease.

As Streefland (2001) has indicated, one reason for continued public opposition to vaccination is doubt in the legitimacy of the state as the keeper of public health. By taking personal responsibility for health and decision-making, groups that are critical towards vaccination depict the parent as conforming to developments in the new public health that are encouraged by the state and the medical profession (Hobson-West, 2007). Parental resistance can then be viewed as

a challenge to the public health representative of collective interest and as articulating a broader shift in the ideology of public health to one in which heterogeneous individual rights and responsibilities have acquired much greater weight (Blume and Zanders, 2006). Reflective of current public health discourse, with its emphasis on the language of choice, empowerment and individual responsibility, official information for parents tends to emphasise the benefit of vaccination to the individual child, and deflects attention from the implicit public health prioritisation of community benefits over individual costs. However, as Hobson-West (2003) has noted, parental refusal to vaccinate their children could actually be regarded as wholly rational if they believe that others will continue to vaccinate, since parents can refuse the jab and avoid the personal risk to their child whilst still enjoy the collective benefits of herd immunity: 'If society is indeed made up of individuals behaving as risk-minimising-autonomous-rational-consumers, then it makes sense to 'free ride'' (p277).

Similarly, Blume (2006) argues that a critical stance towards vaccination is a logical consequence of this ideological shift. Decades of emphasis on personal rights and responsibilities suited to the market paradigm has been encouraged throughout the health care system such that 'what we then see is an ideological conflict at the very heart of public health, in which individual rights on the one hand, and the expert articulation of the common good on the other, are pitted one against the other.' (p639). Indeed Rogers and Pilgrim (1995) point to the contradiction between the UK's NHS policy emphasis on patients' rights to informed consent and practices around vaccination that fail to respect those rights. They argue that in a society which currently promotes health by focusing on lifestyle and individual action, it is vaccination policy, and not the dissenting parents, that should be seen as the anomaly. Within the context of a strong consumer neo-liberal approach to public health with its emphasis on the importance of self-actualisation and personal responsibility, it may then seem surprising were parents to accept vaccines for addiction. However, the dominant position in public health and bioethical discourse has depicted parents not merely as passively accepting vaccination, but in Streefland *et al*'s (1999) term, as constructing a 'social demand', actively requesting the authorities or the health services to provide vaccinations to prevent future harm to their child (cf. Murray, 2004).

7.2. (DE)CONSTRUCTING THE CHILD IN BIOETHICAL DISCOURSE

One of the foremost assumptions in the bioethical debate surrounding the protective use of the vaccine technology is that the child is incapable of choosing for themselves whether they want to be vaccinated or not. Buchanan and Brock (1989), central figures in the bioethical field, identify what they ideally see as necessary conditions a person must fulfil if they are to be regarded as

'competent' to make decisions: 1) A person must have the requisite abilities of understanding and communication in order to participate in 'informed' expression of choice; 2) They must have the capacities for 'reasoning' and deliberation, 3) They must have a set of values or a conception of what is good that is at least minimally consistent, stable and affirmed as his or her own, in order to evaluate particular outcomes as benefits or harms, and to assign different relative weight or importance to them (p30). While in bioethical debate there is a global presumption of competence for adults, there is a global presumption of incompetence for the child since their infancy is seen to preclude the capacities necessarily for competence (Buchanan and Brock, 1989). Concomitant to this is the position that children are excluded from at least the full realm of adult human rights, in particular liberty rights, including the right to self-determination, since these are predicated on the possibility of choice (Archard, 2002). Consequently, children, defined by the United Nations, UN, Convention as: 'every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier' (UN, 1989), are regarded as incompetent with respect to the fully informed and neoliberally autonomous decision-maker over the age of majority, occupying a socio-political space outside the realms of liberty rights, of self-determination, and the possibility of choice (Archard, 2002). The presumed 'incompetence' of the child creates the conditions and space for the designation of a surrogate whose role it is to make decisions in the best interests of the child. Buchanan and Brock (1989) offer an abstract formulation of the role of the surrogate as a highly calculative rationalising subject serving the interests of their charge according to the Best Interest Principle, BIP:

'The best interest principle instructs us to determine the net benefit for the patient of each option, assigning different weights to the options to reflect the relative importance of the various interests they further or thwart, then subtracting costs or "disbenefits" from the benefits for each option. The course of action to be followed, then, is the one with the greatest net benefit' (p123).

In similarly ideal terms, Brock (2005) suggests that the parent/ legal guardian of the child is generally best placed to exercise this responsibility since: '1) Parents will generally love their children and make the effort to further their child's interests, and; 2) They will in general also know their children's needs and interests better, and so will be in a better position to know what will be best for them; 3) As parents, and in particular the mother, are responsible for having created, gestated, and given birth to a child, they have a claim to its being "theirs" ' (pp383-4). The latter is not taken to be a species of property rights, such as espoused by Aristotle, but rather implies that parents are entitled to exercise discretion in raising the child according to their own standards and values unless they otherwise disqualify themselves from so doing (Brock, 2005). Consequently, in the US-commissioned report into the vaccines, Miller and Klanica (2004) quote the US Supreme Court: 'It is cardinal with us that the custody, care and nurture of the child reside first in the parents, whose primary function and freedom include preparations for obligations the

state can neither supply nor hinder' (p284). Parents are presumed to act in the best interests of their children, and the law interferes with their right to make decisions about their minor offspring only in the most compelling of circumstances, thus the parent or parents with custody can generally make medical decisions for their children, free from state interference.

However, children are found wanting in relation to the criteria of the BIP on the basis of developmental psychology, which has globalised the perception that children acquire cognitive capacities according to a universal sequence that is a natural process and ahistorical (Jenks, 2005, Mayall, 2002). But Rose (1999a) has shown that developmental psychology was made possible by the historical context of the clinic and the nursery school which simultaneously allowed for standardisation and normalisation; averages were calculated based upon the performance of children of a certain age in a particular task or activity such as to present a picture of what was normal for children of a certain age. This was then taken to represent an invariant standard body of norms. Further, it has arguably resulted in the conception that children are 'becomings' rather than beings, incompetent, inadequate, emotional, and unstable on their single trajectory towards adulthood, which is by contrast complete, competent, adequate, rational and stable. But complicit in these labels is the Western ideal of the autonomous rational agent of liberal contract theory; competent in the sense of being capable of deciding whether to opt into the social order or social contract - an agent who exercises rational decisions in their own best interests (Mayall, 2002). This has led proponents of children's rights, feminists and sociologists to question the assumption that moral agency and citizenship rights require as a precondition that the person be independent and totally autonomous, an assumption which feminists claim derives from a specifically male experience of social relations which values competition and solitary achievement (Freeman, 1998). Moreover, as Mayall (2002) argues, while Western liberal thinkers regard the autonomous, independent, moral agent as the highest form of life, children themselves respect the principle of interdependence in human relationships, and dependency should not be a reason to be deprived of choice and respect.

Further, since Western liberal contract theory involves a rational man choosing in his own best interests, paternalism is only justified insofar as it acts as a 'substituted judgment', whereby we choose as we have reason to believe that the individual, if competent, would choose; that is, according to the individual's conception of the good, and not our own (Rawls, 1999). However, since within the confines of Western analytical philosophy the child is to be regarded as incompetent precisely because they have no conception of the good, such a hypothetical choice as choosing for the child as some imagined adult version of the child would choose for itself does not lead us to choose as the child would, since the child is comprised of their childish beliefs and desires. Subsequently, within the confines of the debate there is no alternative but to choose, as

adults, what is in the best interests of the child (Archard, 2002). It can further be argued that what 'is best' for any child is necessarily indeterminate, since we cannot, with certainty, make complete and accurate assessments of what will be the outcome of each and every option, as the BIP requires us to do. Buchanan and Brock (1989) note the qualifier 'best' and take this to indicate the complex and comparative nature of judgement. They summarise the principle as follows:

'The best interest principle instructs us to determine the net benefit for the patient of each option, assigning different weights to the options to reflect the relative importance of the various interests they further or thwart, then subtracting costs or "disbenefits" from the benefits for each option. The course of action to be followed, then, is the one with the greatest net benefit' (p123).

However, in order to agree on what course of action provides the greatest net benefit, we must attach values to the options and their outcomes for any choice, which assumes it is possible to objectively determine what is best for the child. The most commonly cited analogy to legitimate parental authority as outlined above is that of a fiduciary relation wherein parents have the authority and responsibility to make certain decisions for and about the child that are to serve their interests (Scott and Scott, 1995). In this analogy, parents are the trustees of their children's rights and interests, and while they may legitimately use their discretion in carrying out their duties (relatively) free from outside interference, these 'discretion rights' to use their best judgement to do their job are purely a function of undertaking their relevant fiduciary duties. That is, parents have limited rights to use their discretion free from outside interference but this is contingent on the parents fulfilling their obligations to promote the child's interests and protect the child's rights (Noggle, 2002). Subsequently, where parents do 'not unequivocally promote child well being', others are morally obliged to step in (Downie and Randall, 1997, p226). Legally, then this responsibility falls primarily to the parent/ legal guardian of the child, and second, the state in its role as *parens patriae*, if it can be shown that the child has been harmed, or is in danger of suffering serious harm (Kopelman, 1997).

In the *Journal of Medical Ethics* Hasman and Holm (2004) considered the fact that parents act in the best interests of their child on a number of occasions, some of which entail medical intervention. In line with other bioethical and legal discussion, they likewise assume that the vaccines are (at least potentially) capable of entirely blocking the effect of the drug, and that they will endure for a lifetime, or at least, a much extended period of time. They explore whether nicotine vaccination could be viewed in the same way as any other vaccination and conclude that it could not, because they consider the use of nicotine to be a lifestyle choice and not a disease, even if addiction to nicotine is considered a disease. While they argue that addiction can be regarded as a negative outcome of smoking, they also hold that it can be seen to contribute

positive benefits to health and social life. Consequently, they argue that it should be left up to the individual to assess and balance these factors and decide for themselves which option to follow. Their argument is then a direct application of the BIP; parents should assign weights to the available options (vaccinate vs. not vaccinate) to reflect the relative importance of the various interests they further or thwart. Since values must be attached to these options and their outcomes, and because parents are choosing on behalf of the child because they have no stable conception of the good through which they can assess the options and their outcomes themselves, they are morally entitled to use their discretion in assessing the options against their own conception of the good. Here, Hasman and Holm (2004) stipulate that the options and their outcomes are to be evaluated against a conception of the good which values health and social life. As regards health, they put forth the beneficial outcomes of the option not to vaccinate as the ability of the individual to derive the stimulant properties of nicotine, such as its appetite suppressing effects, and further the health benefits associated with nicotine aside from its stimulant properties, such as its use in the treatment of ulcerative colitis. From this they subtract the costs of a smoking outcome, which would be the possibility of addiction and the higher morbidity and mortality given the causal links established between smoking and lung cancer, emphysema and coronary disease. In reference to social life, the benefits of smoking put forward are its role in acting as a pause in a hectic daily life, and increased social interaction. The costs would presumably be the risk of the outcome of decreased social interaction, especially since it can be argued smoking is now socially devalued and stigmatised (Corrigan, 2004).

Given these possible benefits and costs of smoking, it is not clear why, when assessed against the stipulated values of health and social life, the positive aspects should override, or even come close to balancing, the negative outcomes, such that the option with the greatest net benefit would be that of smoking. Surely within this conception of the good for persons the weight of the negative outcomes on health greatly outweigh the positive outcomes; the use of nicotine as an appetite suppressant could be replaced by an alternate substance which did not have such negative outcomes, and even if it could not be, surely it would have to be shown that the risk of obesity through the lack of nicotine stimulation was greater than the risk of contracting cancer, coronary disease or emphysema through smoking. Further, Cerny and Cerny (2005) have argued that it is unlikely that a vaccination against nicotine would prevent the use of nicotine in the treatment of ulcerative colitis since the vaccination acts to block the molecule from entering the brain and it is still present in the body; but even if this were not so, the risk of contracting ulcerative colitis is much lower than the risk of contracting cancer, coronary disease or emphysema through smoking. While the option with the greatest net benefit may be less clear for social life, it can be argued that a child that has been vaccinated against nicotine could nonetheless smoke and participate in the social activities of smokers, thus deriving the positive social outcomes while

avoiding the negative health implications of addiction. In short, surely the strict application of the BIP, when framed within an objectivist view of morality which prioritises health as a cardinal virtue, can only rationally lead a parent acting in the best interests of their child to vaccinate them against nicotine. As Archard (2002) has argued, any objectivist interpretation of the BIP requires a universally accepted morality by which these options and their outcomes can be judged. Indeed, Thomas H. Murray (2004), the President of the prestigious bioethics institute, The Hastings Center, admits that if:

'[P]arents focus exclusively on the risks and benefits to health, the decision may seem obvious: use whatever interventions are available to prevent nicotine addiction... By attending only to the direct risks to health, ... parents leave out many other important factors, such as the possibility that struggles with their [child] over control will impair the growth of mutual trust and respect and may lead to rebellion and backlash. Or [the child] may choose another, more rapidly destructive means of declaring [their] independence from parental control... So, if as a framework the balance between risks and benefits is chosen, either all but a small subcategory of such risks and benefits must be set aside—those pertaining to health and safety—or the full range of relevant considerations must be acknowledged, deciding which ones are most important and weighing and balancing them' (Murray, 2004, p207).

7.3. KANTIAN IDEALS AND THE RIGHT OF THE CHILD TO AN OPEN FUTURE

The same interrelated principles as those underlying Buchanan and Brock's (1989) conception of (in)competence, the right to self-fulfilment and the right to self-determination, place limitations on parents rights to use their discretion in deciding what is in the best interests of the child. This is based on what Feinberg (1980) defines as the child's right to an 'open future': '… children are not legally capable of defending their own future interest against present infringement by their parents, so that task must be performed for them, usually by the state... This entails that interventions that foreclose important possibilities in the future are prima facie wrong' (p345). Feinberg's (1980) argument is founded on the 'perfectionist' or 'ideal' theory of the good for persons, which holds that some experiences or states of affairs may have a place in a person's good that is at least partly independent of any pleasure or happiness they will produce for that person, or whether they are personally desired (Brock, 1983). For Feinberg (1986) this ideal is autonomy and the right to self-determination is as fundamental as the right to self-fulfilment. For the mature adult, even if we could conclusively show that that individual was acting contrary to his/her own interests, we would still not be justified in interfering with their choice, providing only that they had voluntarily decided to act contrary to their own best interests. Although respect for the child's future autonomy often requires preventing free choice now, children are

also accorded 'rights-in-trust', subsumed under the title 'right to an open future', which are to be saved for the child until they are an adult but which can be violated in advance. These rights cannot be established against the child's present interests however since they concern the interests of the child *qua* adult. What the child's future interests will be is necessarily indeterminate and contestable. But for Feinberg and other adherents to liberalism there is one future interest that can subsume all the others: the child's interest in becoming an autonomous individual such that they can independently evaluate and choose as appropriate their own ends (Archard, 2002). Consequently, the parent cannot exercise choice on important or basic options in the child's life, but must keep these options open until the child becomes an adult and is in a position to choose among them according to their own conception of the good. In summary, the right of the parent to use their discretion in subjectively determining what is in the interests of the child *qua* child is limited by the objective interest the child *qua* adult has in becoming autonomous through having their important options kept open.

Feinberg's ideal conception of the 'good for persons' can be challenged by the two other major theories, the 'pleasure' or 'happiness' theory and the 'desire' theory, both of which derive the right to self-determination from the right to well-being, since in general individual's will know their own interests better than any other party and consequently are much more capable of directing their own affairs to the end of their own good (Callan, 2002). However, since both theories still maintain the value of autonomy, albeit only instrumentally as a means to the ultimate end value of well-being, it can be held that the recognition and enforcement of autonomy are causally necessary conditions for the achievement of well-being (Feinberg, 1980).

However a more pressing problem in applying the open future principle in any specific circumstance is that it makes impossible demands on parents. It stipulates only that it is in the interests of the child to one day become an autonomous agent, but there is no clear guidance as to what options are to be counted and discounted, and given the inescapable finitude of life it is impossible to keep all their options open (Mills, 2003). As such, Hasman and Holm (2004) argue that given vaccination's irreversibility, which precludes the option of the child to become someone who smokes 'with the purpose of achieving the neurobehavioural effects of nicotine' (p345) it clearly does limit the future options of the child. However, they argue that whether this constitutes a *significant* reduction of future choices will depend on personal values:

'Opinions are likely to differ on this question (and likely to mirror a priori held beliefs about whether smoking is a noxious habit or not), but it is important to note that smoking has a number of social functions, quite apart from the effects of the nicotine absorbed. For some it provides pauses and breathing spaces in a hectic daily life, for others it is an important part of group interactions. Active nicotine vaccination not only blocks the effects of nicotine, it also blocks the child from choosing to exploit the social functions of smoking' (p345).

Arguably, what is considered an important option will vary according to the socio-political context, which is one of the major criticisms of bioethics by sociologists. Principles of autonomy, beneficence, non-malificence and justice, derived from the paradigm of principlism on which bioethics is founded, promotes the myth of a common morality which is universalistic in scope and can supposedly be shared by all regardless of background (López, 2004). This is evident in the discourse of Miller and Klanica (2004) who argue that while no constitutional or common law right to use addictive substances exists, and such use may well be deemed illegal under law, individuals have constitutional and common law protections when it comes to others' attempts to interfere with their bodily integrity to circumvent addiction: 'When anyone seeks to impose therapy on another regardless of consent in the name of public health, protection of third parties, crime prevention purposes—or indeed in that person's own purported best interests—the law will respect the targeted individual's right to refuse treatment unless very strong societal interests are found to justify trumping that person's autonomy' (p277). Administering immunotherapy to a non-consenting adolescent then pits the autonomy interest of the minor against the parent's countervailing determination of that child's best interests. However, they conclude that:

'Given the speed with which cigarette smoking has fallen from grace as an acceptable social activity now that it and a wide variety of life-threatening and other illnesses have been scientifically linked, one can well envision the day (assuming a permanent vaccine becomes available) when childhood vaccination against nicotine addiction could be as routine as vaccination against measles. Whether vaccination against, for example, alcohol addiction could achieve similar "routine" status raises other issues altogether. Since childhood immunotherapy with relatively permanent effects might preclude adult choices about experiencing the pleasurable aspects of moderate alcohol intake, the legal, ethical, and political calculus about condoning parental authority in this area is less certain. The case for parent's authority to give consent for their children's immunotherapy, which has a more or less long-term impact on the children's ability to experience the chemical high produced by controlled substances, lies somewhere in between those two situations' (pp286-287).

However, while Hasman and Holm (2004) only interpret Feinberg's right as imposing negative duties on parents, such that only interventions which foreclose important opportunities are prima facie wrong, it has also been interpreted as imposing positive duties. Mills (2003) argues that this right of the child requires not only that parents do not intentionally isolate their children from other ways of life, but also that they positively 'open up' the future of the child, by exposing the child to as many activities and experiences as possible. On this basis she argues that such a right is undesirable since it would result in a life that was shallow, superficial and exhausting, and also that it is unfairly demanding since it requires parents to encourage their children to pursue all options, even those which are against their own core moral commitments. However, Lotz (2006) reads Feinberg's views on the state-child relationship as suggesting only a negative duty to permit

influences, rather than a positive one to provide influences. Nonetheless, if this were so she argues that there is a marked difference between ensuring exposure to a variety of ways of life, and ensuring experience. Lotz does not claim that there are no positive duties imposed by this right, but rather that it is better construed as a duty on parents 'to seek, within their capacity to provide adequate conditions for a child's emerging autonomy' (p546). Lotz argues that these adequate conditions relate to both 'agent-internal' and 'agent-external' autonomy conditions, where the former relates to the development of competency and authenticity, whereby the child is enabled to develop reflexive attitudes that will allow them to identify with and endorse or repudiate their own desires, values, and motives. The latter refer to aspects of the child's environmental context, such as the provision of a range of feasible and valuable options, but not maximisation of the total number. Of most importance here is the duty of the parent to help in creating the inner capacities required for the conduct of an autonomous life, which can be helpfully understood by reference to Schapiro's (1999) explanation of the 'moral predicament' of the child, based on Rawl's (1999) interpretation of Kantian ethics.

In Kantianism each person is a sovereign authority whose consent is not to be bypassed, hence the 'Kingdom of Ends' ought, for moral purposes, to be populated only by adults since the collective order depends on each person being an autonomous agent with the authority to make up their own mind and cast their own vote on practical matters. We are to respect others as choosers even if we disapprove of the choices they make and there is no general permission to make other people's choices for them simply because they are not likely to choose well on their own. However, for Kant, humans are distinguished from animals by the separation of the subject from their instinct. Humans possess the capacity to reflect on their instinctive desires and to act in opposition to them: 'both by developing desires for objects that are not objects for him by instinct and by restraining his impulse to gratify his desires in general' (Schapiro, 1999, p722). This gives rise to a distinctively human problem; that of working out a substitute for nature's plan, since the subject must choose how to regulate their will according to the now potentially infinite set of desirable objects. In order to do this the individual must resolve the conflicts among their various motivational impulses, such that the outcome expresses their will and capacity for reflective choice. This can only be so if one's volitional laws are already in place, such that one is already governed by a certain constitution with, 'a unified, regulative perspective which counts as the expression of her will' (p729). Since children lack this, they are not as yet in a position to resolve this problem: to act on reasons of their own. Accordingly, children are regarded as lacking the independence required for active citizenship and are treated instead as passive citizens, and subsequently are not entitled to the full range of liberties normally associated with citizenship, such as the right to vote.

Thus from a Kantian point of view childhood is a normative predicament: paternalism is *prima facie* wrong as it involves the bypassing of another's will, but if the being who is bypassed does not really 'have' a will yet, if they are still internally dependent upon alien forces to determine what they do and say, then the objection loses its force (Schapiro, 1999). This is not taken to imply that in order to be a developed agent one must have worked out principles for dealing with every matter one might come across, but rather that there is a limited domain of essential questions, the answers to which determine the individual's 'basic structure' as a person (p730). This must determine where the impulse to pursue any particular desired object stands, relative to the impulse to pursue others, since for Kant, it is the ordering of these impulses which determines the fundamental value of a person's character. As Schapiro (1999) argues, the status of children as one of 'normative immaturity' should then be treated by adults as non-ideal; as a temporary deviation from the norm of active citizenship and hence one that should be overcome, since it acts as an obstacle to morality. This can be achieved by allowing children to progress through childhood via 'domains of discretion' (p733), whereby allowing them to make decisions about matters in one domain of their life will tend to commit them to principles which have implications in another. In this sense Schapiro argues that reason is expansionist, since in achieving hegemony over a limited jurisdiction, it claims at least provisional authority over some of the constitutionally essential domains but not over others.

As children succeed in exercising their own authority over simple matters the domains of discretion can be expanded and new ones added. Allowing children to exercise their own autonomy through domains of discretion is not merely an aid to autonomy but a principle of what Schapiro (1999) terms Kantian nonideal theory, which holds that in order not to abuse our privilege as adults, we must make children's dependence our enemy. On this basis it could be argued that in permanently asserting their values over the child, they condemn them to eternal subjugation to their authority and abuse their privilege as an adult, by making the transient non-ideal status of childhood everlasting. Arguably then, from this perspective, vaccination against addiction could not be taken as a parental right since '… our end as adults cannot be to control children; it must be to make them free to control themselves' (Schapiro, 1999, p736). However, so too can it be argued that addiction is a progressive brain disease with associated decisional impairments, such that users mechanistically become addicts, who are the archetype of the non-autonomous person (Charland, 2002; Cohen, 2002). Thus where the biomedical paradigm of addiction is based on the dualism of autonomy and subjugation (Gomart, 2002), if the right of the parent to use their discretion in subjectively determining what is in the interests of the child *qua* child is limited by the objective interest the child *qua* adult has in becoming autonomous, then surely vaccinating the child against addiction can be put forth as contributing to their future right to self-determination, and not as foreclosing important options.

Murray (2004) concludes that the concept of the child's right to an open future gives wide discretion to parents' judgments about how best to prepare their child for adult life, but it does not leave unlimited discretion and 'it should be anticipated that some, perhaps many, parents will seek to use certain interventions in the belief that they will protect their children against substance abuse, sparking a broad and heartfelt debate over the nature and limits of good parenting' (p210). Moreover, the fiduciary analogy has been criticised for couching parental authority in terms of rights and duties which is argued by some to be an inappropriate expression of the motivation of parents for carrying out the various activities of parenthood. Rather, it reflects the dominant motif of Western liberal theory, since it promulgates notions of contracts and conflict between autonomous individuals, downplaying the value of interdependence in human relationships (Mayall, 2002). Schoeman (1980, 1983) emphasises that parenthood has special value in itself, and not merely as a means to care for and protect children. Downie and Randall (1997) argue that the parent-child relationship should rather be seen as an 'intimate relationship' wherein people find meaning in their lives, where rights are held against the state, which might otherwise interfere with these intimate relationships and which can only prosper under conditions of privacy. However, this too can be criticised, for furthering a different yet equally universalising conception of the parent-child relationship as one based on love and privacy, based on the currently dominant conception of childhood as that promulgated by Rousseau ([1762] 2007) in *Emile*, where children are angelic, untainted by the world, and a source of all that is best in human nature such that their natural virtues and dispositions need only be encouraged, enabled and facilitated into the open.

However, to date there has been no encouragement of this debate by public health officials with the power to influence patterns of use through either restricting access to some or all of the vaccinations, for example through the FDA or the EMEA, or by encouraging their use, for example by offering them through the NHS in the UK or by subsidising them or requiring insurers to cover their cost in the US. In keeping with the dominance of professional expertise in bioethical discourse, there has been little attempt to empirically assess the likelihood of parental demand for vaccines for addiction. As such, this chapter will now examine the way the parent-child relationship is constructed by key groups, and the assumptions and ideologies that underpin these. It will focus especially on the focus groups conducted in the UK with participants recruited as parents with children under 2 years old, although it will also draw on data from the other focus groups conducted with social cocaine users, cocaine users in treatment and smokers, where they also considered the option of vaccination in relation to their own children. It will also draw on 'expert' discourses in the UK and the US, where interview participants discussed their perceptions towards vaccinating their own/ others children specifically in regard to the best interests of the individual child.

7.4. SOCIAL BONDS AND HERD IMMUNITY

The vast majority of parents, taken from across the UK focus groups, were highly critical of the preventative use of the vaccines for cocaine or nicotine for their own child, because they were seen as curtailing the child's future autonomy, which did not fit with dominant notions of what it was to be a 'good' parent. In line with Mackenzie's (1990) 'certainty trough', parents did not tend to challenge the construction of the vaccines as completely blocking drug effects or its very long-term duration, as it was presented to them through newspaper articles and other materials. However, when alternate presentations of its likely temporality were presented to them, although their perceptions were less critical, the vast majority still resisted the medicalisation of drug use, constructing the option to use drugs as enabling the development of the child's autonomy. By contrast, the perspectives of parents drawn from the focus groups with drug users in treatment tended to overlap substantially with the minority of experts who portrayed MCI for nicotine as 'keeping options open' for the child, rather than foreclosing them. As these participants formed a clear subset of views, they will be discussed largely separately, under 'the proximity of risk and the situated nature of autonomy'.

All of the parents in the focus groups stated they had taken all their children for the full range of vaccinations recommended by the NHS, including the MMR, and did not tend to offer searching reflections as to why they had taken their children for vaccination, but constructed accounts whereby it was the 'normal' thing to do for the wellbeing of the child.

F2: 'Same for me actually like you at the time it was all this big MMR fuss especially with my son the eldest one but my sister-in-law's a GP and it was well I think I would have done anyway but it was recommended that I did it because the risk of them actually getting the measles was much greater than them actually getting any side-effects of having the actual injection
F3: That's what I did as well it's that weighing up isn't it I just thought as a parent I'd be much more upset in myself if my child then developed one of those diseases than just if something went wrong through giving the vaccination' (parents, S1/G1).

F6: 'I'd rather she had the injections than got the illnesses didn't give it much thought really
F7: Yeah for us it just felt like it was the recommended thing to do and so we did it really
F8: Yeah I think it never crossed my mind really not having cause I know well I think my knowledge if you don't have the vaccines and you get the illness as you're older it's stronger so we decided' (parents, 1/2).

This is in keeping with Streefland *et al*'s (1999) findings that large-scale acceptance and compliance with vaccination schedules are the collective result of individual decisions by interdependent users:

'People have their children vaccinated because everybody does so and it seems the normal thing to do. There are not necessarily deep reflections behind mothers taking their infants to the child health clinic. They do so because everyone else does, and because it is what good mothers seem to do. Taking their

children for vaccinations has become their habitus. And unless adverse effects or rumours about "bad" vaccines intervene, each collective visit to a vaccination session will reinforce the notion of normality. In this sense, all vaccination users are interdependent, as they support and are supported by each others' decisions' (p1712).

Parents across all groups also frequently reported a sense of obligation to others and the importance of herd immunity as a public good when deciding whether to vaccinate and were quite critical of those who did not vaccinate healthy children, similar to the findings by Skea *et al* (2008) in online discussion forums who noted a feeling of social responsibility was an important factor in the decision to vaccinate. Importantly this was not found to apply in the case of vaccines for addiction, since the implicit analogy to infectious disease was rejected.

F4: 'Also for me I felt that if my child hadn't had them and passed them onto children that weren't able to have them the MMR like my nephew's only like 20 months so he hasn't had all of this yet and my child gave another child who couldn't have the MMR measles that I would feel bad about so that was another reason for me to have them done' (parents, S1/G1).

F19: 'Plus with things like this I suppose it's only that one child whereas the thing with protecting your child against say measles I think it's for instance some parents haven't had their children have the MMR and now there's going to be a big increase in measles em but it's you know for instance I teach so I could go into school and could be a child there who hasn't been immunised against it and then I could carry the disease well the virus and [name of child] could get that from me and that could kill a young baby in theory so that's really irresponsible I think erm whereas this isn't effecting well I suppose people could say it could affect wider society but nah I think we're all in agreement about that [all agree]' (social cocaine user, S3/G1).

This parallels the debates highlighted in the previous chapter. Since the majority of expert and lay participants rejected the implicit infectious disease metaphor, the legitimate grounds for the state to intervene to mandate or promote widespread vaccination against addiction were seen as much reduced. Whilst in the context of infectious disease parents were critical of those who decided not to vaccinate their children, the concept of a 'social' form of herd immunity was not taken as sufficient to imply a moral obligation to vaccinate children against addiction.

7.5. RECREATIONAL DRUG USE AND NOTIONS OF THE 'GOOD' PARENT

As Streefland *et al* (1999) note, the perceived risk of a child getting an immunisable disease can contribute to vaccine acceptance, and the perceived risk of vaccinations being detrimental to health or having negative side-effects can lead to non-acceptance. These perceptions of risk were situational and dependent on the personal narratives of the parents. Where parents were also current smokers, smoking was generally portrayed as either a positive experience for a child, or

an unimportant aspect of life where the threat of addiction did not justify the curtailment of the autonomy of the child.

F17: 'My mum always smoked round me she were annoyed once I started smoking but then she were fine I used to sit and smoke with her in fact I think she used to encourage me to smoke more cause she were bored and I used to stay up with her and smoke and pretty much how I were brought up I would bring my child up if she started smoking I'd speak to her about it but then it's her choice ...so if she wants to smoke she can smoke I'm not bothered like that I mean I were never told not to so I'm not gonna do the same to her' (smoker, S2/G2).

F15: 'My parents were always really strict on smoking my dad hated it he went absolutely schitz, bonkers the lot I couldn't smoke in front of me dad for years I wouldn't be as bad as me dad was with C. I wouldn't be over the moon I wouldn't be happy she started smoking I probably wouldn't be as bad as me dad over it and I wouldn't I mean I'd like her not to but at end of the day it's a decision she can make at the end of the day it's up to her really' (smoker, S2/G2).

F3: 'The chances are one or both will at least experiment with smoking at some time which I'll be happy with but I'll always tell them that I would rather they didn't, you know, talk to them about it' (parent, S1/G1).

Where parents also defined themselves as social drug users, recreational illicit drug use was portrayed as a positive experience for a child, where again their personal distance from problematic drug use or addiction did not justify restricting the child's options for enjoyment.

F1: 'I would be quite happy for my children to experiment and learn from those experiences and believe that everything in moderation is acceptable however if they developed serious problems which is obviously a consequence of experimentation I would have a problem with that but I'd be quite happy for them to try anything well not anything but you know try and have the choice basically, you know all these nasty substances are fun (laughs) you know its if you've got a strong mind I think you can overcome the sense of addiction and you know it depends what kind of person you are' (parent, S1/G1).

F2: 'Recreational drug use I'd be happy in a way (laughs) for my children to try them and experiment with them like I did, of course if it became a problem which is a consequence I wouldn't like it but I'd hopefully deal with it' (parent, S1/G1).

F2 however was also the one parent who was also an ex-smoker, and was conversely initially positive towards protective nicotine vaccination:

F2: 'I'm going to be the one in the room that says a part of me agrees with it and I'm an ex-smoker, I just think you know it is killing loads of people I wish I'd never started smoking I wish I'd never never ever didn't love it as much as I do now you know if someone could of said to me you know they'd take that all away I mean your right it's freedom of choice isn't it but I don't know it's not a good choice is it?' (parent, S1/G1).

However, F2 did later argue that:

F2: 'Although I've said all along I wouldn't have minded if somebody could've given it to me to stop me from feeling like I do now I don't know if I could do that to my children, I've almost accepted in my mind that at least one of my children will and I've actually said to them I think that probably one day you will smoke never hide it from me I think you'd be mad to do it but I won't be devastated because how can I be you know it's all part of learning and its part of life' (parent, S1/G1).

For F2, although addiction to nicotine was regarded as a great burden, and she did view her child as at high risk of smoking, nonetheless, the choice to experiment with smoking was still depicted as a key aspect of adolescence. The view that the *choice* to use drugs was important to adolescence, even where the decision to do so was not regarded positively, was the dominant rhetoric across the rest of the groups with parents, and was applied equally in relation to both smoking and illicit drug use:

F3: 'I'll have to learn more about the risks of all other kinds of drug use because I've never really done other drugs and I don't mind them doing drugs recreationally but I do want them to know the risks' (parent, S1/G1).

F6: 'Just taking away all the good things in life that people enjoy isn't it, you know having a smoke a drink or I mean I personally don't take any drugs but you know people wanna go to a party and take some I don't know cocaine or whatever
F5: Even if it's your daughter
F6: Well, I'd hope that she'd grow up and wouldn't take drugs but that's got to be her choice in the end hasn't it if she smokes or drinks or
F7: But if you could make that choice for her now would you do it
F6: No, I worry about stuff like that but I don't want to wrap her up in cotton wool and keep her at home all the time and not let her explore a little bit probably not want to know about it but if you just have a little bit of fun you know try something then doesn't mean you're going to be an addict and it might mean that she in't gonna like it so at least she's had a go you know' (parents, S1/G2).

Across all the focus groups conducted with parents, smokers and social drug users, participants rejected the dominant construction of addiction as more damaging than the infectious diseases against which children are currently vaccinated (cf. Nutt and Lingford-Hughes, 2004). Although many argued that they could see the advantages in vaccination as an opportunity to protect the child from harm later on, in line with Hasman's (2007) position, they argued that there was an important difference between vaccines for addiction and vaccines for infectious diseases like measles or rubella. Using a substance for recreational purposes was not perceived the same as having a disease, regardless of whether addiction to that substance was considered a disease, and use itself was not considered to lead mechanistically to addiction. The fiduciary analogy of parental control was rejected by these participants, who constructed accounts of parenthood based on mutual respect and understanding in a nurturing environment, not on rights and duties. As Murray (2004) has detailed, within this context, actions are defensible to the degree to which they create or support conditions conducive to the family flourishing and to the values central to family life, both those values intrinsic to healthy families, such as love, loyalty, steadfastness, and forgiveness, and those values made possible by such families, such as emotional resiliency and the capacity for enduring relationships. Crucial to this was that participants felt that the choice whether or not to use drugs was a key domain of discretion; important to identity formation through learning restraint and responsibility, and important in establishing the child's orientation to the wider world and external influences, and constructing boundaries between the child and adult.

F6: 'You can't decide who they're going to be just have to let them grow up have to let go don't you' (parent, S1/G2).

F1: 'To me it's to do with parenting and knowledge and for me it's up to the parent to give the child the choice and by giving these injections you're not giving the child a choice' (parent, S1/G1).

F2: 'I wouldn't want to stifle my children's personality em I wouldn't want to stop giving them the choices that I had be them right be them wrong they're people erm so no I wouldn't give it to my children' (parent, S1/G1).

F5: 'I suppose it would I suppose you might consider giving them it before they get to an age where you think that they're wise enough to make their own choices well after that you wouldn't legally be allowed to give them it anyway I suppose if it's at least if it was something like that you'd only be giving them it while they were in your care whereas if you gave them something that lasted their whole life you'd be giving essentially you'd be giving it to them as an adult as well and even when they're in their 50s they're still living with that choice that you've made sort of thing' (parent, S1/G2).

Hasman (2007) bases his rejection of prophylactic vaccination on virtue ethics, arguing that 'parental (prophylactic or therapeutic) uses of drug vaccines would obstruct the opportunity of children to exercise virtue in resisting the temptation of drugs both now and later in life... [and] would potentially impede their moral development and would be an injustice' (p824). A similar argument was constructed by these participants, where vaccination against drugs was seen to impede the ability of the child to exercise virtue, but it was also extended to reflect the role of the parent, who would likewise lose the ability to be 'good' parent, by imparting the values by which their children would be able to use drugs responsibly should they choose to do so in later life.

F20: 'Hopefully you will install good morals and ethics within your children yourself you know that Ok if they're gonna do drugs then they'll do them in a responsible way
F19: Just like you do with alcohol
F20: That's right yeah' (social cocaine users, S3/G1).

F5: 'I just think if we just give her loads of support and loads of love and she knows we're here for her all the time then she'll be able to make good judgments herself and make good decisions cause that's how she'll been raised sort of thing' (parent, S1/G1).

F14: 'Just tell them the facts and then it's their choice you can't do anything more cause if you do start pinning them down saying no you can't do this you can't do that like I know from personal experience when my mum's told me not to do something and I've just done it because end of day I wanted to do something that I wanted to do' (smoker, S2/G2).

Where this failed, and children faced problems with addiction, parents should be able to 'guide' their children back from addiction and 'be there' for them.

F17: 'I think if your strict on em they go through more I do just leave em to make their own choices their own decisions if they fail then your there to help em after
F15: They're more likely to come to you if they've got any issues' (smokers, S2/G2).

F3: 'I wouldn't give it to my children and I would just hope that as a parent I could just work through any issues and again as an adult if they ended up in that situation they could have it as a last resort …Because I don't agree with taking away the choice I think sometimes addictions can have positive as well as negative effects so' (parent, S1/G1).

F6: 'The last thing you want to do I suppose if your child did come home with an addiction one day is push them away from you that's the main thing isn't it, you want to be there to support them no matter what they've done or what they become' (parent, S1/G2).

Notions of what it was to be a 'good' parent were thus based around the centrality of the worth of autonomy to the child *qua* adult, and thus the temporality of parental control and the relinquishing of direct parental authority at the age of majority. Parental control or guidance should then be more or less indirect, cognitive and environmental, rather than biological and direct. This overlaps considerably with what Scully, Banks and Shakespeare (2006) found in a study with lay participants on prenatal sex selection; that the underlying ideal of the 'good parent' features the relinquishing of (direct) control over their children.

F7: 'Yeah and you as a parent want to do the right thing for your child but you also have to consider the fact that they have to learn and make the choices for themselves and if it was used as a treatment then if somebody did become addicted they could I think it'd be better in that way rather than just the parent deciding what life the child is going to lead I think
F8: Yeah I agree with that I thought it was just before you become addicted and then it not work but if it works as a treatment I think there will be lots more benefits much more using it that way than restricting the kids from little to choices in life' (parents, S1/G2).

Again, parents tended to emphasis the potential unanticipated consequences of vaccination, and place this within a framework which questioned the need or desirability of such a technology (Marris *et al*, 2001). As Streefland *et al* (1999) have argued, where parental non-acceptance of a vaccine is based on a questioning of the need for vaccination, collective non-acceptance may go beyond the sum of individual refusals and become collective resistance, and many lay participants argued that it shouldn't be left up to individual parents to decide for their own children, since this could end up increasing social inequality and would place undue pressure on parents, giving them 'another thing to panic about'.

F15: 'It's just giving people another thing to worry about another thing to panic about and there's too much scaremongering going on as it is about you know what I mean you can't do this eat lots of this sort of berry and drink lots of this and ooh don't touch that you might get liver disease and so on you know what I mean don't have too much of this don't have too much of that and you can't live like that that's not what life's about at the end of the day' (smoker, S2/G2)

Further, they argued that it if was offered it would slowly become a normality, and the weight of the opinion of the public health profession and other parents would make it increasingly difficult for parents to 'opt out' of getting their child vaccinated against addiction, even if they opposed it in principle. This is similar to the findings of Hobson-West (2007), who has argued that from a governmentality perspective, even where there is no overt pressure to vaccinate, the individual is still subjected to the 'moral imperative of vaccination'.

F3: 'I dunno I think a lot of them would opt to just give it to a baby without a second thought
F1: If it became common as in as common as the measles mumps and rubella, let's just say I think most people would probably opt in it depends on what the common sway is I think … If it's you know I do

think its if everybody else does then that's what people do it's unusual for people to say no I'm not going for these injections because of x, y, and z, I think I know one person in the whole world whose children hasn't had these injection erm because of personal choice you know and I don't know how seriously they thought about it... It will become a normality where everyone has these injections but I'm not sure it's a wise thing I don't know I mean it takes away an element of adulthood in some ways' (parents, S1/G1).

F5: 'Think there'd be a lot of controversy about it probably for quite a few years I think people would use it but I think it would take a long before it was used without any sort of you know considered something normal to do I think the controversy would last a long time
F6: I think people would start doing it out of habit because they'd be frightened if they didn't do it if the child ended up with an addiction then it'd be all their fault
F5: Yeah
F6: You know and then you'd have to live with that horrible guilt that you were the one parent that didn't give your child that vaccine so everybody would probably end up having it and then everybody becomes the same
F5: Yeah they'd probably be a lot of peer pressure on the parents [all agree] depending on the social groups and things that they hang around in
F7: Yeah culturally if it was an acceptable thing to do and you chose not to do it then I imagine that would be a bad thing and you'd probably end up giving it just because everybody else did you know cause it would be on their medical records and then they'd be like oh that's the child that didn't have the jab he'll be an addict [laughing] trouble in school and stuff I do think that that would happen and I don't know whether there'd be that much controversy because there's a high population who really would go for it I do I really do a lot of the religious erm groups I'm sure would be very pro this kind of drug cause they think a choice that you make to take a drug is a choice deemed by the devil and all that stuff and I think err there'd be a lot of support for it' (parents, S1/G2).

As such, many participants argued that there should be a debate and collective decision taken by society as a whole before it was used prophylactically, and not left up to individual parents to decide:

F19: 'It shouldn't be their [parents] decision because it's like society takes the decision with certain things but then you're giving that choice to the parent and yes obviously as a parent you make decisions for your child but I think that's quite a I think as a society we would need to decide whether or not that was going to be something we wanted or not' (social cocaine user, S3/G1).

7.6. THE PROXIMITY OF RISK AND THE SITUATED NATURE OF AUTONOMY

Across these focus groups, participants self-consciously constructed their stances as situated, and stressed that they may well think differently if they themselves or someone close to them had experienced severe problems from addiction, at which point the desire to avert danger to the child through the use of the vaccine may well be considered.

F5: 'If you smoked 40 cigs a day and your partner did as well and you had a kid then statistically they've got a really huge chance of becoming a smoker so in that situation if you had bad health as a result of it you might think do I really want my child to live like this as well' (parent, S1/G2).

F7: 'But sometimes you can't you know I'm just thinking of my cousin he's er a heroin addict and he has been for about 5 years and he's tried to come off it lots and lots of times and his parents have been there so much and they've brought him up just the same as my cousin who's a really successful

business man given him the same love everything the same and why does he end up as a drug addict and the other one not and now he has really bad voices and he really struggles with that and you know maybe if they knew that he was gonna be a drug addict they might have wanted to give him that the vaccine I don't know it's a bit difficult maybe ask some people that have really experienced it and they might give you some really different answers I think' (parent, S1/G2).

F4: 'If your child got absolutely off her trolley at 10 years old and you know drinking too much and smoking too much
F1: We'd all have a different attitude
F4: Yeah we would
F1: We'd be saying yes please we'll have this now yeah... I don't know we're probably the wrong set of parents to ask!' (parents, S1/G1.)

F1: 'I find it quite interesting that its only for nicotine and cocaine because for me I think alcohol is a much more needed vaccine em coming from a family of alcoholics basically you know it can destroy people and it costs the NHS millions and I don't know if they're in the process of doing that but that would be something I'd think a lot more about than you know cocaine although I've tried it on very many numerous occasions it's not something that I would ever think this is something I'm going to become addicted to like a lot of class A you know it's something that you do in your recreational time and enjoy I wouldn't want to take that enjoyment away from my children' (parent, S1/G1).

Indeed, a vaccination for alcohol was raised as a topic by many participants as deserving of more serious consideration than vaccines for either nicotine or cocaine, based on their personal experience with alcoholism, and the seriousness of the problems they believed it caused.

In contrast, although widespread rejection of prophylactic vaccination for cocaine was the dominant parental position, the discourses constructed in the focus groups conducted with drug users in a residential rehabilitation centre were a notable exception. Across these groups the majority of participants argued in favour of vaccinating their children against cocaine or heroin, as a means of averting a potential danger to the child in the same way as traditional vaccines, overlapping considerably with the minority of experts in favour of MCI for nicotine discussed in the previous chapter. Although they highlighted personal choice in initiating drug use as key to exposing the individual to the risk of addiction, addiction itself was constructed as a biological process beyond the control of the individual. Embedded within dominant biomedical models of addiction of subjugation, addiction was then often portrayed as a disease 'you cause yourself' (F29, S4/G1).

F33: 'Addiction is a disease it can happen to anybody but usually it happens to what I'd call a weaker link, people who have got long term problems things that they've had in their heads since they were children' (drug user in treatment, S4/G2).

F36: 'I see disease as like a cancer which is spreadable and addiction can be passed onto others, like your circle that you're with. You may not you know set out to be an addict but the circle that you're in, but you know it can easily then that next person can be an addict as well so it's spreadable' (drug user in treatment, S4/G2).

However, whereas across the groups with smokers, social cocaine users and parents, drug use was often defined positively, as emphasised in Chapter 4, in these groups it was described almost exclusively in negative terms. As such, for the majority of these participants, the high incidence of

drug use by family members, partners, friends and associates tended to marginalise the freedom of the neo-liberal individual, such that drug use was not typically put forward as an active choice, but constructed more as the default option, where autonomy was already constrained. Consequently, the majority of participants in these groups said they would vaccinate their children to prevent them from going through what they had, and to prevent them from causing the harm they believed they themselves had. Prophylactic vaccination was not seen as foreclosing important opportunities or choices, but as a means of preventing a constraint on autonomy; not as infringing freedom of choice, but as providing their children with the opportunity to avoid falling into drug use and open up their future lives.

F35: 'Mmmm if it was tried and tested yeah and I knew it for a fact especially with my sons and the environment that they're in cause Glasgow's like drug city man, Glasgow city's just saturated with drugs and most of the kids are all starting to do it now and they're even wilder that what we were when we were growing up know what I mean they're getting ruthless now they're getting fucking, so if I knew for a fact it would be I would do it to my kids yeah definitely' (drug user in treatment, S4/G2).

F32: 'If they give them out at birth when kids are babies and that then I would've done mine yeah, cause I wouldn't want no child of mine to go through what I went through do you know what I mean, whether they went through it through choice or they ended up where I ended up through accident in inverted commas, you know accident, so yeah if I had chance of saying yes then I would've done yeah' (drug user in treatment, S4/G2).

Only F31 objected on moral grounds, rejecting prophylactic vaccination on the grounds that it restricted the autonomy of the child, in line with the dominant talk in the other focus groups:

F31: 'No way no… Because it's taking their choice away again it's always down to you whether we were made to ave choices and takin that choice away from a kid or anyone is wrong d'ya know what I mean you go through things in life because you're supposed to go through all the choices you make not I just think it would be wrong just to if they became heroin addicts or crack addicts or whatever they'd have to go through that to they'd go through that fer a reason d'you know what I mean I don't know what reason that is I can't comprehend what reason they'd go through that for but I don't know I just think it's no you should always have a choice' (drug user in treatment, S4/G2).

7.7. ADOLESCENT REBELLION AND THE TEMPORALITY OF THE VACCINES

As seen in Chapter 6, by emphasising the limited duration of the vaccine, the minority of experts who were in favour of MCI for nicotine addiction deflected the construction of the vaccine as potentially infringing on individual liberty, since the vaccinations could be stopped at adulthood, with the likely depletion of antibodies within a year. Consequently, vaccines were portrayed as protecting the child, either through adolescence or from birth, by protecting the developing brain, such that at the age of majority they would have the necessary competencies to act

autonomously to make the 'right' decision. Further, these participants suggested public health strategies that encouraged the parent to assert their fiduciary rights over the child:

US12: 'I would target the parents the kids aren't going to come kids that age are immortal there's no way to make something like that real but I think you might be able to target the parents I don't see I don't anticipate the kids would have some strong objection to getting vaccinated I guess you don't know until you ask but that's sort of out of my expertise' (Professor of Pharmacology and Medicine involved in development of active nicotine vaccine).

However, it can be argued that all vaccination is better conceptualised as a process rather than a one-off decision, with parents asked to bring their children into the clinic a number of times from 2 months. As Stevenson *et al* (2002) have found, context is important and ongoing consent and collaboration is based on many, sometimes conflicting social and historical factors, such as past experience of other vaccines or health services and day-to-day concerns about the child's welfare. Given the projected need for booster shots every 6-12 months throughout life to maintain peak levels of antibodies, if children were to be vaccinated during their teenage years, this would be predicated on the assumption that parents were willing and able to bring their children into the clinic 1-2 times a year for a booster shot. While delaying use was often viewed as important by other expert and lay participants, a coerced technical fix was not posited as likely to be effective or desirable. Although the law presumes that children under the age of 14 lack the capacity to give meaningful consent to medical treatment, for minors between the ages of 14 and 18 the legal situation is more complicated as it is generally accepted they should become more involved in decisions about their own health care, especially where their assent to treatment will be essential to accomplish any therapy that requires their co-operation.

By bringing individual freedom into the foreground, the likely efficaciousness of vaccination was evaluated very differently by the majority of expert and lay participants who argued that even a short term vaccination during adolescence without the full consent of the child would result in an increase of potential harms to the child if they attempted to circumvent the vaccination through 'normal' acts of adolescent rebellion.

US25: 'What you may be doing if you immunise your child is inadvertently developing someone with a very, very expensive drug habit because they're gonna have to take so much of the drug to get an effect, because they naturally may want to experiment as they get, you know, to be teenagers or whatever. Erm and so you know are they now starting to deal themselves to get the money and... you know create, you know, engaging in crime etc to get the money and you know that maybe... they may be making things worse rather than better. I... I think there's better ways to you know try to prevent your children from using drugs other than just immunising them in the hope that this will protect them … You know they... they would sort... you know not be a losing game to just do you know widespread immunisation without informed consent' (Behavioural Neurochemist & Psychopharmacologist involved in animal models of active cocaine vaccine).

Further, a significant number of parents argued that adolescent rebellion, which often included experimentation with smoking and drugs, was crucial in developing maturity and a sense of

personal responsibility. Where parental control was physically extended over the ability of the child to experience the effects of desired drugs in the present, it was seen to merely postpone adolescence, rather than circumvent it. Further, in so doing, it was considered as more harmful, both because the child would have more financial resources in later life, and the parent would be less able to guide them once they had left the family home:

F4: 'I think one of the problems is that you experiment as a teenager don't you, so how many teenagers that didn't have this would be experimenting in their 20s...
F3: Postpone adolescence
F1: I think that if you put in any age limit its gonna increase its appeal to right we're gonna stop this when your 19 or 25 or 30 or you know you're just gonna go well I can do that when I'm thirty' (parents, S1/G1).

F7: 'Some children are given absolutely no realms for exploration are they and they have to do what their parents do up until they leave home and
F6: Then they go mad they do everything
F7: Yeah yeah
F6: Just rebel
F7: Yeah
F6: Think that's where you've got to be really careful haven't you like if you did have something like that and you were protective over your child till they reached 18 there's only so much you can do then when they've left home and doing their own thing' (parents, S1/G2).

For the vast majority of parents the depiction of the child as globally incompetent with regard to making decisions concerning their own life was clearly contested, rather parents were more likely to align with Noggle's (2002) position that parental authority can be argued to extend after children have acquired the cognitive capacity to assert their own rights because they lack important aspects of moral agency; they are not as yet ready to relate to the community of moral agents in quite the same way as adults. Specifically, children are seen to lack temporally extended agency, which allows a person to pursue a set of goals that remain fairly stable over time and provide for both their short and long term interests and goals:

'Temporally extended agents see the goals and projects of their future selves as their own goals and projects; they see their future happiness and pain as their own. They identify with their future selves' (Noggle, 2002, pp101-2).

Consequently many participants argued that parents should force the child to keep their future options open through not allowing them to have the vaccine, even where the child assented, until the parent was convinced the child had formed a temporally stable position with regard to their future selves that they identified as their own. Often this was based on a 'try before you buy' position, whereby parents felt that unless the child had actually tried the substance, they couldn't be certain that it wouldn't have a role to play in their future lives.

F4: 'Would you not like to get them to an age where you could have a discussion about it instead of giving it from birth say look we can do this if you're interested
F3: Absolutely
F2: Yeah
F1: I don't know I mean what age are we talking here cause I mean how old should children be to decide that because that's basically saying that cause I think they should basically be allowed to try before they decide you know it's like saying I'm never going to have sex ever again and how do you know before you even know really what you're talking about it's
F3: Well I know that if someone would have said to me like my Mum had've ever talked to me about it when I was 12 or so about smoking at that point I was so disinterested I would probably of just said oh yeah Ok I'll have it signed a form saying I'll have it but then of course much older age I started to smoke because I was in my 20's and I don't regret it I still do have a few cigarettes a day I don't regret it I'm fine with that so I would have I wouldn't have known I'd missed out on something but I think I would
F2: That's the key though you wouldn't have known would you see I'm different to you I can't have one or two I don't know
F1: Still you know it's basically saying you're allowing your child the choice but they don't know what they're choosing that's you know at that age
F3: They'd have to be a lot older wouldn't they
F2: And of course they're going to say ooh I don't want ever to do it because they're going to say that as children
F3: Absolutely yeah'(parents, S1/G1).

F7: 'Yeah I think for me if you could give it them at 14 15 you could discuss with them then it could be a choice that was made between all of you based on real reasons that they could appreciate and understand whereas when they're 18 months it's completely the parent's choice and you know if they've got friends that are really into drugs and they don't want to it might be something that they choose to do and so it's almost like when you give alcohol to your kids for the first time it's a choice on your part and theirs for drinking it so I think that's a more interesting angle on it
F6: Yeah
F5: But if they get to the age where there's a lot of drugs around them there's a chance they'll formed some sort of ideas on their own about whether it's something their interested in or not' (parents, S1/G2).

F8: 'I think it's erm a good idea to make the vaccine but to use it more as a treatment than 18 months old give it to your kid and cut that choice of experimenting in life because they will find different things that will become available if stop cocaine and cigarettes and heroin so I think I won't give it to S at 18 months old if at 18 or 16 years I notice there is some kind of addiction I probably encourage him or take [laughing] at that point and if it's available at that point I will reconsider using the vaccine at that time because he's had the chance and if he's not using it properly then yeah' (parents, S1/G2).

Further, in the focus group with drug users in treatment, although F31 was initially the only participant to go against the group and argue that he did not think parents should vaccinate their children against addiction, his argument was very persuasive in the group and shifted the perspectives of all but one other participant, with the majority agreeing with F31 that parents should wait until children were older to enable them to participate in the choice of whether to receive the vaccination, in line with the dominant rhetoric in the other focus groups.

F33: 'It's a personal choice to every person who's sat at table
F34: And a child doesn't have that choice
F33: That's it
F31: I'd be happy for my kid to make that choice once he or she wa
F34: Older
F31: Old enough to make their own decisions know what I mean
F35: Yeah
F31: Eighteen maybe not 16 but 18, 20
F33: Yeah that's their choice

F31: Cos then they've gone through cos when your 18 your still you're not you don't really well even when your 20 I suppose but suppose your old enough to make your own decisions, it could've all gone wrong by then but … they'll still know whether to make up their own mind about the vaccine
F33: That only gives you power of advice then don't it' (drug users in treatment, S4/G2).

The position that parents shouldn't vaccinate their children unless they were already using a drug problematically also dominated expert discourse, with the vast majority arguing that it would only be desirable to use it for minors where they are currently experiencing problems with addiction or they are 'well on your way to that to then put the brakes on' (US29). Further, the limited duration of action of the vaccine meant that many expert participants saw the use of the vaccine preventatively a 'waste' since it would likely only be possible to achieve a significant titer of antibodies once:

US30: 'I think you'd only want to use it as prevention when someone is already having a trouble with the drug you certainly want the vaccine should never be considered like a childhood vaccine that you can vaccinate someone with the thought that one day they might use the drug to protect them you can't do that [because] you would um you know you're still gonna probably look like with the current technology have a limited window of time 6 to 9 months in which you can get a significant titer so I wouldn't want to waste that potential until I need it' (Professor in Pharmacologist and Toxicology involved in development of mAbs and active vaccines).

7.8. DISCUSSION: FROM PASSIVE COMPLIANCE TO A POLICY OF CONCORDANCE

The dominant perception in the bioethical literature, based on an objectivist interpretation of the best interest principle, is that parents would want to vaccinate their children in order to protect their future health and happiness. However, the data collected with parents across the UK focus groups with parents, smokers and social cocaine users suggests that they did not view addiction in the same way as infectious disease, and did not find normative arguments around a 'social' form of herd immunity convincing. Rather using a substance for recreational purposes was not perceived the same as having a disease, regardless of whether addiction to that substance was considered a disease, and use itself was not considered to lead mechanistically to addiction. In this context the physical and temporal extension of parental power over their children did not coincide with their articulations of what it was to be a 'good' parent. Rather than preserving their future autonomy of the child, vaccines for addiction were viewed as restricting the ability of the child to show virtue in choosing not to use drugs, and also as thwarting the conditions conducive to a healthy family. However, they were more favourable towards the idea of vaccines for alcohol, and parents in the groups conducted with drug users in treatment were more likely to perceive prophylactic vaccination for cocaine as a means of preventing a constraint on autonomy; not as infringing freedom of choice, but as providing their children with the opportunity to avoid falling into drug use and open up their future lives. This suggests that participant's view of the

proximity of the risk of addiction to their children had a major impact on their assessments of whether vaccines constrained or enabled autonomy. Further, as noted previously, although lay participants tended not to challenge the construction of the vaccines as completely blocking drug effects or its very long-term duration, when alternate presentations of its likely temporality were presented to them, although their perceptions were less critical, the vast majority still resisted the medicalisation of drug use. Rather, the option to use drugs was perceived as a key domain of discretion to the child's developing autonomy, important to identity formation through learning restraint and responsibility and enabling them to form a basic structure by which they could learn to order their desires. These parents then resisted the medicalisation of drug use and the articulation of pharmacological determinism inherent in the dominant clinical gaze, and evinced alternate technologies of the self and understandings of what it was to be a 'good parent'.

Pharmaceutical anthropology has directed a great deal of attention to lay rationalities about the uses of medicines and the differences between professionals' biomedically-inspired notions regarding the safety, efficacy, and necessity of certain drugs, and the users' considerations. As Streefland *et al* (1999) note, acceptance and non-acceptance need not be mutually exclusive, since there can be gradations of acceptance, with parents changing from acceptance to non-acceptance between one child and the next, in the course of one child's vaccination career, or in the case of a specific vaccination. However, where 'routine' vaccination becomes 'campaign' (through the extra media attention, new vaccination technology or a newly introduced vaccine) people may reflect on basic questions regarding vaccination, and something that was hitherto automatic, like taking a child to be vaccinated, may no longer be so automatic. The expansion of immunisation schedules to include vaccines for addiction may well enhance existing parents' doubts, and trigger discussion as to the worth of vaccination more generally, through the transference of localised contest as to the place of vaccines for addiction to the role of 'experts' in making fundamental decisions about their children's health, without consultation. Vernon (2003), a British GP, has argued that public policy about immunisation illustrates and reflects a current tension in wider health policy between an increased reliance on scientific evidence and a wish to have a patient-centred approach, and between the needs as defined by the experts and the wants expressed by the public. He recommends a move away from the current situation, which largely assumes the passive compliance of the population, to a policy of 'concordance' where evidence-based medicine is not only taken to apply to the individual, but dialogue between perspectives based on different views of the world. As such, the chapter will conclude this thesis by considering the wider implications of the findings on the notion of the neo-liberal individual which underpins the dominant discourses of biomedicine and bioethics. It will also identify potential 'loci for realignment' in the endogenous futures of the vaccines (Schot and Rip, 1996), and reflect on the value and success of framing this thesis as an exercise in constructive technology assessment.

8. BETWEEN MALEVOLENT MOLECULES AND DISEMBODIED COGNITIVISM

'Everything, however, has come to be; there are no eternal facts: just as there are no absolute truths. – From now on therefore, historical philosophizing will be necessary, and along with it the virtue of modesty.'

Friedrich Nietzsche, 'Human, All Too Human, Vol.1' (Part I: No.2, [1878] 1995, p17).

8.1. INTRODUCTION: ANIMAL MODELS AND LABORATORY LOGICS

In many ways immunotherapies for addiction can be seen as a product of their time, an era in which behavioural pharmacologists sought to measure the external drug effects of anything they could train a monkey to take. However, as Campbell (2007) is clear to point out, and I would emphasise from the interviews conducted for this research, behavioural pharmacologists were also a bunch of colourful characters who were not socially dislocated from those that used drugs. Rather, describing addiction in terms of receptors and reinforcers levelled social distinctions between organisms who used drugs of abuse and those that did not. Observing a moving and behaving animal learn to self-administer drugs didn't impose a view of addiction as psychopathology on the subject, rather it defined all brains as possessing the capacity for taking and seeking drugs, and enabled a conscious break with psychoanalysis and a view which they simply didn't feel explained the dependence of the people they knew that used drugs in the alternative sub-cultures of 1930s and 40s America. Schuster reportedly abandoned the project in the late 1970s after receiving calls and letters from parents all over the world asking him to immunise their child so they wouldn't become a heroin addict, in objection to the idea of using the vaccine to prevent rather than just treat addiction (Boyce, 2003). Although this coincided with the entry of naltrexone into the market, the heroin vaccine was arguably largely perceived as ineffective and unnecessary precisely because it was seen as just another means to modulate the reinforcing effects of drugs, to influence the self-administration behaviours of the animal.

As Campbell (2007) notes though, so too do scientists have to take responsibility for the carceral society they create, and by demonstrating that animals could be taught to take drugs, behavioural pharmacologists enabled the addiction paradigm to shift to that of neuropharmacology, which has since indicated many common features between the effects of various drugs on people and on non-human animals. This has led neurobiologists to argue that the long-term neurological effects of sustained drug use observed in animals are largely analogous to what occurs in humans, with psychoactive chemicals seen to change the routine functioning of the neural processes in the

pleasure/reward circuitry of the brain, such that once exposed to the biochemical effects of certain drugs, people and animals will be strongly inclined to use them again. However, as discussed in Chapter 4, although neurobiological theories of addiction have had the positive implications of increasing funding for addiction research and making more humane, less punitive responses to addiction possible, this has come at the price of simplified versions of behaviour controlled by the state of brain receptors and neurotransmitter systems. Dominant scientific perspectives now construct addiction as the flick of a metaphorical switch in the brain that occurs mechanistically as a result of chronic drug use, with such 'neuroadaptations' believed to explain the propensity of former heavy substance users to relapse. Drug use itself becomes depicted as an invasion and unnatural, constituted as the result of a process of pollution and corruption in which foreign substances have hijacked the body's natural reward pathways, disrupting the original balance and self-sufficiency of the body and leaving the addict in thrall to external forces (Keane, 2005).

Constrained then by the laboratory logics of behavioural pharmacology, neuroscience has prioritised objective pathology over subjective and experiential factors, excluding the voice of the patient from constructing their own diagnosis and directing the clinical gaze away from the whole concrete body and towards particular molecular sites where the drug acts, in order to know the 'ideal configuration' of the disease (Foucault, [1973] 2003, p8). As Campbell (2007) argues, in so doing, neuropharmacology has been pursued as a science of difference; used to re-inscribe social hierarchies, locating difference in irreversible brain pathways and divorcing the brain from the body in which it is experienced, promoting a view of pharmacological determinism where malevolent molecules and not social worlds are the prime cause of chronicity. Alongside the increased role of commercial and market interests in furthering the expansion of medical jurisdiction, seeking to exploit new markets through widening diagnostic criteria, such reductionist discourses have reclassified the vaccines as 'magic bullet' treatment technology and public health prevention tactics. This can perhaps help to explain one of the key questions this thesis has sought to address - why techno-economic networks (cf. Callon, 1991) have been more successfully mobilised around the vaccines in the US than in the UK.

8.2. SOCIO-TECHNICAL NETWORKS AND THE NEOLIBERAL INDIVIDUAL

White (2000) notes that reconciling an emerging medical understanding of addictive disease with American ideas of free will and personal responsibility proved particularly difficult because of the challenge it made to the notion of the individual of liberal contract theory. Levine (1978) however

argues that the redefinition of evil or deviance as a disease of the will was carried even further here, precisely because the fundamental importance of 'self-control' to what was an especially or uniquely middle-class nation due to patterns of migration, meant that its negation had to be more clearly defined and combated. It can perhaps be claimed though that where medicalisation has been successful in the US in terms of reconstructing addiction as a chronic relapsing brain disease in official political discourses, it is because it has left unchallenged the underlying conception of the individual that defined its independence in the eighteenth century. As Gomart (2002) notes, although the current biomedical construction of addiction is generally perceived as diametrically opposed to a moral conception of addiction, the distinction between them is often not so clear. In the first, the addict is depicted as overcome by forces beyond their control, in the latter the addict is regarded as an autonomous moral agent, but in fact both abstinence oriented medical approaches and the criminalisation of drug use centre their practices on the moral agent of western liberal moral philosophy, built around the same 'negative' definition of freedom. Indeed the subject implied by the 'New Deal' of the 1930s can be read as the first and last gasp of 'social politics' in the US, and the rise of monetarist economic policies from the 1970s as the resurrection of a notion of subjectivity that had been suppressed but not displaced (Rodgers, 1998).

Drug addiction then presents itself as a uniquely pressing problem, since it excludes the compromised subject from the social contract and prevents them from taking responsibility for their actions. A problem however which can only be solved through complete abstinence, since the presence of the drug of abuse, or similar 'substitution' or agonist drugs, are seen to entirely exclude the possibility of agency, since freedom is quantal; all or nothing. Consequently, the vastly predominant goal of treatment in the US has been that of total abstinence, with maintenance or substitution harm-reduction therapies typically publicly and politically derogated (Payte, 1991). As seen in Chapter 4, where harm reduction approaches have been tolerated, legal and bioethical scholars have tended to protect the underlying ideal of moral agency by justifying such measures in terms of social as opposed to individual benefits. Given this wider socio-political context, in constructing the vaccines as holding the potential to universally enforce abstinence from within the body, legal and bioethical discourses in the US have created political expectations that vaccine technology has the ability to permanently return the compromised subject to the hypothetical social contract with immediate effect. By portraying the vaccine as such a 'magic bullet' the need for varied and broad treatment programmes is undermined, and the cost-effectiveness of the vaccines is vastly inflated, since at the cost of a mere $150 per shot, the addict will cease drug use and become a productive member of society. In the language of the US National Drug Control Strategy of 1995, it will finally provide chronic drug users with the 'effective treatment they require to get off drugs and become taxpayers, instead of tax takers' (ONDCP, 1995, p9). The identification of such a technological opportunity has mobilised political resources

and networks in the US, with NIDA creating a 'protected space' for developing the technology, existing largely outside of the demands of the marketplace, which until the recent Phase II and III clinical trials has proceeding according to its own dynamics, with few checks with the scenario of usage into which it will emerge (Rip and Schot, 2002).

By comparison in the UK, unlike the abstinence oriented approach of the US, there has been a historical allegiance to harm reduction medical approaches, which do not view 'freedom' as the only justifiable outcome of drug treatment (Gomart, 2002). Rather, within this context, harm reduction approaches, including the use of agonist drugs, have been regarded positively. The adherence to a different medical approach can arguably be attributed to a different underlying conception of the freedom of the subject, explained in part by Garland's (1981) thesis that the same conditions which combined to allow the model of addiction as disease to emerge in the UK in the nineteenth century, also led to 'a crisis of the social'; a widespread challenge to the ideologies of the ruling classes, which undermined the notion of individual responsibility for unemployment, poverty and so forth, transforming the notion of the individual subject. This enabled a gradual transition away from a *laissez faire* individualism to an interventionist state (p35). Garland terms these developments 'the birth of the welfare sanction', which recast the relationship between the state and the individual, greatly expanding the legitimate role of state intervention far beyond the limits of the sacred social contract. Whereas the previous conception of the individual, defined in terms of free will, was absolute and essential, either intact or non-existent, the individual of the new moral order came to be understood in terms of character structure; a character which could be fully formed in the context of the responsible subject of law, but also unformed or malformed, capable of being acted upon, shaped and corrected. Penality was reconstituted, not as punishment for transgressing the political agreement, since that was predicated on ideological notions of individual free will, but as a new 'moral therapeutics', legitimated in the name of 'science' and 'humanity', which opened up a correctional system that policed characters rather than crimes, not through sentences imposed by the courts according to the severity of their acts, but according to the diagnosis of their condition and the treatment appropriate to it.

'This entity [the subject] was progressively modified and psychologised, transformed from its former (philosophical) status as essential will to the (positive) status of character structure. In this manner the legal and political ideology of the responsible subject could be preserved (against a determinism which would have it destroyed) but at the same time opened up to intervention. The subject now possessed a structure and determinants (moral education, heredity, environment) which could be the site of interventions, an object to be acted upon' (Garland, 1981, p41).

Consequently, in the UK harm reduction approaches have been justified not only on the basis of reducing the societal costs of addiction, but also on the grounds that they reduce the need of the person to use illicit drugs and improve patient health and wellbeing by enabling drug-dependent people to make *more* autonomous decisions about their drug use (Hall, Capps and Carter, 2008). As such, it could be argued that active immunotherapies have received less political backing in the UK because the need for new abstinence based therapies has not been considered as urgent as across the Atlantic, and government intervention to support and subsidise their development has been viewed as unnecessary (Schot and Rip, 1996).

However, since the 1980s official policy discourses in the UK have shifted away from the language of harm reduction, and towards coercion, arguably due to the increasing global convergence of addiction research science and also the more general rise of neo-liberalism in the UK since the Thatcher administration (Hunt and Stevens, 2004). Drug Treatment and Testing Orders, DTTOs, were first introduced in the UK through provisions in the Crime and Disorder Act 1998 (HO, 1998), and were subsequently replaced by Drug Rehabilitative Requirements, DRRs, under the Criminal Justice Act 2003 (HO, 2003). Although they differ in certain ways, both require offenders who consent to an order being made by the Courts to undergo treatment for their drug misuse and mandatory drug testing. Breaches are referred back to the Courts who can terminate the Order and impose another sentence in its place, including imprisonment. Subsequently, the UK Drugs Act 2005 (HO, 2005) granted police new powers through the implementation of 'Tough Choices' from 1 April 2006. Under 'Testing on Arrest' and 'Required Initial Assessment' powers, anyone suspected of acquisitive offences can now be tested for heroin, crack and cocaine at the point of arrest rather than post-charge. Those who test positive are then required to attend a compulsory drug assessment, even if they are not charged, where refusal to provide a sample or comply with a required assessment can result in a fine of up to £2,500 and/or up to three months in prison. At the same time, the 'Restriction on Bail' provisions of the Criminal Justice Act 2003 (HO, 2003) were rolled out across the whole of England, which allow Courts to deny bail unless the offender agrees to a drug assessment and any recommended follow-up treatment or support. Further, since these provisions, six US style pilot Dedicated Drug Courts (DDCs) have been introduced in magistrates' courts in England and Wales (Kerr *et al*, 2011).

Although the approach to drug treatment in the US and the UK is still vastly different with regard to access, modalities of treatment and wider support mechanisms, such shifts could point to increasing alignment in policies regarding the coercive treatment of addicts in converging socio-political contexts which embed neurobiological models of addiction in political neo-liberalism. The comparative data underpinning this thesis is not sufficient or rigorous enough to make broad claims of how different conditions and causes fit together in some ideal-type setting (Hantrais,

1995). However, given that at the end of 2010 NIDA issued a call for studies to develop a heroin vaccine to be used in developing countries (NIDA, 2010b), the need to better understand how the development and future use of such a technology is located within, and dependent upon, the wider biopolitical strategies of state and subject in cultures outside of the West is crucial, and a key area for potential future research. What can perhaps be argued here though is that if political resources have been mobilised in the US because of the construction of the vaccines as biologically enforcing abstinence, as the technology steps out of the protected space and into the wider world if the reality fails to meet these promises and expectations then the credibility of the professions, institutions and industry involved may be challenged, and the dynamism and momentum upon which their development depended could dissipate (Brown and Michael, 2003). And indeed this is precisely what we are beginning to witness - these promises that sufficiently mobilised resources to allow researchers to nurture such 'hopeful monstrosities' into a semblance of functionality are turning out to be empty, as the vaccines have not lived up to the performativities inherent in such visions which specified what they should be able to do (Rip and Schot, 2002).

In July 2011 Nabi announced that its nicotine vaccine, NicVAX, had failed to meet the primary endpoint of a statistically significant difference in rates of abstinence between patients that had been vaccinated and the placebo group in the first of two confirmatory Phase III clinical trials (Nabi, 2011). Having focused almost exclusively on the development of NicVAX since 2007, after the failure of another late-stage product, Nabi's shares plunged nearly 70% on July 18th, the day the trial results were released, reflecting the biggest percentage drop of any Nasdaq stock that day (Flook, 2011). Shortly afterwards NIDA announced that it would not be funding any further development of NicVAX, leaving the survival of NicVAX, and that of Nabi itself, in severe doubt (NIDA, 2011b). Previously the leading product in the pipeline for active immunotherapies for addiction, the failure of NicVAX follows in the footsteps of Cytos-Novartis' nicotine vaccine, Nic002, and Celtic's cocaine vaccine, TA-CD, which both failed to meet their primary endpoints of improving rates of abstinence in Phase II trials in 2009 and 2006 respectively (Celtic, 2006; Cytos, 2009). Although there are still two other products in clinical development, Celtic's TA-NIC and Independent Pharma's Niccine, both for nicotine addiction, although both have reportedly completed Phase II trials, no results have as yet been released. As such, the stability of the socio-technical networks which have pre-emptively mobilised around the vaccines is very much in question, and the likelihood that they will reach the market is uncertain. As Schot and Rip (1996) argue, such 'forcing' of technology through the creation of a protected space by an actor, most often a government agency, wanting to get certain functions realised in order to solve a pressing problem has frequently resulted in technologies with limited societal robustness or viability in the marketplace, in short with 'expensive failures' (p261). Further, it can perhaps be argued on the

basis of the empirical evidence presented here, that rather than considering active immunotherapies as an 'expensive failure', we might do better to use the insights that can be drawn from CTA in order to explore possible new linkages between a range of aspects such as design options, user demands, and issues of political and societal acceptability (Schot and Rip, 1996). However, in order to allow such 'broad' learning to occur, it is necessary first to reflexively consider what 'deep' lessons can be learnt from understanding the goals, interests, and values that have been embedded in such visions that denote active vaccines a failure.

8.3. TOWARDS A CRITICAL NEUROSCIENCE

Contrary to the homogenising paradigm of the brain disease model of addiction, in recent years a steady stream of papers have shown that alcoholism and drug addiction as a unified progressive disease cannot be verified empirically using either clinical or general population samples; rather, at the aggregate level, there is often poor correlation among different types of problem indicators which are supposed to originate from the same underlying condition (Herd, 2002). This would likely not cause surprise if it is recognised that the meanings drug effects have for human beings are not analogous to the meanings those effects have for non-human animals, and cannot be explained exclusively with respect to biochemical effects in the brain's pleasure/reward circuitry. The vaccines don't 'work' because the social environments of drug users and addicts don't replicate the essential features of the laboratories in which they were developed, and the tracks along which the train travels are frequently interrupted (Latour, 1987). However, if we acknowledge that the sets and settings of drug use are key, and that the meanings drug effects have for people strongly influence how those effects are experienced, then we may assess the vaccines differently (Becker, 1963). However, as Keane (2005) argues, currently even where substance dependence is described as a bio-psycho-social condition to demonstrate the complex nature of addiction and the significant role played by non pharmacological factors, in simple additive terms it implies that the elements of addiction can be divided into easily distinguishable categories and that a clear boundary exists between individuals and the world they inhabit. Further, the biological and pharmacological are given primacy, with the psychological and social seen as influencing or providing the context for an underlying biochemical process, where drugs and their unique chemical properties are seen as initiating and driving the addictive process causing the bodily changes that result in dependence and producing a compulsion beyond individual control. As Weinberg (2002) notes:

'Because they seek to predicate their theories of compulsive drug use on a presumption that certain chemicals invariably produce pleasurable experiences, neurologists systematically occlude the culturally

transmitted meanings of drugs and drug use from their analyses. If our effort is to understand the dynamics of compulsive drug using practices in people then blindness to the meanings of drug experiences is a very serious theoretical handicap. Lastly, we must realize that conceptual resources drawn from neurology are not particularly well-suited to research that seeks to elucidate the subjective experiences and/or the social contexts that foster compulsive drug use or those that foster its amelioration. Theoretical approaches to these kinds of analyses, though they must certainly be open to the possibility of neurological influences on human behavior, must not cast human behavior and experience as merely epiphenomenal to neurological processes' (pp6-7).

Equivalent criticisms however can be levelled in the opposite direction at decision theory, which portrays drug use as a perfectly rational assessment of the options available, and marginalises the experience of the addicted body. Indeed, there is a very real need to 'take biology seriously' (Kushner, 2006). As Weinberg's (2002) praxiological approach suggests, the meanings of drugs and the emotional effects drugs have on us derive to a significant extent from the ways in which we have come to use those drugs in the various social contexts that make up our lives. But because these meanings and emotional effects manifest non-symbolically, pre-reflectively, pre-discursively and unwittingly, it is reasonable to regard their impact on our behaviour as uncalculated and involuntary in a very literal sense. The reality that there will always be cases of addiction without withdrawal to falsify Lindesmith (1968), and human behaviour that defies Nutt's (1997) neurological adaptations, does not make such contributions any less worthwhile; however, as Weinberg (2002) argues, there is a need for theoretical advances which neither prioritise rational cost-benefit assessment and displace the embodied experience of drug use, nor ignore the realities of the social context in which drug cues are learned and experiences felt, reducing the complexities of human behaviour to simple neurological maladaptations.

Both neuroscience and decision theory focus primarily on the individual as agent, on the individual's weighting of incentives and deterrents, on individual acts of choice or behaviour as the unit of interest. However, the high priority placed on autonomy that such approaches imply has been subject to much criticism for being inappropriately individualistic, focused on specific patients whose disease or behaviour is seen to be explained by personal conditions such as genetics, lifestyle and choices. But this does not recognise that social status differences in and of themselves cause disease, since socio-economic status reflects broad access to resources that enable individuals to avoid risks, deal with adversity when it comes, and adjust to changing conditions (Tausig *et al*, 2006). This focus underplays the role of social factors, and ignores critiques of autonomy as a complexly ordered social phenomenon, shielding the extent to which we do not act alone. As Keane (2002) notes:

‘Our individual futures are not separate channels that we can steer independently in any direction, but are more like threads in a woven fabric, the pattern of which is determined by social forces and the relations of power in which we are all embedded. Our decisions alone do not control our futures, and our decisions themselves are not made in an abstract space of pure choice’ (Keane, 2002, p129).

In a different vein to these approaches, Gomart (2002) shows how a paradigm of ‘generous constraint’ emerged in the 1990s in France, as critics of addiction treatment challenged both caregivers and legislators for holding onto a libertarian definition of the dualism of autonomy and subjugation. No longer pitting moral against medical, coercion against care, staff and patients of the ‘Blue Clinic’ redefined the human subject ‘not as autonomous and free, but as an attachment, an entity emergent in constraining relations’, constructed and constituted through varying constraints, such as the choice of drugs, modes of use, and mini-contracts (p546). Arguably, by becoming aware of the limitations of approaches which are predicated on an implicit conception of the neo-liberal individual, we can hope to move towards a harm reduction approach and a critical neuroscience that is more cognisant of the social worlds in which addiction occurs, not in the restricted sense of ‘social factors’ but through awareness of the social-situational contexts and relationships within which addictions are experienced and studied (Campbell, 2007). Campbell (2010) calls then for the addiction field to integrate the insights that neuroscience research has provided on drug use and addiction with those provided by clinical, epidemiological, sociological and economic research. I would argue that one key way in which such progress could be made is by realising that the laboratory logics of behavioural pharmacology which focused on the animal in order to break with psychoanalysis have served their purpose, and that it is high time the subjectivities of the constructed individual were brought back into the fold.

At the beginning of this thesis I noted that I desired to de-ontologise the object of my study, that I was not concerned to search for ultimate truths, and this has not changed. But that does not mean that I have not been concerned with how our collective understanding of what we call 'addiction' has had a very real impact, both on the lives of those who profess themselves to be overcome by forces outside of their control, and indeed on those who claim that their use of licit or illicit drugs has a positive and fulfilling role in their lives. I am unsure how the proposed reintroduction of the term into the official annals of the DSM-V will affect the debate. Although I understand that it was pushed from official discourses in a well-intentioned attempt to counter the negative effects of the social stigmatisation of addicted patients, I agree that there is a difference between the sense of the term 'dependence' in its suggestion of physical adaptations that result in withdrawal symptoms when certain drugs are discontinued, and 'addiction' as the subjective feeling of loss of control over intense urges to take a drug, even at the expense of adverse consequences. Given comparable physical withdrawal symptoms if long-term use of opioids is reduced, the most beneficial modalities of treatment for a patient who has no sense of

compulsion and craving, and a patient who states that they feel unable to control their intake even though they desire to stop, are not equivalent. The former could well be a patient dying of cancer and being prescribed opioids as long-term pain management, and the latter the stereotypical addict of popular consciousness. But so too could they be inverted; there is a growing body of evidence of so-called 'chippers', people that maintain planned, controlled patterns of opiates on a long-term recreational basis, without drug-related negative health or social outcomes, and patients initially prescribed opioids as pain management can go on to develop the feelings of compulsion we associate with 'addiction' (Chabal *et al,* 1997; Shewan and Dalgarno, 2005).

That said, I would ardently disagree with O'Brien, Volkow and Li (2006) that the difference between mere 'normal' physical dependence and such 'addiction' can helpfully be seen to reduce to whether or not the drug was prescribed inside or outside of medical supervision as the DSM-V proposes to do. Rather than excluding tolerance and withdrawal entirely as symptoms of addiction when drugs are used under medical supervision, but allowing the diagnosis of 'addiction' solely on these same symptoms when used outside of medical supervision, I would argue that the diagnosis of addiction should have to require more than evidence of physical adaptations for any drug, whatever the setting of use. Any dichotomous distinction between 'medical' and 'nonmedical' use of drugs is increasingly hard to maintain in the psychopharmacological societies of advanced liberal democracies, where self-medication has become an integral part of contemporary practices of the neurochemical self (Rose, 2003). Nor should it be permissible to diagnose the overarching category of 'addiction', with all that this signifies, purely on the basis of culturally specific appraisals about what a normal and healthy life should look like and the way time and priorities should be organised, as the proposed amalgamation of the sub-categories of 'abuse' and 'dependence' will allow.

When Edwards and Gross (1976) introduced the dependence syndrome, it was composed to show the importance that alcohol consumption had taken on in the life of an alcoholic, and to reflect the drinker's feelings of compulsion. Although their bi-axial concept of alcohol assumed association between alcoholism as a disease and problem drinking, which was defined by social, legal, vocational or medical problems that were the direct result of alcohol consumption, they were seen as distinct in both cause and effect. As noted in Chapter 3, it was the DSM-III-R (APA, DSM-IIIR, 1987) and DSM-IV (APA, DSM-IV, 1994) that made dependence take precedence hierarchically over abuse, portrayed as risk factors for dependence. In DSM-V, abuse will be almost wholly subsumed by 'addiction', such that its criteria will be used to diagnose the maladaptations of disrupted volition itself. But Edwards and Gross (1976) were well aware that what and how we choose to measure the world directly effects what comes into being and how

we understand it, and they were emphatic that the meaning of neuroadaptations could only be found in the voice of the patient which related the interaction between biology and the social. Although R. D. Laing (1965) has come to be most famously associated with the excesses of the anti-psychiatry movement, it can be argued that his fundamental objection was less to the overt enforcement of social control through therapeutic sanctions, than the exclusion of the patient voice from the clinical encounter through the search for objectivity. By viewing behaviour as 'signs' of a 'disease', rather than expressions of an individual's existence, we divert attention away from the local context in which they are comprehendible and also exclude alternate 'technologies of the self', or ways of understanding and being in the world, from consideration. In terms of a better way to conceptualise 'addiction' then, following Room (2007), I would concur that the DSM-V should acknowledge that feeling and affect states cannot be avoided for the diagnosis of addiction, and as such that it should seek to 'unpack' the current diagnosis and centre it around the related experiences of craving, feelings of compulsion and loss or impairment of control:

'That is, the core of the diagnosis would be composed from the third and fourth criteria in DSM-IV and the first in ICD-10 ("a strong desire or sense of compulsion to take the substance"). Such a diagnosis, while still including a range of content, would be located solidly in the realm of the user's experiences and evaluations of his/her use. The greater conceptual coherence of the diagnosis would strengthen our ability to analyse the interrelations and contingencies of different aspects of substance use. It might thus give biological researchers a better target for their animal and other modelling. It would certainly map more readily onto public conceptions of addiction, alcoholism or dependence' (pp205-206).

Room (2007) acknowledges that a dependence diagnosis reformulated around the experience of impairment or loss of control and related concepts would also be culturally conditioned, since one can argue that addiction concepts have a specific temporal and cultural history which implies that there are times and places where such concepts would not be meaningful. However, he concludes that in reconstructing the diagnosis around the user's experience, and not directly dependent on interpersonal and social reactions, would allow it to have broad utility across much of the world. Such a shift in the diagnostic criteria would open up opportunity for the heterogeneity of drug use and addiction to be acknowledged and encourage professionals to accept that different kinds of addictive problems necessitate different kinds of intervention. This could allow for the development of alternative strategies for dealing with drug related problems, particularly strategies raising the possibility of conditioning for controlled alcohol intake, which has become a *bete noire*, due to its challenge to the assumption, widely accepted by the AA lobby, that alcoholism is irreversible (Tournier, 1979). It could also enable more open discussion and reflection on the possibility for harm reduction measures for smoking, which have been excluded from politically legitimate targets since the 1970s due to the ferocity with which abstinence has been pursued by the anti-smoking lobby (Berridge, 1999). Importantly, it could encourage greater

acknowledgment of the complex interactions between biology and the social, political, economic and cultural relations of the twenty first century, and help to overcome the political exigency for abstinence, generating wider political support for harm reduction measures which focus on the actual harms that occur in people's lives as they are daily constrained and enabled by their wider contexts. If these deep lessons are learnt, then it should be possible to modulate the development of the vaccines in order to create a 'better' technology in a 'better' world, which as Schot and Rip (1996) argue, is the ultimate aim of CTA activities.

8.4. IDENTIFYING LOCI FOR REALIGNMENT

As Rip and Schot (2002) note, the functionalities originally envisioned for a technology and the eventually dominant ones may be very different, and intervention strategies cannot simply be based on actors' intentions at the time, and their predictions of eventual achievements. Rather, although the development trajectory optimises the new product, its eventual success requires re-contextualisation, a process which cannot be anticipated fully, let alone determined, at the earlier stages of the trajectory. They admit that understanding the dynamics of technological change and its embedding in society will not necessarily allow intelligent intervention, since this understanding is essentially retrospective and the patterns and regularities found through historical case studies will not always map onto the future. However, they argue that the CTA agent does nonetheless have a modest contribution to make, since by using their understanding of the ongoing dynamics of technological development, they can identify an ‘endogenous future’ which lies midway between attempts at prediction and the suggestion that everything is still possible, outline opportunities for intervention, and specify how such interventions can be productive; in short, engage in constructive constructionism (Rip, 2004).

Of key interest here is the identification of preferred loci for intervention, possible openings and opportunities to realign the supply side, or possible variations of the technology, with that of demand, or the requirements of the societal environment into which they will emerge (Schot and Rip, 1996). As Rip and Schot (2002) note, if such 'loci for realignment' are identified 'just before gelling', then it is still possible to exert influence, while there is also some assurance that a real difference will be made because it will become part of the trajectory. One of the prime opportunities to modulate ongoing developments then occurs as the technology is first introduced into the wider world, where trials can be viewed as an experiment in society rather than the laboratory, through which one can learn about the technology and its impacts. In many ways a regular 'nexus' between variation and selection is already established in the field of pharmaceutical drug development, where trials have become an obligatory activity for technology

developers, and products are routinely modified in response to the scaling up of data collected through Phase II and III clinical trials. Indeed work is already underway to produce 'second generation' vaccines, aimed at increasing and standardising absolute titer levels (cf. Hicks *et al*, 2011). In this sense then there already exists an actual space where loci for realignment can be sought; however, in order for these trials to contribute to the realisation of a better technology we need to learn from them and modulate developments accordingly, and arguably this is not being done. This CTA analysis then seeks to reflexively consider the outcomes of the clinical trials that have been conducted with the vaccines thus far, and use it as an opportunity for real-world learning and subsequent modification of the product in line with user requirements and social acceptability.

8.4.1. Design variation and societal demands: Therapeutic vaccination

In terms of establishing the design variation currently available with vaccine technology, there is still limited in-depth data publicly available on the nicotine vaccines. Since the fieldwork for this thesis was conducted however, there have been two important publications examining the results of the Phase II trials with Celtic's cocaine vaccine, TA-CD. The first was the full results from the Phase IIb clinical trial of TA-CD conducted on an unrestricted outpatient basis with methadone-maintained patients in treatment (Martell *et al*, 2009). The second was the results of a Phase IIa small scale human laboratory study with 10 cocaine-dependent men who did not want to quit (Haney *et al*, 2010). Martell *et al*'s (2009) study did not find a significant difference in complete abstinence between those that had been immunised and the placebo group, although they did find a significant reduction in cocaine use occurred in the minority of patients who attained the target antibody responses (high titer levels, 38%), which lasted up to 2 months. The study authors suggested that although the trial did not achieve a significant difference in complete abstinence with immunisation, it could (and I would say should) be argued that a reduction in cocaine use rather than complete abstinence is therapeutically meaningful. However, they also conclude that:

'While it is not clear whether all cocaine abusers will benefit from persistence of high antibody levels, short-term blockade of cocaine by the vaccine is likely to have limited efficacy as does short term opiate blockade by naltrexone hydrochloride. Thus, the goals for future vaccine development will be to increase the proportion of subjects who can attain the desired antibody levels and to extend these periods of abstinence through long-term maintenance of these adequate antibody levels. We look forward to extending our promising findings in a broader population of cocaine abusers as we also reach for these future vaccine development goals' (Martell *et al*'s, 2009, p1122).

But these findings should be taken alongside Haney *et al*'s (2010) study. Although they did not find a statistically significant relationship between antibody levels and self-reported cocaine use, they did report that the 5 individuals with the highest antibody levels reported a significant reduction in subjective ratings of 'good drug effect', which was associated with lower reported cocaine use, an outcome that was more robust than any medication tested in combination with cocaine using similar laboratory procedures. However, they also found that higher levels of antibodies were associated with an increase in cocaine's tachycardiac effects, which the researchers postulate is because by binding a fraction of the circulating cocaine in the blood, thereby slowing the rise in brain cocaine levels, it effectively increases levels in the peripheral circulation, which increases heart rate. Although participants' heart rate did not exceed the criteria that had been set for continuing with the study, cocaine was only administered twice per session and so likely does not reflect the potential risk of individuals smoking cocaine repeatedly within a short time frame, as is common outside of the laboratory setting. Because the study authors were concerned that the use of the vaccine in a non-treatment seeking group would lead participants to try to surmount the vaccine by using increasing doses of cocaine when not an inpatient, Haney's team repeatedly warned participants, orally and in writing, of the potential dangers of attempting to surmount a blunted cocaine effect. However, the study found that rather than try to override the vaccine, the high responders reported using less cocaine when outside the laboratory: 'anecdotally, they reported trying cocaine but not wasting their money if they did not like the effects' (p64). By contrast, in the Phase IIb clinical trials of TA-CD, which were conducted on an outpatient basis, patients were similarly warned about the risks associated with trying to overcome the blockade, but Martell *et al* (2009) reported that patients in the high-responder group increased their use of cocaine up to ten times their normal dose after week 16 when their antibody levels began to fall relatively rapidly. They acknowledged this increased use most likely reflected efforts to overcome the anti-cocaine antibody blockade, and the study co-ordinator, Dr Thomas Kosten, reported that they had likely continued until they 'just ran out of money' (Harmon, 2009, np).

It is interesting to note then that the risk of overdose through attempting to overcome the blockade was higher in the treatment seeking group than the non-treatment seeking group, that the non-treatment seeking group acted as 'econs' in nudge talk, rationally deterred from trying to achieve a now-blunted short term pleasure by financial disincentives, while those actively seeking treatment nonetheless continued to seek the drug effects until they were prevented from doing so by their financial constraints (Sunstein and Thaler, 2008). However, in terms of realigning design variation with user requirements, it is important to consider more fully the patient characteristics of these groups in order to evaluate how the vaccine would actually be used, and what the consequences of such use would be, especially given that in the drug field, patients'

behaviour in controlled treatment settings and behaviour in ordinary society can differ widely (Ashcroft and Franey, 2004).

Haney *et al*'s (2010) study recruited participants who met DSM-IV criteria for cocaine dependence but were not dependent on any other drug (except nicotine), and who were explicitly not interested in treatment for their cocaine use through a newspaper advertisement. By contrast, Martell *et al*'s (2009) study was conducted with participants meeting DSM-IV criteria for cocaine and opioid dependence who were already enrolled in an outpatient methadone maintenance treatment program, rather than patients from primary cocaine treatment programmes, in order to improve retention rates over the 12 weeks needed to allow the full course of vaccinations to be given. They were also given $15 per week to enhance retention and individual, weekly, 30 to 45 minute cognitive behavioural therapy, CBT, sessions conducted by trained substance abuse counsellors. Although they do not describe patient's history, Martell *et al* (2009) do note that of the 115 study participants, 30 patients had previous methadone maintenance treatment, suggesting that they had long-term problems with drug use and previous quit attempts. In many ways then the patient characteristics map broadly onto the characteristics of the participants recruited for focus groups in the UK with social cocaine users and drug users in treatment respectively, arguably sufficiently in order to be able to use their perspectives to try to understand the strengths and weaknesses of this approach.

In the focus groups with current social cocaine users, all the participants viewed a vaccine for cocaine negatively in regard to their current situation, since they reported their use of cocaine to be a positive aspect of their lives, and one which they felt they would be able to cease if they wanted to, such that a vaccine that prevented them from experiencing the effects of cocaine would restrict their personal freedom. However, when asked to consider whether they thought they would try to overcome the barrier of the blocking effect of the vaccine by taking higher doses of cocaine, they reported the likelihood to be very low, as F19 said, because *'you're not gonna spend your money if you're not getting any effect from it are you?*' (S3, G1). Consequently, these participants argued that if they had been given the vaccine they would either simply use other drugs, or if they could not find a suitable substitute, they would wait until the effects of the vaccine decreased, and then return to their use of cocaine. However, they viewed the voluntary use of the cocaine vaccine in wider treatment programmes positively, provided that it did not detract attention from the psychological and sociological aspects of drug use, which were perceived as crucial if its use was not to lead to an increase in drug overdose or the use of substitute drugs.

By contrast, the vast majority of participants recruited as drug users in treatment viewed a vaccine for cocaine very positively in regard to their current situation, because they regarded their own drug use as highly problematic and wanted to stop, but felt that it was often beyond their control, and thought that a vaccine that blocked them from experiencing the biologically reinforcing effects of cocaine would enable them to achieve abstinence. However, when asked whether they thought they would try to overcome it, drawing on past experiences with naltrexone, a blocker for heroin, they indicated that increasing of dose and swapping of drugs were common, even where they had perceived themselves as fully committed to recovery.

However, unlike Martell *et al*'s (2009) conclusion that short term opiate blockade by naltrexone has limited efficacy, and that future vaccine development goals should focus on increasing the duration of action of the antibodies in order to extend periods of abstinence, this was not necessarily found to align with these users requirements. For all the drug users in treatment that participated in this research, the role of medication in recovery was viewed positively, with both agonist and antagonist pharmacological agents seen as a 'crutch' which enabled them to assert their willpower. For the majority, blockers were construed as most helpful either in 'active' addiction, once they had recognised their use as problematic but felt unable to control it, or in the early stages of 'remission', to protect themselves from relapse after a period of abstinence. The latter was presented as both physical and psychological, with the knowledge that they had taken a blocker constructed as giving them confidence that they could remain abstinent, independent of the actual reduction it had on the effect of the drug. Consequently, blockers were frequently seen as desirable when they knew they were going to be in what they regarded as 'high-pressure' situations, such as leaving prison or a residential rehab, or seeing using friends or relatives again after a period of absence. However, of those that had taken naltrexone, many reported experiencing feelings of panic and loss very quickly afterwards, and when they found themselves within high-pressure scenarios, especially early on in the process of recovery, long term commitments to abstinence had to be balanced against the demands of coping with everyday life. Consequently, for some of these participants, where naltrexone had been taken orally on a daily basis its use had been ceased, either temporarily or longer term, but they reported that the long-term constraint on their ability to use that the 3-month implant had given them had enabled them to return to their community and prevent lapses from becoming relapses when adverse life events occurred and their motivation had temporarily waned. However, for others, they felt the knowledge of having a long-acting opioid blocker had simply pushed them towards other drugs because psychologically it made them fixate on their inability to use heroin. By contrast however, for some of these participants the short-term action of oral naltrexone was constructed as a daily reminder of their choice not to use, which sufficiently stabilised their motivation to enable them to continue with their recovery when they left in-patient treatment.

Non-compliance with daily oral naltrexone is statistically common, and because naltrexone sensitises the opioid receptors it can put the patient at increased risk of opioid overdose if they return to their usual dose after treatment. However, a number of studies have shown that patients are more likely to continue taking the treatment and remain abstinent if they receive family therapy, reside in a supportive family environment, or are supervised on a daily basis (Hulse and Basso, 2000). By contrast, depot formulations of naltrexone which last between one and six months have been found to decrease rates of opioid overdose because they consistently maintain blood levels of naltrexone of naltrexone to block 87-100% of 25mg of intravenously administered heroin, but their use has been associated with increased levels of overdose from other drugs such as sedatives (Hulse *et al,* 2006). Similarly however, although there is still limited large scale data evaluating depot formulations, a small Norwegian study found that their use among opioid-dependent patients after in-patient treatment significantly reduced their use of heroin and other drugs, when they were used alongside other aftercare support including out-patient counselling, vocational counselling, social services and the option to be readmitted into residential treatment (Kunøe *et al,* 2009).

As was clear from the focus groups conducted with drug users in treatment, initial patient motivation was a key factor in recovery narratives, where hitting rock bottom was regarded as essential to establishing a long-term commitment to abstinence. This is supported by the findings of MacIntosh and McKeganey (2001) who have drawn on Goffman's (1986) work on the 'spoiled identity' to explain successful recovery attempts from unsuccessful ones. However, although subjective self-perception of a spoiled identity may be necessary to recovery, it is by no means sufficient. Rather, users challenged dominant constructions of non-compliance as deviant behaviour, presenting themselves as active agents in their treatment, self-regulating or varying their medication practice on grounds connected to the management of their daily existence (Conrad, 1985). Relapse to drug use is a common occurrence, and the understanding that side effects (including abstinence itself) are evaluated against the achievement of specific outcomes highlights the need for medication to be embedded in formal and informal supportive frameworks which can encourage patient retention and enable the positive benefits of the technology to be realised. As such, it must be realised that the synergies of the local contexts in which the patient is situated is likely to have more impact on reducing drug related harms than the absolute duration of action of the vaccine, and that the need for boosters to retain a blocking effect should not be viewed negatively since different patients will benefit from different temporalities of constraint at different points in their treatment journeys. Further, it is very important to recognise that users in drug treatment viewed medication instrumentally, as enabling their autonomy sufficiently to be able not to use when they felt otherwise overcome by compulsion; however, their ultimate aim was almost universally to cease taking any medication,

either agonist or antagonist, because it was seen to preclude the ability to demonstrate 'moral virtue' over drug use which was their ultimate goal.

By contrast, although I have focused on the cocaine vaccine, in the focus groups conducted with smokers participants largely reflected the perspectives of social cocaine users, with the majority viewing a vaccine for nicotine negatively in regard to their current situation, viewing smoking as having a positive role in their lives, whilst also presenting their patterns of use as relatively inflexible, reporting numerous failed quit attempts and labelling themselves as addicted. However, as discussed in Chapter 4, this perhaps reflects the nature of the substance under consideration and the sets and settings of drug use, since although the reappraisal of all drugs in terms of their rewarding or reinforcing effects has led to a broadening out of concepts of addiction and an increasing convergence between tobacco and illicit drugs, nicotine has never entered the category of abuse in the DSM because it does not cause an identifiable state of intoxication and there is no impairment in social or occupational functioning as an immediate and direct consequence of tobacco use. Rather, the concept of nicotine addiction was argued to reflect a shift towards the valorisation of health in certain cultures, whereby a loss of autonomy in the present was inferred by the risk of a physical disorder in the future. Consequently, unlike other drugs of addiction, where the risks of excessive consumption can face users with negative physical and social problems early on in their using career, long-term commitment to nicotine abstinence can be seen to be more difficult to establish, unless social, economic or health implications threaten identity in the present, such as was the case for F2 (S1/G1) when she had continued to smoke during pregnancy. The negative appraisal of the vaccines and their long-term constraint on the user's ability to smoke can then be understood in terms of the new temporal dimension in contemporary constructs of nicotine addiction, which require the individual to balance the risk of negative health outcomes in the future against actual positive pleasures in the present. If this is the case, then it is perhaps likely that should groups have been conducted specifically with ex-smokers or smokers who were currently experiencing negative outcomes due to their consumption of nicotine, then there would have been more substantial overlap with the discourses of illicit drug users in treatment, and further research is required to establish the potential acceptability of the nicotine vaccine to these groups, and to identify their underlying frameworks of evaluation of potential efficacy. However as social cocaine users, they viewed the voluntary use of the nicotine vaccine in wider treatment programmes positively, provided that it did not detract attention from the psychological and sociological aspects of smoking, which were seen as crucial to successful quit attempts.

The failure of the Phase IIb TA-CD study to meet its primary endpoint, and the problems of what is seen as non-compliance, has led Celtic to reconsider the patient characteristics in the trial. In December 2006, Celtic presented the results of the US trial to Project Cocaine Vaccine, a group set up by the Italian Ministry of Health to consider the potential role of vaccines for cocaine in Italy. Celtic noted that there were concerns that the primary endpoint had not been met because it was conducted in a methadone-dependent population, which contained a variety of patient types, including patients not motivated to quit, and patients able to quit without a vaccine, as well of those motivated to quit but in need of support, and indicated that Celtic saw the need for a new Phase IIb study, using non-methadone-dependent subjects (Celtic, 2006b). Later that year it was decided to run a large Phase IIb multi-site trial of TA-CD in Italy and Spain (DPA, 2006). Anecdotally, this was because the cocaine trials were seen to have been challenging due to poor compliance as a result of candidates being unmotivated to cease their cocaine use having entered rehab as an alternative to incarceration, and their status as dual users who primarily participated in the trial in order to access methadone for their heroin addiction (UK3). Italy and Spain were seen to offer potential trial candidates who were primarily cocaine users and who were motivated to cease their use of cocaine, and as such could offer a less challenging clinical trial. Celtic (2006b) also raised the question of whether a reduction in cocaine use could be used as the primary endpoint, rather than abstinence, but the outcomes of these trials and the decision as to whether the primary endpoint was reconsidered have as yet not been reported.

However, although trials with users whose primary drug of choice is cocaine would be valuable, such trials are arguably an unrealistic representation of the likely requirements and demands of those that will use it. Of the 173,760 patients considered problematic drug users in the UK National Drug Treatment Monitoring System (NDTMS) between 1 April 2009 - 31 March 2010, only 3.6% reported crack cocaine as their primary drug, but 36.9% were dual-users of both crack cocaine and heroin (HSC, 2011). As Ashcroft and Franey (2004) have argued, there is a real need for pragmatic clinical trials here, rather than the simple trials of safety and efficacy normally used for licensing purposes, because in the absence of trials which permit a realistic assessment of the effectiveness of a vaccine in the sorts of situation in which it would be most useful, we will have no real sense of its value, even if it becomes a licensed product. The use of cocaine by heroin-dependent individuals, or by patients in methadone or buprenorphine maintenance treatment is substantial and has negative consequences on health, social adjustment and outcome of opioid-addiction treatment (Leri, Brunaeu and Stewart, 2003). With no other pharmacological treatments primarily for cocaine, in contrast to the current trends for pharmaceutical companies to churn out efficacious medications of dubious clinical utility, although the vaccines may be judged inefficacious according to the logic of clinical trials predicated on abstinence, they do nonetheless hold real potential to be clinically useful (Abraham, 2010). However, owing to the

polydrug use and chaotic lifestyles of those most positive towards their development and the most likely to benefit from their use, the potential for patients to drop out of treatment, or to attempt to overcome or circumvent the blockade is high.

This has major implications for the potential use of the cocaine vaccine coercively within the criminal justice system, CJS. In the first major national assessment of the effectiveness of drug treatment in the UK in over a decade, a report by the Home Office (Barnard *et al*, 2009) found that referral through the CJS seemed to have little positive or negative effect on the motivation of individual treatment seekers. This was the case whether the referral was voluntary or through a mandated route such as a Drug Rehabilitation Requirement, DRR, or other restriction on bail. Those who were already motivated to address their drug use said they were pleased to have the opportunity to access treatment rather than go to prison. But they also reported that some people who accessed drug treatment through the CJS did not want to stop using drugs but only wanted to avoid jail, and that their contact with treatment services had not meant that they became motivated to stop taking drugs. As discussed previously, although initial patient motivation cannot by itself account for successful recovery attempts, since these are also enabled and constrained by the daily socio-situational contexts and relationships within which the addict exists, the potential for the lack of initial motivation through referral by the CJS does raise serious concerns about the temporal conflict between the duration of the vaccines and short-term, pragmatic considerations of wanting to avoid incarceration, which could unacceptably increase risk of overdose and substitute drug use, with severe negative consequences for both the user and society.

As emphasised by the vast majority of interviewees in both the UK and the US who were involved in the development, and potential use and regulation of these new technologies, they will only be useful for a small subset of highly motivated patients, and in order to reduce the risk of psychological and physical harm they must be embedded in wider formal and informal treatment contexts which also consider the psychological, sociological and environmental factors of drug use and enable the recovering addict to thrive. Recursively, by taking into account these social-situational contexts and relationships, the efficacy of the vaccines will be increased through improving patient retention and enabling the positive aspects of the technology to be realised. Within this context, even if 90% of patients do not wish to take an anti-cocaine vaccine, if 10% do, and it will help a third of those to reduce their use, then arguably it is a very good technology. However, the complex patient characteristics of their future users need to be taken into account, and there is a real need for systematic investigation of the impact of the cocaine vaccine on the interaction of cocaine and opioid use patterns among dual users, and the outcomes of their use in different sets and settings, in combination with other therapies and interventions, both

pharmacological and non-pharmacological. In summary however, I would argue that such systematic trialling and equally importantly, collective learning from these trials over sufficient timescales to gain real insight into the potential effectiveness of this new technology will fail to materialise unless the complexities of drug treatment are genuinely acknowledged, and abstinence is not viewed as the only acceptable outcome of treatment.

8.4.2. Design variation and societal demands: Prophylactic vaccination

As it stands there simply is no available design variation that contains the necessary technological script to allow the vaccine to be used preventatively on a large scale, since the risk, cost and logistics of vaccinating teenagers every 3-6 months, on the basis that there is a 1 in 3 chance that they will develop sufficient levels of antibodies to prevent them from experiencing the biological effects of a specific drug they have never used, in order to ultimately prevent them from getting a 'disease' they may never get, even if they do choose to use that specific drug, simply could not be justified. Importantly however, although dominant biomedical and bioethical discourses may consider preventative vaccination to hold the promise of protecting the child's latent autonomy in order to ensure the non-subject reaches the age of majority with the full capacity to opt into the social contract, should the UK government choose to pursue design variation that would allow for MCI, it is questionable what public support they would find. Indeed, the vast majority of potential users in the UK and interviewees involved in knowledge production in the UK and the US, were highly critical towards the potential widespread preventative use of vaccines for cocaine or nicotine, which were found to focus far too much on identifying simple biomedical mechanisms, and too little on why people seek to use drugs and how their patterns of use are socially shaped. The construction of epidemiological models which located risk in the generalised environment and the child as passive were heavily contested, and by emphasising the liberty of the child in initiating drug use, participants expressed profound doubt over the likely effectiveness of the new technology, even where it was considered to be completely effective in blocking specific drug effects and to last for a much protracted period of time. Further, in the focus groups with smokers, social drug users and parents, participants were quick to interrogate the major premise, or general truth on which arguments for widespread preventative vaccination are based (Becker, 1998); that drug use and even perhaps addiction are states we would necessarily want to prevent.

The dominant perception in the bioethical literature, based on an objectivist interpretation of the best interest principle, is that parents would want to vaccinate their children in order to protect their future health and happiness. However, the data collected with parents across the UK focus

groups with parents, smokers and social cocaine users points to the existence of alternative value structures and assessments of the role of drug use in society. In this context the physical and temporal extension of parental power over their children did not coincide with their articulations of what it was to be a 'good' parent. Rather than preserving the future autonomy of the child, vaccines for addiction were viewed as restricting the ability of the child to show virtue in choosing not to use drugs, and also as thwarting the conditions conducive to a healthy family life. Crucial to this was that the vast majority of these participants felt that the choice of whether or not to use drugs was a key 'domain of discretion' to the child's developing autonomy, important to identity formation through learning restraint and responsibility, establishing the child's orientation to the wider world and external influences, and constructing boundaries between the child and adult (Schapiro, 1999). The important exception here was the voice of drug users in treatment in the UK, who were more likely to perceive prophylactic vaccination for cocaine as a means of preventing a constraint on their child's autonomy rather than infringing on their freedom of choice, by providing them with the opportunity to avoid falling into drug use and open up their future lives. However, the difference between these perspectives can be seen to reflect how wider social, economic and cultural settings impact on parents conceptions of the proximity of risk, and highlight the situated and context-bound nature of autonomy. Further, these participants likewise emphasised that the choice to vaccinate a child preventatively should be done in a participative way, and not enforced if they were not to threaten the foundations of family life, and arguably, the sentiment that was being expressed here could be far better addressed through drawing political attention to the social and economic structures of inequality and health, rather than the prophylactic use of vaccinations for addiction (Berridge, 2003).

This then is a strong argument for the inclusion of lay moral reasoning in debates around technologies which could potentially have a major impact on the societies in which we live and through which we come to understand ourselves. As a medically framed perspective, arguably bioethics acts not as source of critical oversight to biomedicine, but rather as an 'opportunity for ethics experts to cope with dilemmas generated by technologies, which came to be seen, ironically, as value neutral in their creation even while they were problem-causing in their effects' (Stevens, 2000 in López, 2004, p876). The implicit or explicit assumptions of universal morality, largely consequentialist modes of reasoning, the primacy of autonomy as instrumentally valuable in achieving well-being, and Western ideas of rationality and independence work to narrow bioethical debate about human life to one centred on proper techniques and means (Evans, 2002). Through the physical exclusion of the mad which came to be negatively constitutive of Enlightenment reason, neo-liberalism excludes 'unreason' itself (Kelly, 2010). But as the enterprising subject of contemporary discourses of public health pursues the rational avoidance of risk in the unquestioned pursuit of health as the ultimate demonstration of the care of the self,

it arguably diminishes by degree as diseases become diversified and combine with one another (Foucault [1973] 2003). In embodying an Apollonian figure of rationality and restraint, discourses built on the neo-liberal subject cannot allow for the Dionysian elements of irrationality and passion which nonetheless are present in society (Nietzsche, [1872] 1995), or account for creatures such as Dostoevsky's underground man who declares:

'It is indeed possible and sometimes positively imperative... to act directly contrary to one's own best interests. One's own free and unfettered volition, one's own caprice, however wild, one's own fancy, inflamed sometimes to the point of madness – that is the one best and greatest good, which is never taken into consideration because it will not fit into any classification, and the omission of which always sends all systems and theories to the devil' (Dostoevsky, [1864] 2003, pp33-34).

And in projecting the ideal of alleged rational, disinterested and disembodied activity of logical argumentation into the social world itself, 'bioethics prescinds the messy details and attachments that give our lives meaning and vigor, the nagging contradictions that make us squirm and struggle, and the social, political and economic arrangements that simultaneously create and constrain us' (Hoffmaster, 2001, in López, 2004, p879). Given this, two specific action points will now be outlined, regarding this CTA agent's recommendations for how to constructively modulate the future development of the vaccines.

8.4.3. Specific points for action

The 'action' perspective of CTA adopted here raises deep questions regarding the 'value profile' of CTA agents. As Schot and Rip (1996) argue, CTA agents are intermediaries between a future world and the present situation, and therefore the issue of representation is pertinent. If there is no consensus a CTA agent has to accept responsibility for the goals embedded in its action, to 'choose sides' about the possibilities and risks of technological progress, and about the legitimacy of the public concerns and their spokespersons. However, on the basis of this research, whilst readily admitting its limitations, I would tentatively argue that across interviewees located in the US and UK, selected on the basis of their involvement with the development and potential use of the vaccines, in their capacity as policymakers, researchers, clinicians, industrial developers or regulators, and the focus groups conducted in the UK with potential users of the technology in their capacity as smokers, drug users and parents, there is a broad consensus that in the endogenous future outlined above, 'better' vaccines for addiction could be developed, that would contribute in some modest way to a 'better' society.

Further, these conclusions are backed up by the findings of a survey conducted by the Italian Ministry of Health's Project Cocaine Vaccine in 2006, in order to determine the acceptability of an anti-cocaine vaccine trial and the perception of efficacy of the anti-cocaine vaccine by professionals (n=170) and cocaine users (n=174) in Italy (Bertoncelli, 2006). Although not peer-reviewed, the results presented at the Verona Congress in 2006 indicated that both professionals and cocaine users were positive towards a clinical trial being conducted in Italy, because they saw the vaccine as potentially helpful in overcoming dependence and preventing relapse. However, the majority strongly emphasised that it would only be useful and effective if it was associated with psychological support and clear information was given to patients about the mechanism of action of the vaccine, in order to improve its efficacy and reduce unreal expectations of a 'magic' solution to dependence. With regard to prevention, the majority of both groups thought that vaccinating people who have never used cocaine in order to avoid future use would be ineffective, although, as found here, a minority of cocaine users were in favour of preventative vaccination for 'at risk' groups. These results are further supported by the findings of the UK Government's 2004 Brain Science, Addiction and Drugs Project, discussed in the introduction to this thesis, which again indicated broad support for the voluntary use of the vaccines within wider treatment regimes, and very limited support for their coercive or preventative use (Beddoes and Rudat, 2005). As such, I would argue that there is sufficient evidence to support the potential use of the vaccines in the treatment contexts outlined above, and to reject its prophylactic use. However, as an 'outsider' it must be acknowledged that this CTA agent encounters the problems of authority and credibility which can prevent them from being able to actually exert influence and effect change (Schot and Rip, 1996). What then are the specific points for action that I would seek to present to those with sufficient 'shadow of authority' to align the heterogeneity of actors' interests and strategies and guarantee a coherent direction?

(1) First, that the primary endpoints of the clinical trials should be realistically reassessed in line with the requirements of the users that are most positive towards them and most likely to benefit from their use. In short, that a statistical difference in reduction of drug use over the placebo group, in those that attain target antibody levels (high titer levels) be regarded as an appropriate primary endpoint to establish efficacy for the purposes of Phase II and III clinical trials. If such a reappraisal can be made, development should then continue to seek to increase the proportion of subjects who can attain the desired antibody levels; however due consideration should be given as to whether a vaccine which can generate target antibody levels in 38% of candidates, or more than 1 in 3 patients, as already achieved by the cocaine vaccine TA-CD, be deemed acceptable for the purposes of licensing, providing it meets appropriate safety and efficacy criteria as outlined above (i.e. a reduction in cocaine use). Research should also continue to

establish the possibility of extending the duration of target antibody responses for between 3-6 months, with the use of boosters; however design variations which provide an effective antibody blockade of shorter duration should not be considered to be without clinical utility, and should be deemed acceptable for the purposes of licensing, providing again that they meet appropriate safety and efficacy criteria. Further, however, if the vaccines as described are successfully licensed, Phase IV trials should ensure thorough and systematic evaluation, not only to detect rare or long-term adverse effects in wider populations, but also to establish the wider combinations of pharmacological and non-pharmacological therapies and social-situational contexts in which the positive and productive effects of the vaccines are most fully enabled.

(2) Second, that resources should not be directed to attempts to generate second generation variation designs with the potential to increase the duration of the vaccines beyond 6 months without boosters. Further, that if any serious political consideration is to be given to the potential prophylactic use of the vaccines, it should be done in tandem with the inclusion of more formal and representative public engagement, before socio-technical commitments become entrenched, with a clear understanding of the objectives of the engagement and transparent processes indicating how the outcomes will be used (Kluver *et al*, 2000).

Although it may be politically difficult to modulate the development of the technology according to these recommendations in the socio-historic context of the US, due to the lobbying efforts of pressure groups, a lack of societal backing and other barriers, it is possible that they could be successfully reoriented in the UK, with its historic acceptance of harm reduction measures. In Dec 2005 an article in the Times reported that Xenova, the British company that owned TA-CD prior to Celtic, had been invited to give a presentation to officials from the (then) Department of Trade and Industry, DTI, the Department of Health and the Home Office, who were reportedly taking a close interest in the American trials. They quoted a DTI source as saying: 'Xenova were invited to tell us about their US experience, but the real reason for the meeting was to find out why the vaccine wasn't being trialled in the UK and work out what we could do about it' (Carr-Brown and Leake, 2005). If such is true, then I would argue that there is a normative argument to be made for political authorities in the UK to step in and seek to trial the vaccines here in order to enable their potential progression onto the market, and that perhaps there is also the political will to do so.

Although the spin-off and start-up companies that have taken cocaine immunotherapies through their early stages have frequently emphasised the vast market potential for such products as seen in Chapter 3, if we remove from these estimates the use of the vaccines coercively or

preventatively, and acknowledge that, as seen with naltrexone, many cocaine users in treatment will not want to take the vaccine, the potential population characteristics are likely far less desirable in terms of number or purchasing power. Indeed, the lack of large-scale investment interest in the cocaine vaccine necessary to take it through Phase III clinical trials can be said to indicate the reservations held by 'Big Pharma' towards the commercial worth of this product (Chalk, 2006). In times of austerity and cutbacks it is perhaps not realistic to expect the UK government to support and subsidise large scale clinical trials in this area, as NIDA have sought to do in the US; however, as Schot and Rip (1996) outline, the creation of a future government procurement program that creates an assured market for the technology, should it meet the specified requirements, could also have a technology forcing effect. Although it has not been the focus here, I would make a similar argument in favour of a government procurement programme for monoclonal and catalytic immunotherapies for cocaine overdose, where again the relatively small number of patients combined with their lack of purchasing power can be seen to act as a big deterrent to large-scale pharmaceutical investment. Although the specific technological variations of these would need to be developed through further study with user requirements and the societal environment of usage; however, should they be successfully aligned, there would be the added potential for passive immunotherapies to be used as an adjunct to active vaccination in drug treatment, either sequentially as a means to provide an immediate supply of antibodies as a bridge to long term treatment, or in tandem as a means to address the variability of human response to active vaccination.

The question of whether a similar argument can, or should, be made in relation to a government procurement programme for the nicotine vaccine is, I would suggest, less compelling; not on the grounds of a personal assessment of nicotine addiction as less problematic for some people than cocaine addiction, but on the basis of market potential. About 20% of the adult population in the UK and the US smoke (Ash, 2011; CDC, 2011), and over 70% state they wish to quit (CDC, 2011; Thyrian *et al,* 2008), as such the smoking cessation market was estimated to be worth over $1.6bn in 2009 (VisionGain, 2010). Both Nabi and Cytos found pharmaceutical giants willing to fund Phase III clinical trials in return for a slice of the (large) profits on the horizon. Nabi may yet fail, but it represented an extremely compelling risk-reward for investors, and if the primary clinical endpoints for active nicotine vaccines are similarly reassessed, companies developing them are not likely to be short of willing risk takers.

8.5. CONCLUSION: A 'POST-ADDICTION' POSTSCRIPT

Schot and Rip (1996) acknowledge that CTA agents will act to some extent from their own perspectives and interests, but emphasise that there should always be an argument in terms of anticipation, societal learning, reflexivity, and goals at a meta level that justifies the agent's orientation and strategy. I reflected on my own when asked to locate my work in a primary discipline during my viva, and I finally situated it within critical public health. Essentially I regard this thesis as a critique of contemporary public health discourses which, by philosophically prioritising a conception of the neo-liberal individual, have placed questions of social reform and regulation outside the legitimate remit of medicine and public health. As Perdiguero *et al* (2001) have argued, by modelling risk factors to explain illness and disease on the basis of individual behaviour and genetics, but ignoring the broader settings of the interactions and meanings of these factors, a preventative discourse has developed that often dismisses further consideration of the interconnected economic, social, cultural and political conditions of human life. Consequently, this leads policy makers to develop micro-policies that address specific diseases at an individual clinical level, and deflects attention from the wider relationship between social and economic structures of inequality and health (Berridge, 2003). If such a critique is taken seriously and if this thesis has convinced the reader that the contemporary 'drug problem' and the dominant biomedical model of addiction need not be conceptualised as they currently are, then it begs us to question whether there are indeed better ways to conceptualise the current 'drug problem', and if so, how this can be achieved.

Levine (1978) argues for a 'post-addiction' model of drug and alcohol problems, based in part on developing critiques of the medical model of deviance in general, which rather than focusing on the interaction between individual and drug, directs attention to the relationship between the individual and the social environment. He provides a charmingly clear and practical example around drunk driving, where in place of taking an individualist perspective and viewing drink drivers as those who have lost their ability to 'manage' in the world because of drink, we focus, instead, on the interaction between social life and transportation.

'If drinking is "normal" activity, then perhaps the phenomenon of drunken drivers is not a drinking problem, but a transportation problem. Indeed, if one thinks about it, we live with a bizarre system of transportation: In order to get from one place to another people are required, at all hours of the day and night, to execute high-speed manoeuvres, through a maze of obstacles, with a ton of machinery. There would, of course, be serious opposition to a redefinition of the problem of drunken drivers as a transportation problem – from automobile companies, for example. As was true at the beginning of the 19th century, developing a new model of alcohol problems would necessarily be part of a reformulation of social problems in general. Thus even if a new paradigm or model does emerge, it will have to compete and coexist with the addiction

perspective for a long time – just as, for the last 200 years, the addiction model has had to compete and coexist with the pre-addiction view' (Levine, 1978, p166-167).

I would argue that such a post-addiction model would not replace the need for perspectives which seek to modulate the biologically reinforcing effects of drugs where an individual experiences a sense of loss of control and willingly seeks help from the medical profession. The role that drugs take in helping and hindering people as they navigate these 'liquid times' (Bauman, 2007) is multiple and complex, and the approaches necessary to help people to overcome problems they may experience as a result of such use must be necessarily diverse. To fail to acknowledge the benefits that biologically oriented approaches can bring would be to deny the reality of the experiences of many of those involved in this research. Nor should it be taken as an attack on the AA model of abstinence, since, as Levine (1978) acknowledges, the proliferation of Twelve Step groups bears testimony to the continued effectiveness of organisational methods which direct attention to the interaction between the individual and the deviant activity to help the individual to stop being deviant.

However, there is great value to be gained from moving away from conceptions of drug use and addiction in which the absence of drugs is idealised in ways that foreclose the space for talking about other approaches to public health and social good (Campbell, 2007). The co-existence of a post-addiction model of drug use could help to draw political attention and resources to alternate ways of conceptualising and managing the role of psychoactive drugs in contemporary society more widely. In particular it could force us to admit that drug use can be a serious health risk, but that the global drug prohibition regime, driven by ideology and political convenience, has arguably become a counterproductive failure, which both marginalises and stigmatises people who use drugs but do no harm to others, and disproportionately increases the harms experienced by those that are most socially and economically disadvantaged (GCDP, 2011; Transform, 2009). In this age of neo-liberalism, political rhetoric is rife with the language of libertarian paternalism and policies which nudge us in the direction of the purportedly objectively derived collective good. But with the development of vaccines that have the potential to change the landscape of both drug treatment and prevention, I would argue that it is time to overcome the short term horizons of the electoral cycle and enter into an open debate on shared cultural values and the role of drug use within this, and to embark on robust experimentation and evaluation of harm reduction, decriminalisation and legal regulatory policies that may help us achieve these.

9. APPENDICES

9.1. ADVERTISEMENTS, FOCUS GROUP SERIES 1

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

PARTICIPANTS NEEDED FOR A FOCUS GROUP ON VACCINATIONS FOR ADDICTION

As part of a social science PhD research project at the University of York I am conducting a series of focus groups on the public perception of vaccines for drug addiction, which prevent users from experiencing the 'high' normally associated with drug use.

The purpose of the study is to understand the attitudes and perspectives of parents on the development of 'vaccines' against drug addiction for children. However, please be assured you do not need any prior knowledge as you will be given information during the group.

To take part in the study you need to be:

- Aged 18 years or above and be either
- A parent or legal guardian of a child or children under 16 years old

You will need to participate in one discussion group with up to 5 participants. It will take up to 2 hours of your time and refreshments will be provided. The focus group will be recorded but participants are guaranteed anonymity and confidentiality. To thank you for your time and any expenses incurred you will receive a £10 Boots voucher. The next group will take place:

[TIME AND PLACE]

If you are interested in taking part, or would like more information, please call, email or text and I will get back to you with more details.

Abbi Hobbs, PhD Research Student, Science & Technology Studies Unit, University of York, Y010 5DD
Tel: 07876 770161 or Email: adh501@york.ac.uk
Web: http://www.york.ac.uk/depts/soci/research/reshobbs.htm

9.2. ADVERTISEMENT, FOCUS GROUP SERIES 2

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

PARTICIPANTS NEEDED FOR A FOCUS GROUP ON VACCINATIONS FOR ADDICTION

As part of a social science PhD research project at the University of York I am conducting a series of focus groups on the public perception of vaccines for drug addiction, which prevent users from experiencing the 'high' normally associated with drug use.

The purpose of the study is to understand the attitudes and perspectives of smokers on the development of 'vaccines' for nicotine dependence. However, please be assured you do not need any prior knowledge as you will be given information during the group.

To take part in the study you need to be:
- Aged 18 years or above and be either
- A current smoker OR to have ceased smoking within the last five years

You will need to participate in one discussion group with up to 5 participants. It will take up to 2 hours of your time and refreshments will be provided. The focus group will be recorded but participants are guaranteed anonymity and confidentiality. To thank you for your time and any expenses incurred you will receive a £10 Boots voucher. The next group will take place:

[TIME AND PLACE]

If you are interested in taking part, or would like more information, please call, email or text and I will get back to you with more details.

Abbi Hobbs, PhD Research Student, Science & Technology Studies Unit, University of York, Y010 5DD
Tel: 07876 770161 or Email: adh501@york.ac.uk
Web: http://www.york.ac.uk/depts/soci/research/reshobbs.htm

9.3. ADVERTISEMENT, FOCUS GROUP SERIES 3

THE UNIVERSITY of York

PARTICIPANTS NEEDED FOR A DISCUSSION GROUP ON COCAINE VACCINES

Please note this is not a therapeutic group, I am interested in your views and perspectives as users of cocaine who are outside of treatment facilities. All participants are guaranteed anonymity and confidentiality.

The discussion groups will take place in [PLACE] in April 2008. Travel expenses will be reimbursed. If you are interested in taking part please see my website or contact me for more details.

Abbi Hobbs
Science & Technology Studies Unit
University of York
Y010 5DD, UK
Office: +44 (0)1904 433577
Mobile: 07876 770161
Email: adh501@york.ac.uk
http://www.york.ac.uk/depts/soci/research/reshobbs.htm

9.4. ADVERTISEMENTS, FOCUS GROUP SERIES 4

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

SOCIAL SCIENCE STUDY ON VACCINATIONS FOR ADDICTION

Research study on the perspectives of people with drug dependency on the development of vaccines for addiction

A discussion group is being conducted as part of a sociological research project on the development of vaccines for drug addiction.

The purpose of the study is to understand the attitudes and perspectives of people with drug dependency on the development of vaccines for addiction. You do not need any prior knowledge to take part, you have been asked because of your personal experience with drug use and treatment.

The study will consist of participation in one discussion group with up to 6 participants and will involve approximately 2 hours of your time. I will be running two groups at [PLACE] on **Tuesday 9th October**. The first group will run from **2pm until 4.15pm** and will be aimed at those on TPI, the second group will run from **5.30pm until 7.45pm** to allow those at Daycare to participate. Both groups will be run downstairs in the basement, by myself, Abbi, and a colleague of mine from the University of York, Sarah.

The focus group will be recorded but all identifying information will be removed and participants are guaranteed full anonymity and confidentiality. Participants will be given a £10 Tesco Voucher to thank them for their time. Please put down your name below if you are interested in taking part and I will come and speak to you about it. If more than 10-12 people wish to take part I will pick at random!

Thank-you!

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

SOCIAL SCIENCE STUDY ON VACCINATIONS FOR ADDICTION

Research study on the perspectives of people with drug dependency on the development of vaccines for addiction

Thank-you to all those who put their names down, however I can only have 6 people per group so I have selected all three women who put their names down, and picked men at random. Those selected are listed below. To say thanks to those who volunteered and were not picked I will leave some crisps and chocolate in the communal room!

For those selected: Both groups will take place on **Tuesday 9th October**. The first group will run from **2pm until 4.15pm** and the second group will run from **5.30pm until 7.45pm**. You will be given a fifteen minute break in the middle and will be given your £10 Tesco voucher at the end of the group. Refreshments will be available so please come down fifteen minutes before the group starts to help yourself to these.

I need all those selected to fill in an informed consent sheet so please ensure you see me sometime today and I will go through the form with you. I will stay at work till I have seen everyone, but those at Daycare please come see me as soon as you get back.

Thank-you!

9.5. RESEARCH PARTICIPANT INFORMATION SHEET, FOCUS GROUP SERIES 1

Research Participant Information Sheet

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

You are being asked to participate in a discussion group about the development of vaccines for addiction. It is being conducted by Abbi Hobbs, as part of a PhD in Sociology at the University of York. The aim of this research study is to examine the current development of vaccines for drug addiction and the ways in which they might be used in the future. Please read all the following information, and discuss any questions you may have with Abbi, before deciding whether to participate in this study.

You do not need any prior knowledge of drug use, addiction or these new treatments to take part; you have been asked to participate because of your personal experience as a parent.

Study procedures

The discussion group you are being asked to participate in will involve up to 5 participants and will take approximately 2 hours of your time. The study will take place at [TIME, DATE] in [VENUE, TOWN] and will be conducted by Abbi Hobbs from the University of York. Refreshments will be provided.

The group will involve a discussion about your experience in making medical and other decisions on behalf of your child(ren). It will also cover your opinions and perspectives on drug use and the development of vaccines for addiction, and in particular their possible use in children before they have begun to use drugs. However, please be assured you do not need any prior knowledge as you will be provided with materials, such as newspaper cuttings and case studies, during the group. The session will be audio-recorded and transcribed.

Confidentiality and anonymity

You are guaranteed complete confidentiality and anonymity if you decide to participate in this discussion group. Identifying comments such as names and places made during the group discussion will be erased from the audio-recording and will not appear in the transcript. In addition, you are asked to keep in confidence information that identifies or could potentially identify other participants and/or their comments.

Storage and dissemination of data

The audio recordings will only be heard by the researcher, Abbi Hobbs and a few others directly involved in the research project such as her supervisor, Nik Brown and possibly a transcriber. They will be retained for five years, as demanded by University regulations and will be stored on the researcher's password protected computer. After this period the recordings will be destroyed.

The transcript of the group will be stored in the UK DATA Archive, as required by the researcher's funding body, the Economic and Social Research Council. While other persons will have access to this material no identifying information about you will be contained in the transcript. The findings from this study will form a part of the researcher's PhD and may also be published, or used in presentations, however, they will not contain any identifying information about you.

Freedom to refuse or withdraw

Participation in this study is entirely voluntary. While there are no direct benefits to you from participation in the study, it may aid others in understanding how this new technology can best be used to help people with drug dependencies. If you decide to take part in the study you can withdraw at any time without reason or prejudice and, should you wish, you can also withdraw any data you have supplied to date. However if you have any questions regarding this or any aspect of this study or the information you have been given, please contact the principal investigator, Abbi Hobbs.

Reimbursement

In appreciation of your time given to this session and any expenses you have incurred, you will be given a £20 Boots Voucher at the end of the session.

Informed Consent

The researcher is legally required to obtain voluntary informed consent from you, in order to protect your rights. This procedure ensures that you have read the information given to you above and understand what the study entails and have voluntarily agreed to participate.

If, after having read this information sheet and speaking to the principal researcher (Abbi Hobbs) about any questions or queries you may have you decide to participate, the researcher will ask you to sign a form stating that you voluntarily agree to participate in this study. This is done in order to protect your rights as a research participant, and ensures that you have been provided with enough information to make an informed decision about whether to participate. A copy of this form will be given to you at the same time as this information sheet.

Ethical approval

I would like to assure you that this study has been reviewed and received ethics clearance by the Graduate Board of Studies, in the Department of Sociology at the University of York. However, should you have concerns resulting from your participation in this study, which you would prefer not to discuss with the principal investigator, please contact the Chair of the Graduate Board of Studies, Dr. Robin Wooffitt on: rw21@york.ac.uk.

Results of investigation

If you would like to be kept informed of the results of this study please let the researcher know or go to the researcher's web page which is updated regularly at:

http://www.york.ac.uk/depts/soci/research/reshobbs.htm

You will be given a copy of this information sheet to keep.

9.6. RESEARCH PARTICIPANT INFORMATION SHEET, FOCUS GROUP SERIES 2

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Participant Information Sheet

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

You are being asked to participate in a discussion group about the development of vaccines for addiction. It is being conducted by Abbi Hobbs, as part of a PhD in Sociology at the University of York. The aim of this research study is to examine the current development of vaccines for drug addiction and the ways in which they might be used in the future. Please read all the following information, and discuss any questions you may have with Abbi, before deciding whether to participate in this study.

You do not need any prior knowledge of drug use, addiction or these new treatments to take part; you have been asked to participate because of your personal experience with smoking.

Study procedures

The discussion group you are being asked to participate in will involve up to 5 participants and will take approximately 2 hours of your time. The study will take place at [TIME, DATE] in [VENUE, TOWN] and will be conducted by Abbi Hobbs from the University of York. Refreshments will be provided.

The group will involve a discussion about your experience with smoking and smoking cessation medications. It will also cover your opinions and perspectives on the development of vaccines for addiction, but you do not need any prior knowledge as you will be provided with materials, such as newspaper cuttings or case studies during the group. However, please be assured you do not need any prior knowledge as you will be provided with materials, such as newspaper cuttings and case studies, during the group. The session will be audio-recorded and transcribed.

Confidentiality and anonymity

You are guaranteed complete confidentiality and anonymity if you decide to participate in this discussion group. Identifying comments such as names and places made during the group discussion will be erased from the audio-recording and will not appear in the transcript. In addition, you are asked to keep in confidence information that identifies or could potentially identify other participants and/or their comments.

Storage and dissemination of data

The audio recordings will only be heard by the researcher, Abbi Hobbs and a few others directly involved in the research project such as her supervisor, Nik Brown and possibly a transcriber. They will be retained for five years, as demanded by University regulations and will be stored on the researcher's password protected computer. After this period the recordings will be destroyed.

The transcript of the group will be stored in the UK DATA Archive, as required by the researcher's funding body, the Economic and Social Research Council. While other persons will have access to this material no identifying information about you will be contained in the transcript. The findings from this study will form a part of the researcher's PhD and may also be published, or used in presentations, however, they will not contain any identifying information about you.

Freedom to refuse or withdraw

Participation in this study is entirely voluntary. While there are no direct benefits to you from participation in the study, it may aid others in understanding how this new technology can best be used to help people with drug dependencies. If you decide to take part in the study you can withdraw at any time without reason or prejudice and, should you wish, you can also withdraw any data you have supplied to date. However if you have any questions regarding this or any aspect of this study or the information you have been given, please contact the principal investigator, Abbi Hobbs.

Reimbursement

In appreciation of your time given to this session and any expenses you have incurred, you will be given a £10 Boots Voucher at the end of the session.

Informed Consent

The researcher is legally required to obtain voluntary informed consent from you, in order to protect your rights. This procedure ensures that you have read the information given to you above and understand what the study entails and have voluntarily agreed to participate.

If, after having read this information sheet and speaking to the principal researcher (Abbi Hobbs) about any questions or queries you may have you decide to participate, the researcher will ask you to sign a form stating that you voluntarily agree to participate in this study. This is done in order to protect your rights as a research participant, and ensures that you have been provided with enough information to make an informed decision about whether to participate. A copy of this form will be given to you at the same time as this information sheet.

Ethical approval

I would like to assure you that this study has been reviewed and received ethics clearance by the Graduate Board of Studies, in the Department of Sociology at the University of York. However, should you have concerns resulting from your participation in this study, which you would prefer not to discuss with the principal investigator, please contact the Chair of the Graduate Board of Studies, Dr. Robin Wooffitt on: rw21@york.ac.uk.

Results of investigation

If you would like to be kept informed of the results of this study please let the researcher know or go to the researcher's web page which is updated regularly at:

http://www.york.ac.uk/depts/soci/research/reshobbs.htm

You will be given a copy of this information sheet to keep.

9.7. RESEARCH PARTICIPANT INFORMATION SHEET, FOCUS GROUP SERIES 3

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Participant Information Sheet

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

You are being asked to participate in a discussion group about the development of vaccines for addiction. It is being conducted by Abbi Hobbs, as part of a PhD in Sociology at the University of York. The aim of this research study is to examine the current development of vaccines for drug addiction and the ways in which they might be used in the future. Please read all the following information, and discuss any questions you may have with Abbi, before deciding whether to participate in this study.

You do not need any prior knowledge of drug use, addiction or these new treatments to take part; you have been asked to participate because of your personal experience with cocaine.

Study procedures

The discussion group you are being asked to participate in will involve up to 5 participants and will take approximately 2 hours of your time. The study will take place at [TIME, DATE] in [VENUE, TOWN] and will be conducted by Abbi Hobbs from the University of York. Refreshments will be provided.

The group will involve a discussion about your experience with cocaine and other drug use. It will also cover your opinions and perspectives on the development of vaccines for addiction, but you do not need any prior knowledge as you will be provided with materials, such as newspaper cuttings or case studies to aid discussion, during the group. The session will be audio-recorded and transcribed.

You have been selected for this focus group on the basis of your drug use. To take part you need to meet the following criteria:

- Have used cocaine at least 25 times during your life-time;
- Have not followed any treatment aimed at modifying your use of cocaine in the last 2 years;
- Have used cocaine at least once in the 6 months prior to the date of this study;
- Have a structured everyday life: a job, are a student or have other kinds of legal economic resources and a permanent residence;
- Have not had any contact with social authorities due to your drug consumption;
- Be over 18 years of age.

Please note: If you would like any information about treatment for drug use please discuss this with the researcher who will be able to provide information about services in your area.

Confidentiality and anonymity

You are guaranteed complete confidentiality and anonymity if you decide to participate in this discussion group. Identifying comments such as names and places made during the group discussion will be erased from the audio-recording and will not appear in the transcript. In addition, you are asked to keep in confidence information that identifies or could potentially identify other participants and/or their comments.

Storage and dissemination of data

The audio recordings will only be heard by the researcher, Abbi Hobbs and a few others directly involved in the research project such as her supervisor, Nik Brown and possibly a transcriber. They will be retained for five years, as demanded by University regulations and will be stored on the researcher's password protected computer. After this period the recordings will be destroyed.

The transcript of the group will be stored in the UK DATA Archive, as required by the researcher's funding body, the Economic and Social Research Council. While other persons will have access to this material no identifying information about you will be contained in the transcript. The findings from this study will form a part of the researcher's PhD and may also be published, or used in presentations, however, they will not contain any identifying information about you.

Freedom to refuse or withdraw

Participation in this study is entirely voluntary. While there are no direct benefits to you from participation in the study, it may aid others in understanding how this new technology can best be used to help people with drug dependencies. If you decide to take part in the study you can withdraw at any time without reason or prejudice and, should you wish, you can also withdraw any data you have supplied to date. However if you have any questions regarding this or any aspect of this study or the information you have been given, please contact the principal investigator, Abbi Hobbs.

Reimbursement

In appreciation of your time given to this session and any expenses you have incurred, you will be given £20 in cash at the end of the session.

Informed Consent

The researcher is legally required to obtain voluntary informed consent from you, in order to protect your rights. This procedure ensures that you have read the information given to you above and understand what the study entails and have voluntarily agreed to participate.

If, after having read this information sheet and speaking to the principal researcher (Abbi Hobbs) about any questions or queries you may have you decide to participate, the researcher will ask you to sign a form stating that you voluntarily agree to participate in this study. This is done in order to protect your rights as a research participant, and ensures that you have been provided with enough information to make an informed decision about whether to participate. A copy of this form will be given to you at the same time as this information sheet.

Ethical approval

I would like to assure you that this study has been reviewed and received ethics clearance by the Graduate Board of Studies, in the Department of Sociology at the University of York. However, should you have concerns resulting from your participation in this study, which you would prefer

not to discuss with the principal investigator, please contact the Chair of the Graduate Board of Studies, Dr. Robin Wooffitt on: rw21@york.ac.uk.

Results of investigation

If you would like to be kept informed of the results of this study please let the researcher know or go to the researcher's web page which is updated regularly at:

http://www.york.ac.uk/depts/soci/research/reshobbs.htm

You will be given a copy of this information sheet to keep.

9.8. RESEARCH PARTICIPANT INFORMATION SHEET, FOCUS GROUP SERIES 4

Research Participant Information Sheet

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

You are being asked to participate in a discussion group about the development of vaccines for addiction. It is being conducted by Abbi Hobbs, as part of a PhD in Sociology at the University of York. The aim of this research study is to examine the current development of vaccines for drug addiction and the ways in which they might be used in the future. Please read all the following information, and discuss any questions you may have with Abbi, before deciding whether to participate in this study.

You do not need any prior knowledge of drug use, addiction or these new treatments to take part; you have been asked to participate because of your personal experience with drug use and treatment.

Study procedures

The discussion group you are being asked to participate in will involve up to 6 participants and will take approximately 2 hours of your time. The study will take place at [TIME, DATE] in [VENUE, TOWN] and will be conducted by Abbi Hobbs from the University of York, with the help of a colleague from the University of York, Sarah Woodhall from the Department of Health Sciences. Refreshments will be provided.

The group will involve a discussion about your opinions and perspectives on the development of vaccines for addiction. You may also be asked to discuss your own experiences with drug use, although you need only share what you feel comfortable with. However, please be assured you do not need any prior knowledge as you will be provided with materials, such as newspaper cuttings and case studies, during the group. The session will be audio-recorded and transcribed.

Confidentiality and anonymity

You are guaranteed complete confidentiality and anonymity if you decide to participate in this discussion group. Identifying comments such as names and places made during the group discussion will be erased from the audio-recording and will not appear in the transcript. In addition, you are asked to keep in confidence information that identifies or could potentially identify other participants and/or their comments.

Storage and dissemination of data

The audio recordings will only be heard by the researcher, Abbi Hobbs and a few others directly involved in the research project such as her supervisor, Nik Brown and possibly a transcriber. They will be retained for five years, as demanded by University regulations and will be stored on the researcher's password protected computer. After this period the recordings will be destroyed.

The transcript of the group will be stored in the UK DATA Archive, as required by the researcher's funding body, the Economic and Social Research Council. While other persons will have access to this material no identifying information about you will be contained in the transcript. The findings from this study will form a part of the researcher's PhD and may also be published, or used in presentations, however, they will not contain any identifying information about you.

Freedom to refuse or withdraw

Participation in this study is entirely voluntary, and does not comprise part of your treatment regime. While there are no direct benefits to you from participation in the study, it may aid others in understanding how this new technology can best be used to help people with drug dependencies. If you decide to take part in the study you can withdraw at any time without reason or prejudice and, should you wish, you can also withdraw any data you have supplied to date. However if you have any questions regarding this or any aspect of this study or the information you have been given, please contact the principal investigator, Abbi Hobbs.

Reimbursement

In appreciation of your time given to this session and any expenses you have incurred, you will be given a £10 Tesco Voucher at the end of the session.

Informed Consent

The researcher is legally required to obtain voluntary informed consent from you, in order to protect your rights. This procedure ensures that you have read the information given to you above and understand what the study entails and have voluntarily agreed to participate.

If, after having read this information sheet and speaking to the principal researcher (Abbi Hobbs) about any questions or queries you may have you decide to participate, the researcher will ask you to sign a form stating that you voluntarily agree to participate in this study. This is done in order to protect your rights as a research participant, and ensures that you have been provided with enough information to make an informed decision about whether to participate. A copy of this form will be given to you at the same time as this information sheet.

Ethical approval

I would like to assure you that this study has been reviewed and received ethics clearance by the Graduate Board of Studies, in the Department of Sociology at the University of York. However, should you have concerns resulting from your participation in this study, which you would prefer not to discuss with the principal investigator, please contact the Chair of the Graduate Board of Studies, Dr. Robin Wooffitt on: rw21@york.ac.uk.

Results of investigation

If you would like to be kept informed of the results of this study please let the researcher know or go to the researcher's web page which is updated regularly at:

http://www.york.ac.uk/depts/soci/research/reshobbs.htm

You will be given a copy of this information sheet to keep.

9.9. RESEARCH PARTICIPANT STATEMENT OF INFORMED CONSENT FOR FOCUS GROUPS

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Participant Statement of Informed Consent

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

I have read the information presented in the information letter about the discussion group being conducted by Abbi Hobbs from the University of York. I have had the opportunity to ask the researcher any questions related to this session, to receive satisfactory answers to my questions, and any additional details I wanted. I am aware that I may withdraw from the session without penalty at any time by advising the researcher of this decision. I understand that the group will be audio recorded and that a copy of the transcript may be stored in the UK data archive. In appreciation of my time given to this session I am aware that I will receive a [enter amount and form, e.g. £20 Boots Voucher] at the end of this session.

This project has been reviewed by, and received ethics clearance from the Graduate Board of Studies, in the Department of Sociology at the University of York. I understand that if I have any comments or concerns resulting from my participation in this study, I may contact the Chair of the Graduate Board of Studies, Robin Wooffitt, at: rw21@york.ac.uk. With full knowledge of all foregoing, I agree, of my own free will, to participate in this session and to keep in confidence information that could identify specific participants and/or the information they provided. I will receive a copy of this document for my records.

Name of Participant:	Name of Researcher:
Signature of Participant:	Signature of Researcher:
Date:	Date:

9.10. RESEARCH PARTICIPANT REIMBURSEMENT RECORD FOR FOCUS GROUPS

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Participant Reimbursement Record

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

Payment received	Name of Participant	Signature of Participant
.....	.....	.....
.....	.....	.....
.....	.....	.....
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FGS1: £20 voucher each and additional £10 voucher for childcare if necessary
FGS2 and FGS4: £10 voucher
*FGS3: £20 Cash**

Name of Researcher: .....

Signature of Researcher: .....

Date: .....

*N.B. As agreed by Graduate Board of Studies during ethical approval, see Chapter 2.

9.11. GENERIC FOCUS GROUP SCHEDULE

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Focus Group Schedule

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

Date	
Time	
Location	
Facilitator	Abbi Hobbs
Series and group composition	
Number of participants	
Male/ Female ratio	

Checklist

- ☐ No. x black thick markers
- ☐ 1 x flip-over
- ☐ 2 x post-its
- ☐ 1 x copy script for facilitator
- ☐ 1 x copy case studies for participants
- ☐ No. x compensation for expenses
- ☐ 9 x name tags
- ☐ 1 x voice recorder + batteries
- ☐ 1 x microphone
- ☐ 1 x back up device and microphone
- ☐ No. x participant information sheets
- ☐ No. x informed consent documents
- ☐ 1 x participant payment sheet

Arrival of participants [TIME]

- A quarter of an hour before the start, the participants enter
- Participants can take refreshments
- Go through participant information sheet and retain for future reference
- Ask if anyone has any questions
- Ask participants to sign informed consent and retain for future reference
- Ask participants to wear name badge

Start of the meeting and introduction (15 minutes) [TIME]

- The facilitator opens the meeting and welcomes everyone
- Facilitator introduces herself and explains the subject and aim of the meeting. Emphasise NOT WORKING FOR PHARMACEUTICAL COMPANY
- Facilitator clarifies the programme using the flipchart:

"After the introduction, we will first discuss your [state drug use, children etc.]. After that, we will discuss what vaccines for addiction are before looking at a number of questions/issues around these vaccines by way of examples. We will conclude with a discussion about your main perspectives and opinions. We will be using various materials such as post-it's and a flip-over chart to help in structuring the group and to make sure everyone gets their turn."

- [IF] THERE WILL BE A QUICK BREAK HALF WAY THROUGH MEETING [STATE TIME]
- IF GROUP NEEDS TO BE SHORTER (1.5 HOURS) REMOVE BREAK
- Legitimate participant's right to manage discussion – "*if you tend to get off the track, someone will usually pull the group back to"; "I'll jump in if I have to, but usually one of you takes care of that for me."*
- (NB. For Series 4, emphasise not part of daycare/ group therapy sessions. Also format was more 'hands-on' using more post-its and interactive materials to sustain attention and make information more accessible. Materials were read out by facilitator or one of the participants who volunteered as not all participants were literate)

"This meeting is about the development of vaccines for drug addiction. You were all invited to take part in this group because [state why selected, e.g. personal use of cocaine, parent etc.]. I'm not trying to teach you anything, rather want to hear and learn from your experiences. I'm researching addiction and what different groups think about it, and also looking at different treatment programmes for addiction, but without talking to people who [have used drugs/ are trying to stop/ are parents] I couldn't understand what different user groups might think about them, so your experiences and views are really important to me. Specifically I'm looking at the development of a new type of treatment which works like a vaccine and prevents the user from feeling the 'high' associated with the drug, and potentially it could also be used before a person has ever even used a drug, but we'll come back to this later."

- Clarify group rules
- Please respect others privacy by not repeating what hear in group without permission
- Speak clearly and not over one another
- Mobiles turned off or on silent
- Welcome to question other people's opinions but please be respectful
- Stress it is confidential and when the research is written up it will be anonymous
- Ask people to only share what they feel comfortable with
- Ask if there are any questions

Clarify that the recorder is being turned on.

Exercise 1: Round Robin (5 minutes) [TIME]

- The participants introduce themselves to the group in turn, say name and something about themselves [how many children/ drug use etc] to get everyone to say something so can recognise voice, ensure use names frequently throughout group.

Exercise 2: Background (10 minutes) [TIME]

- Introductory questions specific to group, use of post-its to ensure everyone says something and encourages response. Use prompting questions such as *"Does anyone else feel differently?" "Has anyone had a different experience?"*

Exercise 3: Introduce vaccines using newspaper article (15 minutes) [TIME]

- Use folder with questions/materials specific to group.

Exercise 4: Examine relevant issues using case study 1 (15 minutes) [TIME]

- Use folder with questions/materials specific to group.
- **OPTIONAL**. If discussion is proceeding well and time is limited use one case study (BSAD) only.

Exercise 5: Examine relevant issues using case study 2 (20 minutes) [TIME]

- Use folder with questions/materials specific to group

Exercise 6: Summary and Concluding remarks (10 minutes) [TIME]

- Clarify most important issues for people.
- Close group and thanks participants for coming.
- Remind them how they can be kept informed of results if interested.
- Give participants reimbursement.

9.12. FOCUS GROUP MATERIALS FOR SERIES 1

Routine childhood immunisation programme
Each vaccination is given as a single injection into the muscle of the thigh or upper arm.

When to immunise	Diseases protected against	Vaccine given
Two months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b (Hib) Pneumococcal infection	DTaP/IPV/Hib and Pneumococcal conjugate vaccine (PCV)
Three months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b (Hib) Meningitis C (meningococcal group C)	DTaP/IPV/Hib and MenC
Four months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b (Hib) Meningitis C (meningococcal group C) Pneumococcal infection	DTaP/IPV/Hib and MenC and PCV
Around 12 months	*Haemophilus influenza* type b (Hib) and meningitis C	Hib/MenC
Around 13 months	Measles, mumps and rubella (German measles) Pneumococcal infection	MMR and PCV
Three years and four months or soon after	Diphtheria, tetanus, pertussis and polio Measles, mumps and rubella	DTaP/IPV or dTaP/IPV and MMR
Girls aged 12 to 13 years	Cervical cancer caused by human papillomavirus types 16 and 18	HPV*
13 to 18 years old	Tetanus, diphtheria and polio	Td/IPV

* Human papillomavirus vaccine
This vaccine was introduced into the routine immunisation programme in September 2008.
For more information, visit www.nhs.uk/hpv.

For more information visit www.immunisation.nhs.uk

Questions to consider

- Which of these have your children had?
- Are there any they haven't had?
- How did you feel about your children getting vaccinated?
- What things about any of the vaccines concerned you?

HPV - the big facts

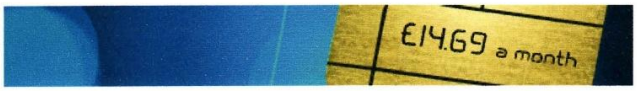
The new HPV vaccine for 12- to 13-year-old, Year 8 girls, that protects against cervical cancer

- Cervical cancer is caused by a virus – the human papillomavirus (HPV for short)
- The virus is spread during sexual activity with someone who is infected with the virus
- The virus infects the entrance to the womb – the cervix
- Mostly the virus is killed by the body's immune system – but not always
- If the virus stays in the body it can cause cervical cancer – sometimes many years later
- There's now a vaccine that can stop the virus causing cervical cancer – the human papillomavirus vaccine or HPV vaccine for short
- The vaccine needs to be given before someone starts having sex because having it after won't get rid of the virus if it has already infected the cervix
- There are several types of human papillomavirus that cause cervical cancer. The vaccine only prevents two of them so it is essential that women go for cervical screening tests when they are older. These tests pick up anything unusual in the surface of the cervix that might lead to cancer
- Having the HPV vaccine at school will protect young girls against cervical cancer later in life

Questions to consider

- Have you heard of the HPV vaccine?
- What are your initial thoughts on the HPV vaccine?

The Independent: Children to get jabs against drug addiction



THE INDEPENDENT

July 25, 2004

Children to get jabs against drug addiction

By Sophie Goodchild and Steve Bloomfield

Ministers consider vaccination scheme. Heroin, cocaine and nicotine targeted

A radical scheme to vaccinate children against future drug addiction is being considered by ministers, The Independent on Sunday can reveal.

Under the plans, doctors would immunise children at risk of becoming smokers or drug users with an injection. The scheme could operate in a similar way to the current nationwide measles, mumps and rubella vaccination programme.

Childhood immunisation would provide adults with protection from the euphoria that is experienced by users, making drugs such as heroin and cocaine pointless to take. Such vaccinations are being developed by pharmaceutical companies and are due to hit the market within two years.

The Department of Trade and Industry has set up a special project to investigate ways of using new scientific breakthroughs to combat drug and nicotine addiction.

A national anti-drug immunisation scheme is one of the proposals being put forward by the Brain Science, Addiction and Drugs project, an expert committee of scientists appointed by the Government earlier this year.

Professor David Nutt, a leading government drugs adviser who sits on the committee, told the IoS that anti-drug vaccines for children are likely to be among the panel's recommendations when it reports next March.

Professor Nutt, head of psychopharmacology at the University of Bristol and a senior member of the Advisory Council on the Misuse of Drugs, said: "People could be vaccinated against drugs at birth as you are against measles. You could say cocaine is more dangerous than measles, for example. It is important that there is a debate on this issue. This is a huge topic - addiction and smoking are major causes of premature death."

According to the Government's own figures, the cost of drug addiction - through related crime and health problems - to the economy is £12bn a year. There is a strong incentive for the Government to find new ways to halt spiralling addiction. Last week, the IoS revealed that cocaine use had trebled in Britain with increasing numbers of users switching to highly addictive crack cocaine.

Questions to consider

- What are your initial thoughts on vaccines for drug addiction?
- Do you think a vaccine against addiction is the same as the current nationwide measles, mumps and rubella vaccination programme?
- How does it compare to the HPV vaccine?
- What benefits/ drawbacks might there be from a national programme of vaccination?
- What benefits/drawbacks might there be from only vaccinating children 'at risk' of becoming smokers or drug users?
- Does it make any difference whether the vaccine is for a legal drug or an illegal drug?

BSAD Foresight Case Study: Nadia and Harjap

Nadia and Harjap have a beautiful baby boy, Sam. He's the spitting image of his mum and everything about him is perfect – at least, everything they can see. He's 18 months old today, Wednesday, 26 March 2025. Time to get the results of his addiction check. Nadia's great grandfather had smoked, until he died at 60, and she wants to make sure that they protect Sam from things that he can't control. So they had him tested for addiction.

They've already had the test done – the doctor had Sam's gene chip, with his individualised genetic information. Today, they're going to get the results. They log on to the clinic site and go through the security checks – iris scans and voice recognition – including Sam's. It's so much better like this – you don't want to have to sit in a crowded waiting room surrounded by people from your neighbourhood, who will naturally be nosy.

The doctor comes on screen. He's smiling – this is reassuring. But to Nadia's dismay, he says that the test results are positive. Sam's genes show a predisposition to addiction. This doesn't mean he'll inevitably become an addict, of course – but then there are so many temptations out there and you never know what might happen in the future. Smoking's illegal now, but you can still do it if you know where to look and there are campaigns to legalise it again, since the advances in cancer detection and treatment.

To be on the safe side, the doctor recommends that Nadia and Harjap get Sam vaccinated. This would mean that a particular range of drugs he takes in the future won't reach or affect his brain. Of course, the doctor cautions, this only works against the specific drugs covered by the vaccine. He reminds them that there's always someone out there developing new substances – and that there's a lot of money to be made in discovering something that the vaccination doesn't work against. So he also suggests that Nadia and Harjap keep a close eye on Sam as he grows up, watching for signs of those bad old great-grandfather genes – and bring him back for his booster – and possibly introduction to a new vaccine – when he's 8 years old and again at 13.

Questions to consider

- Is the overall situation believable? Why/why not?
- What are your views on this situation?
- Who benefits? How do they benefit?
- Who might not benefit? Why?
- Who should make decisions regarding vaccination of the child?
- How concerned are you that your child(ren) will become addicted to drugs?
- Do you think the vaccine would be effective?
- What more would you want to know about the vaccine?

Summary:

- Do you think there is a need for vaccines for addiction?
- If the vaccine did become available, what issues would you think about when deciding whether or not to give your child the vaccination?

9.13. FOCUS GROUP MATERIALS FOR SERIES 2

Questions to consider

- When did you start smoking? Can you remember the situation?
- How long have you been smoking for since?
- How many do/did you smoke?
- In what circumstances do/did you smoke/ not smoke?
- What are the main effects of smoking/ not smoking?
- What's the longest you've been without a cigarette in the last year? What you were doing?
- Would you say you wanted to keep smoking? Why/ why not?
- If you would like to stop, what difficulties are you facing?
- If you have stopped smoking, what helped you to quit?

STRUGGLE
COPE

The initial few days without any nicotine are often the hardest part of going smokefree, as this is when you are fighting the physical addiction. Nicotine replacement products can help you get past this. You use them in the early stages. After the nicotine cravings pass, you'll find it much easier to overcome the mental side of the habit.

You can get lots of different types of Nicotine Replacement Therapy (NRT) – and they work. NRT doubles your chances of successfully going smokefree by helping you manage your withdrawal symptoms. Because it goes into your body differently to nicotine from cigarettes, it's much less addictive. NRT does not contain tar, poisons or carbon monoxide the way cigarettes do, so it doesn't cause cancer.

You can get a prescription for NRT, or buy it over the counter, and follow the instructions on the packet. It's suitable for most adults, but if you have a heart or circulatory condition, or are on regular medication, you should get the OK from your doctor. Likewise if you are pregnant, you should ask your doctor or midwife before using NRT.

WHAT NEXT?
Choose the product that is best for you.

1. GUM
Chew the nicotine gum gently and then park it in the side of your mouth. The nicotine is then absorbed through the lining of your mouth.

2. PATCHES
Nicotine patches work well for most smokers and can be worn around the clock (24 hour patches) or just during the day (16 hour patches).

3. INHALATOR
Much like a plastic cigarette, the inhalator releases nicotine vapour which gets absorbed through your mouth and throat. If you miss the hand to mouth aspect of smoking these may suit you.

4. MICROTABS
These small tablets contain nicotine and dissolve when you place them under your tongue.

5. LOZENGES
Lozenges are sucked slowly to release the nicotine and take about 20-30 minutes to dissolve.

6. NASAL SPRAY
The spray delivers a swift and effective dose of nicotine through the lining of your nose.

As well as NRT, there are other products available on prescription that do not contain nicotine that can help you go smokefree, such as:

ZYBAN (NOT SHOWN)
Zyban (Bupropion hydrochloride) is a treatment which changes the way that your body responds to nicotine. You start taking Zyban 1 to 2 weeks before you quit and treatment usually lasts for a couple of months to help you through the withdrawal cravings.

CHAMPIX (NOT SHOWN)
Champix (Varenicline) works by reducing your craving for a cigarette and by reducing the effects you feel if you do have a cigarette. You set a date to stop smoking, and start taking Champix tablets 1 or 2 weeks before this date. Treatment normally lasts for 12 weeks.

TO FIND OUT MORE ABOUT NRT, SPEAK TO YOUR STOP SMOKING ADVISOR, OR ALTERNATIVELY ASK YOUR LOCAL GP OR PHARMACIST.

20

Questions to consider

- Have you heard of any of these medications?
- Have you tried any of them?
- What are their benefits/ disadvantages?
- What other things have you tried to help you stop smoking?
- What do you think makes support to stop smoking effective/ not effective?

Could this jab cure smokers? | Mail Online

Click here to print

Mail Online

Could this jab cure smokers?

A new anti-addiction vaccine could be the answer for smokers who lack the willpower to quit for good, scientists said today.

The same vaccine might help cocaine users overcome their addiction, they believe. It may even be possible one day for parents to have their children immunised against future dependency on cigarettes or drugs.

The vaccine works by stopping addictive substances, such as nicotine and cocaine, from entering the brain and stimulating the reward centres that generate cravings.

Trials are at an early stage, but they are already showing promising results. The vaccine has been shown to be safe and well-tolerated in the case of both smokers and cocaine users.

Tests on cocaine users have gone one stage further and indicated a strong immune response.

Dr Campbell Bunce, head of cellular immunology at Xenova Research, the Cambridge-based company developing the vaccine, said: "You can imagine it being used by parents of adolescents, who might want their children to be protected against a drug-taking habit.

"That is something with ethical considerations that we would have to consider." Cocaine users reported that the immunisation reduced the sense of euphoria they felt after taking the drug.

So far, the nicotine trials had not progressed beyond checking doses and evaluating safety. The next stage will be to measure antibody levels in the blood of vaccinated smokers.

Dr Campbell described the research today at the start of the British Association Festival of Science, which is taking place at the University of Salford.

He said he did not envisage the vaccine stamping out cravings for cigarettes straight away. Nor would it alleviate the withdrawal symptoms associated with giving up smoking, such as anxiety and depression.

But the vaccine could help to ensure that people who quit never take the habit up again. "Often an ex-smoker will relapse at a party, in a moment of weakness," said Dr Campbell. "Hopefully, the presence of these antibodies will reduce the hit of the cigarette and that desire for another cigarette will be significantly blunted."

One possible concern, he said, was that people might be tempted to smoke more to get the same "buzz" they were used to. It was not yet known whether this would happen.

Producing a vaccine against nicotine or cocaine is difficult because the molecules are so small they tend to be ignored by the immune system. For this reason, the experimental vaccine combines the chemicals with proteins the immune system can recognise.

Antibodies then stick on to the molecules, making them too large to pass through the natural barrier between the blood and the brain.

http://www.dailymail.co.uk/health/article-195300/Could-jab-cure-smokers.html?printi... 22/05/2009

Questions to consider

- What are your initial thoughts on vaccines for nicotine addiction?
- What benefits do you think it would have?
- What disadvantages do you think it would have?
- Do you think it would be effective?
- Do you think people would smoke more to overcome the vaccine?
- Are they similar to other smoking cessation medications?
- What ethical considerations do you think there might be?
- What more would you want to know about the vaccine?

The Independent: Children to get jabs against drug addiction

THE INDEPENDENT

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Questions to consider

- What are your initial thoughts?
- Do you think a vaccine against cocaine addiction is the same as the current nationwide measles, mumps and rubella vaccination programme?
- What benefits might there be from a national programme of vaccination?
- What drawbacks might there be?
- What benefits might there be from only vaccinating children 'at risk' of becoming cocaine users?
- What drawbacks might there be?
- Does it make any difference whether the vaccine is for a legal drug or an illegal drug?

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Questions to consider

- Is the overall situation believable? Why/why not?
- What are your views on this situation?
- Who benefits? How do they benefit?
- Who might not benefit? Why?
- Do you think people can have a predisposition to addiction?
- Should a parent be able to decide whether or not to have their child vaccinated against nicotine addiction?
- Does it make any difference whether the vaccine is for a legal drug or an illegal drug?
- What more would you want to know about the vaccine?

Summary

- Do you think there is a need for vaccines for addiction?
- If the vaccine did become available, what issues would you think about if you were offered it?

9.14. FOCUS GROUP MATERIALS FOR SERIES 3

Questions to consider

- When did you first use cocaine? What was the situation?
- How long have you been using for since?
- How often do you use?
- How do you use cocaine? Snort/ smoke/ inject?
- Do you use it with other drugs?
- Where do you get it from?
- What do you spend on cocaine?
- In what circumstances do you use/ not use?
- Who do you use/ not use with?
- What is your period of heaviest use?
- Have you not used for one month or longer since beginning use?
- What are the main effects of use/ abstinence?

- Do you still remember your opinion of cocaine before you first used?
- Has this changed since you started to use?
- Do you have a preferred national policy regarding cocaine use?

BBC NEWS

Cocaine vaccine 'stops addiction'

A vaccine which can help cocaine addicts break their addiction has been developed by a UK pharmaceutical company.

Trials carried out in the US showed almost half of those given the TA-CD vaccine, developed by Xenova, were able to stay off the drug for six months.

The vaccine does not stop the craving for cocaine, but will stop addicts experiencing a high when they take it.

The company says this prevents the people becoming re-addicted.

> " **If their underlying issues aren't addressed, people may move on to another drug** "
> Drugscope spokeswoman

In the study, the TA-CD vaccine was compared with a dummy version.

David Oxlade, chief executive of Xenova, told BBC Radio 4's Today programme: "This is the third study in the US that we are reporting on today, and it shows that almost half the addicts were able to stay cocaine-free for six months.

"That is a quite remarkable position."

Antibodies

Mr Oxlade added: "The vaccine for cocaine addicts works in very much the same way a regular vaccine works.

"The reason cocaine addicts can take the drug for years without mounting any sort of immune response is because the drug has very small molecules."

He explained that the vaccine is created by attaching the cocaine to a large protein molecule which is used to stimulate the body's immune system to produce antibodies that recognise the drug.

Mr Oxlade added: "It stops the cocaine from being able to get across from the blood into the brain, which is where you get the high and, of course, where you get the addiction.

"If somebody takes the vaccine as part of a programme in a drug centre and after a month or so is out and takes another dose of cocaine, they won't get the high and they won't get the re-addiction."

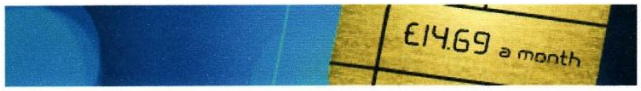
He said it was possible that addicts would simply switch to another drug, but said evidence from three US trials showed that only happened in a small number of cases.

A spokeswoman for Drugscope told BBC News Online: "This is a really interesting study. It's clear that the vaccine seems to be working well for some cocaine addicts.

Questions to consider

- When did you start smoking? Can you remember the situation?
- What are your initial thoughts on vaccines for cocaine addiction?
- What benefits do you think it would have?
- What disadvantages do you think it would have?
- Do you think it would be effective?
- Do you think people would swap to another drug?
- What ethical considerations do you think there might be?
- What more would you want to know about the vaccine?

The Independent: Children to get jabs against drug addiction



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Questions to consider

- What are your initial thoughts?
- Do you think a vaccine against cocaine addiction is the same as the current nationwide measles, mumps and rubella vaccination programme?
- What benefits might there be from a national programme of vaccination?
- What drawbacks might there be?
- What benefits might there be from only vaccinating children 'at risk' of becoming cocaine users?
- What drawbacks might there be?
- Does it make any difference whether the vaccine is for a legal drug or an illegal drug?

BSAD Foresight Case Study: Mark and Jen

Mark came home late on Friday nights. He'd joined a local reading group and after some great debates – which sometimes got heated – the group went down to the local pub and had a couple of drinks, just before closing. He felt relaxed and happy afterwards and knew that Jennifer would be pleased to see him.

As he got closer to home, he started to hear the sirens and see the flashing lights. He wasn't really worried – there was always something going on and it wasn't usually serious – just a few kids messing around. But when he turned the corner, he realised the ambulance and police bikes were outside his house and he began to run. He was glad he'd only stayed for a pint – his head was clear.

Jen stood in the front doorway, lit by the hall light, wrapped in a pink blanket. He could see Tom's little face, looking sleepy and confused, peeking out from underneath. Jen was pale and shaking. He wrapped her in his arms. 'What happened?' 'Those kids … I knew something should have been done about them … I told you, I told the Neighbourhood Watch, I told the community health and safety people – but nobody took any notice … I've seen it before, with the kids at school, but nobody listened.'

She was right. She'd often come home and talked about the change in behaviour of some of the kids in her class, after they'd had been on a course of cocaine blockers. They'd been used in the States first and seemed to work well, with limited side-effects. Her pupils had changed from being antsy and aggressive and unable to concentrate, to focused and attentive young people. The amount of crime in the school had gone down, the layabouts hanging round the school gates drifted away and exam results started to improve.

Mark always worried about the ethics. It's not right to give young people these things, just to make them into good little pupils, he'd said. Jen said she didn't care – she just wanted her family to be safe in its own home – and she worried about him walking home from the pub on Friday nights.

Cocaine use had grown and grown. More and more people were using crack and heroin. It was a terrible social problem. Education programmes didn't seem to have worked and it was people like them who suffered, people who didn't live in the big gated estates with the security, but in ordinary houses on ordinary estates. Her sister had got involved – gone out with a big dealer, led the high life for a while then been arrested and put on the treatment. It'd been all over the papers – Jen was really embarrassed and angry with her sister. She knew that if Tom ever got involved in drugs when he was older, she'd want him to take the treatment rather than hit the headlines like her sister had.

She'd done a bit of work, looking at how the vaccines worked. Basically, they just stopped whatever drug people were taking from working. The vaccine plugged up the bit of their brain that the drug targeted so the drug couldn't get a hold of it. This meant people could take it but they wouldn't feel any effects. Well, it was more complicated than that, but that's what she'd understood from looking at the website of the companies that made the treatment. The vaccine had been around for a long time but it had taken a while to get the law through that allowed it to be used.

Doctor, parent and school all had to agree for them to be used on the kids. But it was automatic for criminals – people in prison or on community sentences. As soon as anyone arrested was tested positive for illegal drugs, they were given the vaccine, and being released meant agreeing to boosters on a regular basis. You went on a register and if you didn't show up for your appointment, they picked you up and you went back to prison. Mark said not enough was known about the vaccines and that it wasn't fair to make this kind of thing compulsory – it took people's

choices away and the children would suffer in the end. Jen thought that if people made such poor choices then they had to take the consequences. It was safer for the rest of society.

She'd felt safe too. Then this had happened. People hadn't listened to her and she'd been the one who suffered. They hadn't harmed her – just told her to shut up while they took everything they could carry and sell. The look in their eyes told her that she shouldn't make a fuss. Now, the house was a wreck. They'd be on the treatment soon though – that thought comforted her. 'Stop thinking about it.' Mark hugged her tight. 'You were right, I was wrong. Sorry.'

Questions to consider

- Is the overall situation believable? Why/why not?
- What are your views on this situation?
- Who benefits? How do they benefit?
- Who might not benefit? Why?
- Should parents/ schools be able to decide whether or not to have children vaccinated against cocaine addiction?
- Should the vaccine be compulsory for anyone?
- What more would you want to know about the vaccine?

Summary

- Do you think there is a need for vaccines for addiction?
- If the vaccine did become available, what issues would you think about if you were offered it?

9.15. FOCUS GROUP MATERIALS FOR SERIES 4

Why do you think you started using drugs?

- Write down three reasons why you think you started using drugs. Use a separate piece of paper for each of these.
- In turn, each read these aloud to the group.
- After listening to each other, place all these reasons on the table and each select one reason, either your own or someone else's which best represents to you why people in general use drugs.
- Do you all agree with the six factors?
- Do you think this applies to all drugs, or only specific ones? For example, do you think the same applies for alcohol use/ nicotine use?

What does the word

‘addiction’

mean to you?

Addiction is a lack of will-power	Addiction only applies to drugs
Addiction is something that can happen to anyone	Addiction is a disease
Addiction is psychological	Addiction is inherited

Agree Disagree

What is addiction?

- You have each been given one statement about addiction, read it out in turn and say whether you agree with it or not. Why?
- Place it on the table next to either the 'agree' or 'disagree' sign. Other group members may disagree with your decision, if so try to find out why. You can move if after it you wish to. If you are unsure whether you agree or disagree then place it in the middle.
- Are there any more statements you would like to add, that you either agree or disagree with?
- When you have finished, try and come up with a group definition of addiction.
- Do you all agree with it? Why? Why not?
- Who do you think would agree/ disagree with your definition?

What do you think of medications for addiction?

- Write down all the medications you've been given during treatment for your addiction, these can include medication for sleeping and depression if you think they were connected to your drug use.
- Read them out then put them in the middle.
- Explain why you were given each of them, and how you felt they helped or didn't help you
- When everyone has done this, as a group select the three most helpful medications and the three least helpful medications, and explain why you think this.

What do you think of treatment more generally?

- What other forms of help have you been given during your treatment to try and get better?
- What did you find helpful or unhelpful? Why?

Why do you think people often lapse/ relapse during treatment?

- Go round the table, say whether you have ever lapsed or relapsed?
- What do you think the difference is?
- What happened?
- Why do you think it happened?

BSAD Foresight Case Study: Mark and Jen

In the area where Jen and Mark lived there had been a major problem with drug-related crime, as there was in so many inner-city areas these days. New strategies of intervention and education had been tried, but nothing had seemed to have much effect. In the last year though a vaccine had been developed for addiction.

Jen had done a bit of work, looking at how the vaccines worked. Basically, they just stopped whatever drug people were taking from working. The vaccine plugged up the bit of their brain that the drug targeted so the drug couldn't get a hold of it. This meant people could take it but they wouldn't feel any effects. Well, it was more complicated than that, but that's what she'd understood from looking at the website of the companies that made the treatment. The vaccine had been around for a long time but it had taken a while to get the law through that allowed it to be used.

Now it was automatic for criminals – people in prison or on community sentences. As soon as anyone arrested was tested positive for illegal drugs, they were given the vaccine, and being released meant agreeing to boosters on a regular basis. You went on a register and if you didn't show up for your appointment, they picked you up and you went back to prison. Mark said not enough was known about the vaccines and that it wasn't fair to make this kind of thing compulsory – it took people's choices away. Jen thought that if people made such poor choices then they had to take the consequences.

Questions to consider

- What is your own experience of court-ordered treatment for addiction?
- What positive or negative effects do you think mandatory treatment has for a person's recovery? Why?
- Thinking about your own experience, what do you think would happen if a person was given a vaccine for either cocaine or heroin as part of a court-order?
- Do you think you would take higher doses of a drug to try and overcome the effects of the vaccine?
- If you were only given a vaccine for your drug of choice do you think you would swap to other drugs to get high?
- Do you think the positive and negative effects would be any different if they had voluntarily asked for a vaccine?
- What are your thoughts on whether it is fair to make a vaccine compulsory for drug addicts?
- Does it make any difference if the person has only broken the law in taking an illegal drug, compared to breaking other laws in addition?

What do you think of the vaccine as a treatment for addiction?

- Considering all that you have discussed, what are your thoughts on the vaccine?
- Would you consider having it if it became available? Why? Why not?
- What benefits do you think it would have?
- What drawbacks do you think it would have?
- What do you think would happen if the vaccine only reduced the effect of the drug, rather than stopping it completely?
- What difference do you think it might make if the vaccine worked against a single drug, or multiple drugs?
- If you could only be vaccinated against one drug, which one would it be? Why?
- In what ways do you think it's similar or different to the other medications you have taken?

What do you think of using the vaccine preventatively in children?

- Imagine you had been vaccinated against a particular drug when you were a child, what effects do you think it might of had?
- If you have children, would you consider getting them vaccinated against one or more drugs? Which ones? Why? Why not?
- Who should decide whether a child should be vaccinated against drugs? Parents? Government? Doctors? No-one? Why?
- Does it make a difference if the drug is a legal one, such as alcohol or nicotine? Why?

9.16. RESEARCH PARTICIPANT STATEMENT OF INFORMED CONSENT FOR INTERVIEWS

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Research Participant Statement of Informed Consent

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

You are being asked to participate in an interview about the development of active immunotherapies for drug dependence. It is being conducted by the principal researcher, Abbi Hobbs, as part of a PhD in Sociology at the University of York. The aim of this research study is to understand the way in which these vaccines are being shaped by new scientific knowledge, changing ideas about the nature of addiction, established policies and practices for drug treatment, and the potential social, ethical and regulatory concerns raised by their use.

Please read all the following information, and discuss any questions you may have with the researcher, before deciding whether to participate in this study.

- The interview will take up to 1 hour of your time and will be audio-recorded and transcribed. However, your name and identifying information, such as the name of your organisation will not appear in the transcript.

- The digital recording will only be heard by the researcher, Abbi Hobbs, her supervisor, Nik Brown and possibly a transcriber. It will be retained for five years, as required by University regulations and will be stored on the researcher's password protected computer. After this period the recording will be destroyed.

- The findings from this study will form a part of the researcher's PhD and may also be published, or used in presentations, however they will not contain any identifying information about you.

- Participation in this study is entirely voluntary. If you decide to take part in the study you can withdraw at any time without reason or prejudice and, should you wish, you can also withdraw any data you have supplied to date. However if you have any questions regarding this or any aspect of this study or the information you have been given, please contact the principal investigator, Abbi Hobbs.

- This study has been reviewed and received ethics clearance by the Graduate Board of Studies, in the Department of Sociology at the University of York. However, should you have concerns resulting from your participation in this study, which you would prefer not to discuss with the

principal investigator, please contact the Chair of the Graduate Board of Studies, Dr. Robin Wooffitt on 01904 433063 or email: rw21@york.ac.uk.

- If you would like to be kept informed of the results of this study please let the researcher know or go to the researcher's web page which is updated regularly at:

  http://www.york.ac.uk/depts/soci/research/reshobbs.htm

I confirm I have read the information presented above and have had the opportunity to ask the researcher any questions related to this research and any additional details I wanted. With full knowledge of all foregoing, I agree, of my own free will, to participate in this session. I will receive a copy of this document for my records.

Name of Participant:	Name of Researcher:
Signature of Participant:	Signature of Researcher:
Date:	Date:

9.17. GENERIC INTERVIEW SCHEDULE

THE UNIVERSITY of York

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Interview Schedule

Project Title:	Reconstructing addiction: A sociological examination of the development of vaccines for drug addiction
Project Code:	A0033501
Researcher:	Abbi Hobbs, Research Student, Department of Sociology, University of York, Heslington, YO10 5DD
Contact:	Email adh501@york.ac.uk, Tel: (01904) 433577
Supervisor:	Dr Nik Brown, Deputy Director SATSU, Department of Sociology, University of York
Date:	[Day/Month/Year]

BACKGROUND OF INTERVIEWEE

- Tell me a bit about your background, what brought you to the broad research area?
- Why were drawn specifically to research around nicotine/cocaine/alcohol/gambling addiction?
- In your words, what is addiction?
- (If say disease) Would you categorise it in the same way as other diseases?
- Drug addiction often conceptualised in policy discourse as contagious do you think this is a helpful analogy?
- Would you delineate between behavioural addictions such as gambling and drug addictions?
- If employed by industry – different to basic/university research in any way?
- If involved in clinical trials and research do you think much about regulatory approval? In terms of EMEA, MHRA, FDA etc?

IF NOT DIRECTLY INVOLVED IN VACCINE DEVELOPMENT

- Have you heard of the vaccines? What do you know about them?
- If not does it surprise you? What are your first thoughts?
- If yes when did you hear about them, can you remember what your first thought at the time?
- Similarities and differences to current medications – such as – for nicotine NRT and bubupropion, cocaine – sometimes disulfiram, methadone, buprenorphine (subutex)
- Vaccines normally for viruses, how did drug addiction come to be seen as amenable/ susceptible to treatment or prevention by same means?

IF DIRECTLY INVOLVED

- How did you come to be involved in vaccine development?
- What are the major advantages/ disadvantages of the technology?
- What have been the main hurdles to their development/ potential regulation?
- Similarities and differences to current medications – such as – for nicotine NRT and bubupropion, cocaine – sometimes disulfiram, methadone, buprenorphine (subutex)
- Vaccines normally for viruses, how did drug addiction come to be seen as amenable/ susceptible to treatment or prevention by same means?

END USE OF VACCINES

- Do you see a difference between prevention and treatment of addiction?
- How do you think it might be decided who is vaccinated? Currently addicted adults? Targeted adults? If prevention – universal, or targeted? How define 'at risk'?
- Do you see any difference between vaccines for cocaine and nicotine (or PCP etc)? Either more likely to readily accepted by scientific or medical community?
- Do you think the vaccines could be readily assimilated into existing drug treatment or would they necessitate a new way of doing things?
- Do you think they would be more likely/ more successful being used for prevention or treatment?
- From your perspective do you think they are likely to raise any concerns – social/ ethically/ regulatory/ clinically?
- Three key areas normally cited – stigmatisation and discrimination, parental right to vaccinate child against addiction, coercively under criminal justice proceedings – which most important?
- Technical/ scientific difficulties – overdose/ swap? How do you see these? Is there a need for a life-long vaccine?
- Is there a right to use drugs even when illegal to actually do so?

WIDER VIEWS ON DRUG TREATMENT AND POLICY

- Do you think about wider issues around drug policy? What kind of effect does your view of addiction have on your conception of the policies that surround drug use? Illicit/ free market?
- What think about current state of drug treatment, if you were deciding where to direct money would it be towards pharmacotherapy's or something else? Same for nicotine and cocaine?

9.18. CLIENT CONFIDENTIALITY AGREEMENT FOR TRANSCRIPTION

HireATypist
For All Your Typing & Transcription

HireATypist will adhere to the following wording. If required we will sign and send you a copy of this for your records.

Confidentiality Agreement

The parties to this agreement are Hire A Typist, whose office is situated at 29 Sydney Place, Lockerbie, Dumfriesshire, Scotland, DG11 2JB and Abbi Hobbs whose residence is situated at University of York, 4 Belmont Mews, Belgrave Road, Bingley, West Yorkshire, BD16 4NB.

HireATypist confirm that:

We will not divulge information howsoever learned about The Client's clients, The Client's associates or The Client's client's associates to the press or any party that may result in information being passed to the press in any country.

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J E Simeon 29/5/09.

Signed on behalf of HireATypist by

J E Simeon - Owner
HireATypist

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