THE EVOLUTION OF REGULATORY STRATEGIES IN RELATION TO NICOTINE PRODUCTS AND THEIR IMPLICATIONS FOR PRODUCT INNOVATION AND HARM REDUCTION

CATRIONA ROOKE, BA Hons., MRes.

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Abstract

The current "smoking epidemic" is a global problem for governments and organisations concerned with public health. Recently, this problem has been conceptualised as one of regulation. Within the tobacco control community, there has been growing concern that the division of regulatory responsibility for conventional tobacco products (i.e. cigarettes, cigars, pipe tobacco) and alternative modes of nicotine delivery (nicotine replacement therapy products such as gums, patches and inhalers) is having adverse effects on the innovation of new medicinal products and on providing smokers with acceptable alternatives to cigarettes, the most harmful and widely used nicotine product. The 'alternatives' are mainly regulated as pharmaceuticals; therefore, must reach safety standards comparable with those required for medications rather than being compared with the known harm caused by tobacco smoking. Whilst a number of commentary and position pieces have discussed this problem, there has been little empirical work on how the current UK regulatory set-up evolved and what impacts it has.

This research gap is addressed using semi-structured interviews and documentary analysis to analyse empirically the evolution and implications of divided regulatory responsibility for nicotine products in England. Adopting an actor-network theory approach, I investigate the actor-networks assembled around key non-human actors – tobacco and nicotine – focussing on developments from the 1970s until the present. In particular, I investigate the relationship between the regulatory regime and harm reduction ideas, and how they impact on the development of new medicinal nicotine products within the pharmaceutical industry. I underline the way that the regulatory regimes both shape and are shaped by the heterogeneous networks in which they are enmeshed. The thesis concludes by considering whether there are alternative approaches to regulation that would be more efficient and effective. I suggest that the regulation of recreational drug use is underpinned by 'deep conflicts in values' (Prosser 2006) and propose that further debate over the aims and limits of nicotine regulation is needed.

The thesis deals with developments up until and including the 30th of November 2010.

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Introduction

> "...the most dangerous and addictive nicotine products *[smoked tobacco]* remain only slightly regulated, in great disproportion to their hazard, and are freely available and widely used. Tobacco companies are also free to develop or modify, and bring to market, new smoked tobacco products and other tobacco derivatives with little regulatory control. By contrast, medicinal nicotine products, which are the safest source of nicotine, are generally subject to the highest levels of regulation since they are generally classified as drugs. This is almost certainly a major disincentive to new product development and innovation, and to market competition to create better and more effective cigarette substitutes. The present regulatory system also discourages innovation through the real or perceived likelihood that most effective smoking substitutes, which would almost certainly be more addictive than the present range of medicinal products, would be subject to even stricter controls on marketing and supply, or perhaps even prevented from coming to market." (Britton & Edwards 2008, p.441)

In a Lancet 'viewpoint' piece Professors John Britton and Richard Edwards (2008) outline the above inconsistency in the regulation of nicotine products. They argue that the safest nicotine products, 'medicinal nicotine', are regulated more stringently than smoked tobacco, the most 'dangerous and addictive'. Furthermore, they argue that this situation has consequences; it discourages the development of 'better and more effective cigarette substitutes' and leads to the:

> "Unnecessary perpetuation of current smoking by millions of people, especially in disadvantaged communities, and a continued epidemic of avoidable death and disability... most of the millions of smokers alive today will therefore continue to smoke tobacco, and half will die as a result" (2008, p.444).

In recent years, the issue of nicotine regulation has been high on the tobacco control agenda in the UK. The Royal College of Physicians (RCP), a leading voice on smoking and health issues, has written extensively about regulation (2000, 2002, 2007, 2008); which also is one of the campaigning public health charity Action on Smoking and Health's (ASH) key priorities. A number of articles written by well-known academics in the tobacco control field have appeared (e.g. Britton & Edwards 2008; Britton & McNeill 2001; Gilmore et al. 2008; Gray et al. 2005; McNeill et al. 2001; McNeill & White 1998; Page 1998; Sweanor 2000; Warner et al. 1997). This thesis takes the anomaly that Britton and Edwards (2008) highlight as its central problem: why are different nicotine products regulated differently, and what impacts does this have? I begin with a discussion about why tobacco use is a problem and the nature of the problem. I then outline the main focus of the thesis and the research questions, the approach I take to answer these questions and the structure of the thesis.

The smoking problem

According to the World Health Organisation (WHO):

> "Tobacco use is one of the biggest public health threats the world has ever faced. It kills more than five million people a year – an average of one person every six seconds – and accounts for one in 10 adult deaths. Up to half of current users will eventually die of a tobacco-related disease." (WHO 2010)

Smoking is seen as a global problem: cigarette smoking is increasing rapidly in developing countries and 80% of the world's smokers now live in low or middle income countries (World Bank 1999). Tobacco smoking has, for some time, been considered to be the biggest cause of avoidable death and disability in developed countries (Edwards 2004). In the European Union (EU) it is estimated that smoking kills over 650,000 people each year (McNeill & Godfrey 2004). Smoking prevalence varies from 16% in Sweden to 42% in Greece with an EU average of 29% (European Commission 2010). Smoking is often conceptualised in the public health literature as a four stage 'epidemic' in which the prevalence of smoking in men rises to between 50-80% (with women's prevalence rising later) remains stable and then begins to decline, followed by a corresponding rise and fall in smoking-attributable mortality three to four decades later (Lopez et al. 1994). The UK is considered to be in the later stages of this model. At the peak of the 'epidemic', in 1948, about 82% of men and 41% of women smoked tobacco (Wald & Nicolaides-Bouman 1991). Overall smoking prevalence fell from 45% in 1974 to 35% in 1982, and then continued declining more slowly (about 1% every 2 years) until 1994 when it levelled out at about 27%. Since 2000 smoking prevalence has been declining by about 0.4% a year (Robinson & Bugler 2010).

The 2004 report by the US Surgeon General concluded that: "Smoking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general" (US Department of Health and Human Services 2004, p.25). Tobacco smoking has now been positively associated with over 40 diseases: for most, the association is strong and viewed as causal (RCP 2007; US Department of Health and Human Services 2004). A prospective study of British doctors established that about half of smokers die prematurely from their habit, a quarter of these in middle age, and life expectancy is reduced on average by about 10 years (Doll et al. 2004)

The greatest impact of smoking on mortality is from lung cancer, ischaemic heart disease and chronic obstructive pulmonary disease (a clinical syndrome which

encompasses chronic bronchitis and emphysema) (RCP 2002). Smoking has also been linked to a number of other cancers including: throat and mouth, oesophageal, bladder, kidney, stomach, pancreatic, and leukaemia, as well as gastric ulcers and circulatory diseases, and a number of non-life-threatening diseases. Smoking during pregnancy has been linked to several problems including reduced birth weight and increased risk of 'placental abruption' (in which the placenta detaches from the wall of the uterus) (West & Shiffman 2007). There is evidence that 'passive smoking' causes a number of diseases including increasing the risk of developing lung cancer, ischaemic heart disease, chronic obstructive pulmonary disease and stroke in non-smokers (RCP 2007). Stopping smoking reduces the risk for all fatal disorders, although not to the same level as for people who have never smoked, and there is a clear relationship between the age of stopping smoking and the risk of dying prematurely (RCP 2007)

Currently[1], the overall prevalence of smoking among adults in the UK is 21%: more than ten million adults smoke. Differences in smoking prevalence between men and women have decreased since the 1970s and similar proportions now smoke. Smoking has declined in all age groups; however, since the early 1990s smoking has been highest amongst the 20-34 age group: currently 30% of 20-24 year olds and 27% of 25-34 year olds report that they smoke. The majority of smokers start before the age of 18. Smoking has been falling more rapidly in 'non-manual' groups since the 1970s and is now lower among households classified as professional and managerial (16%) than routine and manual (27%). Smoking prevalence also varies considerably between ethnic groups and by region of the UK, with a higher prevalence in Scotland and the north of England[2]. Smoking is, therefore, considered to be 'one of the most significant factors underlying the differences to be found in the health and life expectancy of the wealthiest and the poorest in our society' (DH 2010a, p.18). Smoking is estimated to cost the National Health Service (NHS) at least £2.7 billion a year in England (DH 2010b). Around 462,900 hospital admissions (5%) and 81,400 (18%) deaths among adults of 35

[1] The following account of adults' smoking prevalence (unless otherwise specified) is taken from the General Lifestyle Survey, formerly known as the General Household Survey, published by the Office for National Statistics. This is a national survey covering adults aged 16 and over living in private households in Great Britain. The most recent figures are from the 2008 report: *Smoking and Drinking among adults, 2008* (Robinson & Bugler 2010). It is based on a survey which ran from January to December 2008. Each year questions are asked about adults' smoking habits.

[2] Although, this does not take account of occupational group, which may explain some of the variation.

and over in England were estimated to be attributable to smoking in 2008/09 (The NHS Information Centre 2010). It is estimated that between 1950 and 2000 six million Britons died from tobacco-related diseases (Peto et al. 1994).

Smoking is also widely viewed as a problem of 'dependence' or 'addiction': 'a situation in which a drug or stimulus has unreasonably come to control behaviour' (RCP 2000, p.93). Tobacco dependence and withdrawal syndromes are classified as substance use disorders under the WHO International Classification of Diseases (ICD), and nicotine dependence and nicotine withdrawal are included in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM). Abstinence from smoking has been found to be associated with a set of symptoms – anxiety, restlessness, poor concentration, irritability and urges to smoke – that can be seen as the 'cigarette withdrawal syndrome' (RCP 2000). Evidence that nicotine replacement (e.g. with nicotine chewing gum) reduces the severity of cigarette withdrawal syndrome suggests that nicotine dependence is a major component of dependence on smoking. There is evidence that smokers maintain a relatively consistent nicotine intake, that failure to maintain this intake results in symptoms of nicotine withdrawal, and that the major psychological motivation to smoke is the avoidance of 'negative mood states' caused by withdrawal of nicotine (RCP 2000). Common to classifications for drug dependence are: difficulty in controlling the use of a drug, giving priority to drug use over other important obligations, continued drug use in the knowledge of harmful consequences and tolerance to the effects of the drug. Nicotine and smoking are deemed to meet the criteria for substance dependence (RCP 2000); however, the form of delivery is considered to be an important determinant of nicotine's addiction potential – cigarettes are considered to be particularly addictive (RCP 2000).

Around three quarters[3] of smokers would like to stop smoking altogether; however, just over half feel that it would be either very or fairly difficult to go without smoking for a whole day. Three-quarters of current smokers have tried to give up smoking in the past and about a quarter in the past year. Forty three per cent of smokers reported having

[3]Data on adults' smoking behaviour and attitudes are taken from the Office for National Statistics Omnibus Survey. The latest report is *Smoking-related Behaviour and Attitudes, 2008/09* (Lader 2009). This survey was carried out during September and November 2008 and February and March 2009 and sampled adults aged 16 and over living in private households in Great Britain.

sought some kind of advice or help for stopping smoking in the last year. In 2009 10,757,537 people in England set a quit date through the NHS Stop Smoking Services who offer support to help people quit smoking, including group therapy, one-to-one support and pharmacotherapy (The NHS Information Centre 2010).

What should be done about the smoking problem?

In the UK, a report on *Smoking and Health* published by the RCP in 1962 put forward proposals for government action on smoking:

i) More education of the public and especially school-children concerning the hazards of smoking
ii) More effective restrictions on the sale of tobacco to children
iii) Restriction of tobacco advertising
iv) Wider restriction of smoking in public places
v) An increase of tax on cigarettes, perhaps with adjustment of the tax on pipe and cigar tobaccos
vi) Informing purchasers of the tar and nicotine content of the smoke of cigarettes
vii) Investigating the value of anti-smoking clinics to help those who find difficulty in giving up smoking (RCP 1962)

For the most part, these remain the basis for current tobacco policy. 'Conventional', established tobacco control interventions include public information campaigns, health warnings, raising taxes, bans on the advertising and promotion of tobacco, restrictions on smoking in work and public places and help with quitting smoking (WHO 2008b; World Bank 1999). As John Britton pointed out in his preface to the 2007 RCP report: "Current national and international tobacco control policies focus, quite rightly, on measures that help to prevent people from starting smoking, and help existing smokers to quit" (RCP 2007, p.xi). As others note, these interventions focus on reducing demand (Borland 2003; Callard et al. 2005).

A number of commentators within tobacco control have more recently argued that not enough progress is being made in reducing the prevalence of smoking and that there is a need to go beyond the conventional measures discussed to consider 'supply side' interventions. Some (Borland 2003; Callard et al. 2005; Liberman 2003) suggest the problem lies with the production of tobacco by profit-maximising corporations and suggest the way that tobacco is sold needs to be altered. Borland (2003) argues for a model where companies would continue to manufacture products but they would be marketed by an agency with a mandate to reduce harm, whilst Callard et al (2005) suggest that tobacco should instead be supplied by non-profit enterprises. Khoo et al

(2010) make a case for phasing-in a total ban on tobacco by banning the provision of tobacco to any citizen born in or after a set year. Others underline the need for better tobacco product regulation. Gray & Kozlowski (2003) suggest that the modern cigarette is 'unnecessarily dangerous' and should be regulated to reduce toxicity, whilst Henningfield et al (2004) suggest it ought to be regulated to reduce attractiveness through gradual elimination of nicotine. The RCP (2000) argue that smokers continue to smoke cigarettes because they are addicted to nicotine; therefore, tobacco products ought to be subject to safety regulations that are consistent with other drugs and a co-ordinated regulatory framework should be established.

Raw (1997) suggests that a distinction ought to be drawn between the delivery device and drug delivered, and a shift made from the aim of reducing prevalence of tobacco use to reducing disease through product regulation: he underlines the need to establish a 'level playing field' for the regulation of all nicotine delivery products. Sweanor (2000) also observes that there is an 'exceedingly uneven playing field' for nicotine products, with the most harmful products subject to little regulation and the least hazardous stringently regulated, and suggests that nicotine regulatory systems need to be reformed to maximise the reduction in risk. The RCP (2007) also highlight this imbalance, suggesting that: "Given the huge differences in the proven or likely hazards of these products to individual and public health, this represents a substantial and illogical regulatory imbalance" (2007, p.180). They argue that this imbalance works against public health and, to encourage the development of improved nicotine delivery systems, a clear regulatory framework that assesses products in relation to health impact is needed. Warner, Slade and Sweanor (1997) make a similar argument about how the emerging 'nicotine maintenance market' might be shaped, whilst Warner et al (1998) highlight the need for a levelling of the playing field and discuss issues in bringing it about. Similarly, Gray et al (2005) argue for a long term, comprehensive nicotine policy that reduces the attractiveness and addictiveness of tobacco-based nicotine delivery systems and provides alternative sources of acceptable 'clean nicotine'.

Thesis focus, approach and structure

The thesis evolved out of this discussion about the regulatory imbalance for nicotine products. Ann McNeill, Professor in Health Policy and Promotion at the University of Nottingham, and Deborah Arnott, director of ASH, shared these concerns and had participated in discussions about how the regulation of nicotine products might be

improved. They felt that little progress was being made in these discussions and hoped that research into the development and effects of regulation might produce new ideas on this problem. They approached Robert Dingwall, then Director of the Institute for Science and Society at the University of Nottingham, to bring his knowledge of socio-legal approaches to regulation and social science research methods to the project.

The following research questions were formulated in order to investigate how this problem came about, what impacts it has and what might be potential solutions:

i. *How did different nicotine products come to be regulated in different ways: in particular, how did Nicotine Replacement Therapy (NRT) fall primarily within the scope of pharmaceutical regulation?*
ii. *Does the current approach to regulation:*
    a. *Impede the effectiveness of harm reduction goals?*
    b. *Constitute a barrier to the innovation of a greater variety of, and more effective, products?*
iii. *Are there alternative approaches to regulation that might be more efficient and effective?*

The scope and limits of this study are discussed in Chapter three; nevertheless it is necessary to make a few points here. Although the regulation of nicotine products has international, European and UK-wide dimensions (which will be outlined in detail in Chapter one), some, more recent, changes are applicable only to England and not the rest of the UK. Therefore, while some of what is covered in this thesis will have wider applicability, the decision was made to focus primarily on the situation in England. This study commenced in September 2007 and the collection of data was concluded by the end of May 2010. As with any study of current events, the situation under study is dynamic and has evolved during and after my research took place: for instance a new tobacco strategy was published by the Department of Health (DH) in February 2010 and the Medicines and Healthcare products Regulatory Agency (MHRA) launched a consultation on the regulation of nicotine products in the same month. More significantly, in May 2010 a new coalition government of Conservatives and Liberal Democrats took office, and in November 2010 published a white paper outlining their plans for public health (DH 2010b). In general, events or publications deemed significant to the topic of this study were included in the analysis; however as the data collection occurred prior to the change of government, the implications of this change will not be taken into account in the body of the thesis. The significance of current debates will be discussed in my conclusions.

Much has been written on the history of tobacco control (Goodman 1993; Lock et al. 1998; Wagner 1971) and, in particular, the discovery of the link between smoking and lung cancer (Berridge 2007; Brandt 1990; Doll 1999; Lock et al. 1998) and the subsequent policy response have been well explored (Berridge 2006, Berridge 2007; Feldman & Bayer 2004; Lock et al. 1998; Read 1996). Berridge (2007, 2006) suggests that accounts of the last half century have been dominated by 'activist' histories using tobacco industry documents that tell a story of 'denial and delay' (Glantz et al. 1998; Pollock 1999; P. Taylor 1984) and focus on US policy (Brandt 1990, Brandt 2007; Feldman & Bayer 2004; Rabin & Sugarman 1993; Studlar 2002; P. Taylor 1984). There have been fewer accounts focussing on the UK or of the period during which NRTs emerged (the 1970s and 80s), and there are especially few studies linking the development of NRTs into this history. There has been little empirical work on how the current UK regulatory set-up evolved and what impacts it has, especially on the availability and effectiveness of NRT treatment.

Read (1996) uses the idea of policy networks to explore the relationship between the British government and the tobacco industry in the UK, focussing on 'producer' and 'issue' networks. Virginia Berridge's (2007) *Marketing Health* is a detailed account of UK tobacco policy, which uses tobacco as a lens through which to examine the 'stages of change' in the discourse of public health during the latter half of the twentieth century. She suggests that the 'delay' of central government in the 1950s was in part located in an accommodation to the 'fundamental reorientation of public health' to lifestyle diseases and the new role for governments of 'persuading their citizens to alter their personal habits'. She describes the emergence of a 'new health activism' and new policy communities bringing science into a closer relationship with policy making (Berridge 2007, p.15). Berridge's account of the time during which nicotine gum was developed highlights the medicalisation of smoking and particularly the growing importance of addiction: "The rise of the concept of addiction to nicotine as a 'policy fact' signified the enhanced role of pharmaceutical interests, the role of treatment and of medicalised ideas." (2007, p.241) She also draws attention to the different networks in which different ideas about smoking were embedded and the changing positions of tobacco and nicotine: tobacco moving closer to illicit drugs and nicotine becoming seen as a medicine.

As outlined in the last section, a number of papers and reports within the public health field have raised the issue of regulatory imbalance. The majority of these are commentary or position pieces (e.g. Britton & Edwards 2008; Britton & McNeill 2001; Gilmore et al. 2008; Gray et al. 2005; McNeill et al. 2001; McNeill & White 1998; Page 1998; Sweanor 2000; Warner et al. 1997; RCP 2008). The Health Select Committee (House of Commons Health Committee 2000) took evidence on 'measures against smoking' in 1999. It reviewed the regulatory measures on tobacco and views of stakeholders on their effectiveness. However, there has been substantial change in regulatory regimes since this time. The RCP's *Protecting Smokers; Saving Lives* (RCP 2002) considers the views of parliament, the available resources for regulating tobacco in the DH and the European Union and compares these to the Office of Tobacco Control in Ireland and the UK food and medicines regulatory agencies. In *Harm Reduction in Tobacco Control* the RCP reviewed the evidence on the role of nicotine in smoking and the mechanisms of tobacco addiction in humans; the 'risk profiles' of smoked and smokeless tobacco products; the relationship between tobacco use and economic deprivation; and considered the existing regulations that apply to nicotine products and the ethical arguments for various interventions in the 'nicotine market'.

Science and technology studies and actor-network theory

Many of the themes that Berridge's work (e.g. 1998, 1999a, 2001, 2006, 2007) draws out – developments in various scientific disciplines and their changing importance for tobacco control and public health; the emergence of new concepts through which to conceptualise tobacco use; the changing relationship between science and policy for tobacco control – suggest that a science and technology studies (STS) approach could shed further light on, and bring new insights to, this situation. There are a number of technologies, substances and medico-scientific concepts that occupy a central place in this topic: cigarettes, NRTs, smokeless tobacco, nicotine, addiction. STS approaches have a common interest in examining the complexity inherent in carrying out scientific work or making and disseminating technologies. They investigate the impact of the social, economic and political on – and their interaction with – the scientific and the technical. In this thesis one particular variant of STS approach, actor-network theory (ANT), is adopted to investigate the research questions.

ANT is a strand of broader 'material semiotic' ideas in STS (others include the work of Donna Haraway 1991; Sheila Jasanoff's "co-production" 2004; and Andrew Pickering's "mangle of practice" 1995) that describe the:

> "...enactment of materially and discursively heterogeneous relations that produce and reshuffle all kinds of actors including objects, subjects, human beings, machines, animals, 'nature', ideas, organisations, inequalities, scale and sizes, and geographical arrangements" (Law 2007, p.1)

Key to the ANT approach is the concept of heterogeneous networks. The network metaphor highlights a relational approach to reality: the form and properties of entities come from their relation to other things and not because of essential qualities. The addition of heterogeneity emphasises that these networks of relations are made up of human, material and semiotic actors. Moreover, ANT emphasises the importance of 'following the actors' under study, tracing the relationships they make and understanding their concepts rather than imposing a predetermined framework. ANT is used in this study to trace the formation and transformations of the networks in which central actors such as cigarettes and NRTs are embedded.

Thesis structure

After a more detailed discussion of the current regulatory situation for nicotine products in Chapter one, Chapter two provides an overview of some of the key characteristics of ANT, introducing commonly used concepts as well as shifting emphases in ANT accounts. It begins to investigate how an ANT study might be carried out and raises some important problems associated with deploying ANT, such as how does one go about following the actors in practice? And how does one choose actors to follow? Chapter three begins by attempting to provide a working answer to some of the questions raised in the previous chapter. First I outline some of the key debates in qualitative research on ontology, epistemology and the position of different kinds of data, and try to locate ANT's position within these. I then discuss my approach to the question of how to utilise ANT. Initially I discuss this issue generally, then I move to on to provide an account of how this question was answered practically in my research design, collection and analysis of data.

Having set out the main preoccupations of ANT and how I plan to make use of it, Chapter four turns to my first research question of how different nicotine products came to be regulated in different ways, and in particular, how NRTs fell primarily within

the scope of pharmaceutical regulation. As well as tackling this question, it demonstrates more clearly and in practice the utility of ANT for this study. To do this I relate two main stories: firstly, I give a broad outline of the history of tobacco use and control; secondly, I narrow my focus and present a case study that investigates the development of nicotine gum and its emergence on the UK market as *Nicorette*. These two sections allow me to trace the translations that central actors such as tobacco, nicotine gum and nicotine have undergone and the relations they have been drawn into, and how these processes have impacted on the regulation of nicotine products. I then introduce and examine the concept of medicalisation to further develop an understanding of these translations.

The next two chapters turn to the effects of nicotine regulation. In Chapter five I continue tracing the growth of, and shifts in, the anti-tobacco coalition from the 1980s: the extension of control over cigarettes; the stabilisation of the concept of nicotine addiction and how this reshaped the tobacco control network. I then turn my attention to concept that is currently being deployed in an effort to further reshape the tobacco control network. I suggest that this concept, 'harm reduction', draws together and translates various discussions within tobacco control and has implications for how various nicotine products, particularly NRTs, are understood and circulate. This chapter explores the second research question on how the current approach to regulation impedes the effectiveness of harm reduction goals; however, it also reframes and inverts this question, asking how the harm reduction concept is shaping the tobacco control network. Chapter six builds on this discussion of harm reduction and moves on to consider the second aspect of research question two: does the current approach to regulation constitute a barrier to the innovation of a greater variety of, and more effective, products? It investigates the impact of harm reduction and regulation on product innovation. Having described the development of nicotine gum and its problematic and partial transformation into a medical product in Chapter four, this chapter picks up from the 1980s to examine the various ways the NRT assemblage has been translated and configured during the last three decades. It looks at the development of different types of NRT products; the changing ways NRTs have been controlled; their shifting enrolment in the treatment sector; and their changing position within the tobacco control community. I then examine the ways both the current

regulatory situation and the harm reduction concept impact on the development and distribution of new NRT products.

The final chapter shifts focus from examining the historical evolution and current impacts of the frameworks regulating nicotine products to explore the question: *'Are there alternative approaches to the regulation of nicotine that would be more efficient and effective?'* I move from describing the construction and shape of the networks around nicotine regulation to a consideration of how these networks might be reshaped. I consider how the future of tobacco/nicotine regulation is envisaged within the tobacco control community, and then contrast this with the way effective regulation is conceptualised within the regulation and governance literature. This chapter concludes by drawing attention to the gap between these literatures. Finally, to present my conclusions I begin by summarising the key findings of the thesis by focussing on four processes that I suggest have emerged as key as the thesis has unfolded: i) the un-black boxing of the cigarette; ii) the construction, packaging and extending through time and space (Prout 1996) of nicotine addiction; iii) the concept of medicalisation and the enrolment of medical networks; and iv) regulatory intervention and orderings. I then turn to the implications of this thesis for nicotine regulatory policy. I draw on Prosser's (2006) suggestion that regulation 'revolves around deep conflicts of values' to propose that further debate over the aims and limits of nicotine regulation is needed.

Before moving on to introduce ANT, it is necessary to give a clear picture of the current regulatory situation for nicotine products; therefore, the next chapter outlines what exactly nicotine products are and lays out the current status of their regulation in the UK.

Chapter One: Nicotine Regulatory Regimes

Having laid out the main problem that this thesis engages with, the questions it sets out to answer and the approach that it takes, it is necessary to provide a description of the regulatory regimes as they currently stand in England and introduce the objects these regimes control.

Types of nicotine product

Nicotine is an alkaloid found in the nightshade family of plants. It has a high toxicity: a 40-60 mg dose can be lethal for humans; however in low concentrations (1 mg) nicotine acts as a stimulant. Nicotine products include two main categories: tobacco and NRT (also called 'medicinal nicotine'). More recently products have been developed that fall outside these two categories.

These categories can be further divided according to how the nicotine is delivered – inhaled into the lungs, absorbed in the mouth, through the skin or sniffed into the nose. Tobacco products can be categorised by whether they are smoked (cigarettes, cigars, rolling tobacco) or smokeless (dry nasal snuff and oral moist tobacco, compressed tobacco products and chewing tobacco). Commercial tobacco is made from the leaves and other parts of the *Nicotiana tobaccum* plant. Cigarettes are made up of tobacco, with flavourings and other ingredients added, rolled in paper, usually with a filter. Moist snuff consists of fine particles of tobacco containing moisture, which are sometimes flavoured. It is used orally either by placing a pinch of tobacco or a small porous packet of tobacco (often referred to by its Swedish name: *snus*) between the cheek or lips and gum. Dry snuff is powdered tobacco, often containing flavour and additives, that is sniffed into the nose. Tablets of ground and compressed tobacco have recently been developed for oral use. Cigarette-like products[4] that heat tobacco to deliver nicotine, whilst claiming to deliver less tar and other toxins, are another recent innovation. NRTs are pharmaceutical products containing nicotine, but none of the other harmful substances in tobacco, that are intended to help people stop smoking. They include different forms such as gums, patches, 'inhalator', nasal spray, micro-tablets and

[4] Often referred to as 'potentially reduced-exposure products' or PREPs (see Institute of Medicine 2001) – here the term is used to refer to cigarette-like products that result in potentially decreased emissions of some toxicants.

lozenges. Other products include topical gels such as 'Nicogel', 'nicotine water' and 'electronic cigarettes'. The typical electronic or 'e-cigarette', according to the WHO: "Is made of stainless steel, has a chamber for storing liquid nicotine in various concentrations, is powered by a rechargeable battery and resembles a real cigarette. Users puff on it... it produces a fine, heated mist, which is absorbed into the lungs." (WHO 2008a)

Filter cigarettes are the most widely smoked type of tobacco in the UK, although the proportion of people smoking hand-rolled tobacco has increased since the early 90s (from 18% of men and 2% of women in 1990 to 38% of men and 20% of women in 2008). Pipe and cigar smoking have declined since the 1970s and now make up a very small proportion of smoking, with 3% of men using either (the percentages for women have been 'scarcely measurable' since 1978 (Robinson & Bugler 2010)). In the UK chewing tobacco is used almost exclusively by minority groups of South Asian origin (RCP 2007).

Regulatory regimes[5]

Oral snuff

The supply and sale of oral snuff, excluding chewing tobacco which was in common use among South Asians in the UK, was banned under the Consumer Protection Act 1987. European Council Directive 92/41/EC[6] banned the marketing of tobacco products for oral use, except those intended to be smoked or chewed, in Member States (except Sweden which negotiated an exemption when it joined due to an established tradition of *snus* use).

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[5] The RCP report on *Harm Reduction in Tobacco Control* (2007) and the ASH Law Guide (ASH 2010a) outline the regulation of tobacco products in some detail and this section draws heavily from these sources.

[6] The Tobacco for Oral Use (Safety) Regulations 1992 enacted this Directive, and the ban was retained in Directive 2001/37/EC. This Directive was challenged in the European Court of Justice by British American Tobacco over the proscription of descriptors such as 'mild' and 'light' and later by Swedish Match on the prohibition of the sale of tobacco for oral use; however, on 10 September 2002 and 7 September 2004 (respectively) opinion by the Advocate General declared provisions contained in the directive 2001/37/EC as valid.

Smoked and chewed tobacco products

Price

The price of cigarettes reflects the manufacturers' price, duty, tax and the retail margin. Duty and tax levels on tobacco products in the UK are set by the Treasury. The Finance Act 2001 sets out rates of duty on tobacco products. Tobacco products in Europe are subject to excise tax and value added tax. Tax in the UK is high relative to other countries. A recent EU Directive[7] updated EU rules on the structure and rate of excise duties on tobacco products. It is intended to bring the minimum excise duties on hand-rolled tobacco in line with those for cigarettes and narrow the differences between Member States' tobacco taxation levels.

Advertising and marketing

Advertising of 'a product consisting wholly or partly of tobacco and intended to be smoked, sniffed, sucked or chewed' is banned in the UK by the Tobacco Advertising and Promotion Act 2002. Under this act tobacco advertising on billboards, in print media, by direct mail and through sponsorship is prohibited[8]. The Tobacco Advertising and Promotion (Display) (England) Regulations 2010 prohibit tobacco advertising and displays at the point of sale in England (to come into force in 2011 for large shops and 2013 for all others).

Product regulation

The DH is responsible for regulating tobacco product content and design. Tobacco companies are free to bring new brands of tobacco to the market without reporting them to any regulatory authorities, although the Secretary of State must be notified of brands to be produced and discontinued, along with tar, nicotine and carbon monoxide (CO) yields and samples of new products for testing. There is no post marketing surveillance system. Tobacco additives in smoked tobacco are controlled by a voluntary agreement and the scrutiny of additives is undertaken by the DH and its Technical

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[7] Council Directive 2010/12/EU

[8] Directive 2003/33/EC later required Member States to prohibit the advertising and promotion of tobacco products with a cross border effect in the press and other printed publications, in radio broadcasting, in information society services, and through tobacco related sponsorship, including the free distribution of tobacco products.

Advisory Group. EU directive 2001/37/EC[9] on the manufacture, presentation and sale of tobacco products sets maximum yields for tar (10mg), nicotine (1mg) and CO (10mg) in cigarettes; requires the disclosure of ingredients for all tobacco products; requires that text such as 'light' or 'mild' or other signs that 'may mislead the consumer into the belief that such products are less harmful' be removed; stipulates that health warnings cover 30% of the front and 40% of the back of tobacco packaging; and enables Member States to add picture warnings to tobacco packaging[10]. The Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007 (Picture warnings) requires pictorial warnings that depict and explain the health consequences of smoking to be placed on the back of cigarette packs in the UK. The European Commission (EC) has recently consulted on possible revisions to this Directive as a response to diversification of the tobacco products market. The options outlined and their implications will be considered at greater length in Chapter seven. The EC Scientific Committee on Emerging and Newly Identified Health Risks recently reported on the 'addictiveness and attractiveness of tobacco additives' (2010) in order to better understand the issue prior to regulation.

Place and age of sale

The DH regulates where tobacco products can be sold in the UK. A license is not required so tobacco products can be distributed and sold from any retail outlet that is value added tax registered. The Protection from Tobacco (Sales from Vending Machines (England)) Regulations will prohibit the sale of tobacco from vending machines in 2011. Sale of tobacco to persons under 18 is prohibited in England and Wales by The Children and Young Persons Order 2007[11].

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[9] Which incorporates directives 92/41/EC banning the sale of oral snus, 89/22/EC and 92/41/EC on labelling and 90/239/EEC on tar levels, and was implemented by the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 in the UK. Yields of hand rolled tobacco are not included.

[10] Decision 2003/641/EC established 'rules for the use on tobacco packages of colour photographs or other illustrations to depict and explain the health consequences of smoking'.

[11] Which updates and amends the Children and Young Persons (Protection from Tobacco) Act 1991 in which the minimum age was 16.

Smoke-free places

The Smoke-free (Premises and Enforcement) Regulations 2006[12] prohibited smoking in 'enclosed or substantially enclosed' places that are open to the public or used as a place of work in England[13] and came into force on the 1st July 2007. The EC has also issued a recommendation on smoke-free environments[14].

Other products

The tobacco industry has not yet launched any of their novel cigarette-like products in the UK; moreover, it is not clear how they will be regulated, or by whom, if they are launched. Non-tobacco, recreational nicotine products that are currently available in the UK, such as e-cigarettes and Nicogel, come under consumer protection regulations only. The MHRA have recently consulted on whether to bring these products under the medicines licensing regime and the outcome is expected in early 2011. The details and implications of the consultation will be further discussed in Chapter seven.

The FCTC

The WHO Framework Convention on Tobacco Control (FCTC) is a global health treaty that commits countries to implement a range of tobacco control measures. The treaty requires parties to the convention to:

- Enact and undertake comprehensive bans on tobacco advertising, promotion and sponsorship;
- Ban misleading and deceptive terms on cigarette packaging such as "light", "low-tar" and "mild";
- Implement rotating health warnings on tobacco packaging that covers at least 30 percent (ideally 50 percent or more) of the display areas – this may include pictures or pictograms;
- Protect people from tobacco smoke exposure on public transport, and indoor work and public places;
- Adopt or maintain taxation policies aimed at reducing tobacco consumption; and

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[12] Under the Health Act 2006. It included exemptions for places where people live (such as hotels, care homes and prisons etc) and performances, and gave National Authorities power to make vehicles smoke free.

[13] Scotland implemented smoke-free legislation in 2006 under the Prohibition of Smoking in Certain Premises (Scotland) Regulations 2006.

[14] Council Recommendation 2009/C296/02 recommends that Member States 'provide effective protection from exposure to tobacco smoke in indoor workplaces, indoor public places, public transport and, as appropriate, other public places as stipulated by Article 8 of the WHO Framework Convention on Tobacco Control' and 'develop and/or strengthen strategies and measures to reduce exposure to second-hand tobacco smoke of children and adolescents'.

- Combat illicit trade in tobacco products.

The treaty entered into force in February 2005. It was signed by 168 of the 192 WHO member states and 156 WHO member states have become parties to the Convention. The UK signed the treaty on the 16th June 2003 and ratified it on the 16th December 2004.

NRT

NRT products are regulated under the medicines regulatory framework. In the UK medicines are regulated by the Medicines Act 1968. It regulates, in part, the manufacture, distribution and importation of medicinal products; however it has been amended so it is in line with EU legislation in this area. Council Directive 2001/83/EC[15] regulates the licensing, manufacture of, and wholesale dealing in, medicinal products within the EC, whilst Directive 2003/94/EC lays down principles and guidelines of good manufacturing practice. This framework is implemented by the MHRA[16] with assistance from the Commission for Human Medicines[17]. The MHRA is responsible to the DH. In the UK a product is defined as medicinal by presentation or function:

A. Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

B. Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. (MHRA 2007, p.11)

The MHRA currently considers any product claiming, or implying, that it can assist in the cessation of smoking to be a medicine (presentation).

A 'marketing authorisation' setting out conditions for the use of a medicine is required before a new medicine can be sold. Licenses are needed for companies involved in all stages of the manufacture and distribution of medicines and the manufacture, distribution and supply of medicine must meet safety and quality standards. A post-marketing surveillance system is in place for medicines. There are several routes through which a medicine can be licensed within the EU. In the 'centralised' procedure, which is mandatory for certain types of medicines; a single application is submitted to the

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[15] Amended by Directives 2004/94/EC, 2004/24/EC and 2002/98/EC

[16] Formerly the Medicines Control Agency

[17] Formerly the Committee on the Safety of Medicines (CSM)

European Medicines Agency and is then valid in all Member States. The 'decentralised procedure' is for medicines that have not yet been licensed in the EU and enables simultaneous consideration and approval in two or more Member States, whilst in 'mutual recognition' a company can ask additional Member States to recognise the marketing authorisation for a medicine that has already been licensed by the regulator in one member state. Finally, products that fall outside the scope of the centralised procedure can be licensed through a single Member State's national procedure.

In the UK, the Licensing Division of the MHRA authorise clinical trials[18] of potential medicines and assess applications for marketing authorisation. They require:

> "A detailed description and composition of medicine products including the function and rationale for inclusion of each ingredient in the product, a detailed description of the manufacturing process and data on the stability of the product. This includes flavouring. The content of the active substances must be expressed quantitatively per dosage unit. The results of biological and toxicity testing are also required." (RCP 2007, p.178)

The benefits, risks and adverse effects of a medicine are normally weighed up against placebo; however, in 2005 a working group set up by the CSM accepted that the use of NRT ought to be weighed against smoking tobacco and lifted the restrictions on use by pregnant women, people with cardiovascular disease and lowered the minimum age of use from eighteen to twelve. The use of NRT as part of a controlled strategy for quitting smoking and for temporary abstinence were later licensed in addition to the original indication of smoking cessation, and the period of use was extended to nine months.

NRT was initially licensed as a prescription only medicine in 1980 and placed on the 'blacklist' of products not available on reimbursable NHS prescription. The National Health Service (General Medical Services) Regulations 2001 (amendment) removed NRTs from schedule 10 of the General Medical Services which lists drugs that General Practitioners (GPs) cannot prescribe. The Medicines General Sale List Order 2001 (amendment) gave some NRT products general sales list (GSL) status meaning products are available in any retail outlet that is lockable (the product must be sold in an

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[18] Phase one trials (with less than 100 subjects) are to find out how the drug works in the body and whether side effects increase at higher doses; phase two (with several 100 subjects) looks at whether the drug works in patients with a particular condition or disease and identify common short term side effects; and phase three trials (several 100 – several 1000) gather data on how well the drug works and how safe it is in the general population including the range and degree of side effects.

unopened manufacturers pack): mostly supermarkets. Other NRT products are only available through pharmacies.

The MHRA Patient Information Quality Unit also control supporting information (for professionals and consumers), and advertising and marketing claims in line with Directives. The Summary of Product Characteristics provides information about how a medicine should be used to doctors and pharmacists, whilst information is provided to patients through the label and patient information leaflets. Advertising to the public is allowed for products with pharmacy medicine (for sale under the supervision of a pharmacist) and GSL status. Advertising is controlled through a combination of statutory measures[19] and codes of practice, and must comply with the information in the Summary of Product Characteristics and present the product objectively. The price of medicines is controlled by the Pharmaceutical Price Regulation Scheme which determines the profit made by pharmaceutical companies on the sale of medicines to the NHS. NRT on prescription either costs the consumer a small fixed amount or is free for those who qualify. NRT is most commonly sold in weekly pack sizes. Value added tax on NRT was lowered from 17.5 to 5% in 2007, for one year in the first instance and then permanently.

In summary, tobacco products in England are controlled by a variety of instruments, which work on different scales: a WHO global health treaty, EU legislation and recommendations, and UK-wide and England-specific legislation. The content and presentation of tobacco products is currently the area in which there is least control. NRT products are regulated within a comprehensive medicines regulatory framework at both the EU and UK level. Some products that are classified neither as tobacco nor as medicinal currently fall outside of both of these regulatory regimes. The next chapter introduces the approach used to examine these regulatory regimes: actor-network theory.

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[19] The legal base for the control of advertising is contained in the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994, both as amended, which implement Title VIII of Directive 2001/83/EC on the advertising of medicines for human use.

Chapter Two: Actor-Network Theory

Introduction

The complex links between scientific ideas, technological innovations, and policy and regulatory debates are central to understanding nicotine regulation. As noted in the introduction, concepts and theories from science and technology studies (STS) are therefore well placed and potentially valuable to this area of study. In general, STS has been interested in examining the complexity inherent in carrying out scientific work or making and disseminating technologies. Scholars have investigated the impact of the social, economic and political on – and their interaction with – the scientific and the technical. For example, STS work has underlined the importance of paying attention to the way science is organised, examining what it is that scientists do in practice, unravelling what sorts of assumptions are imbedded in technologies, and understanding that technologies do not always do what is expected of them as they enter complex relationships with the people who use them. Actor-network theory (ANT) was thought to be particularly relevant for the attention it pays to the relations technologies are embedded in and the networks they are part of, and its focus on to what technologies do, as well as what people do. This chapter outlines the origins of ANT, criticisms levelled at it and the directions in which it has developed more recently. I examine key ANT concepts and what they mean for my investigation of nicotine regulation, particularly how ANT may be used to understand the legal element of my study.

The field of STS is generally seen as originating in the Sociology of Scientific Knowledge (SSK) of the 1970s. Whilst the work of scholars such as Kuhn (1962) and Merton (1973) shifted the understanding of science from 'a formal activity that creates and accumulates knowledge by directly confronting the natural world' (Sismondo 2009, p.1) to a focus on the social organisation of science, the 'strong programme' in SSK (e.g. B. Barnes 1974, 1977; Bloor 1991, 1983) argued that the content of scientific knowledge should also be understood as a social product. Pickering (1992) suggests that SSK sees scientific knowledge '...not as the transparent representation of nature, but rather as knowledge relevant to a particular culture, with this relativity specified through a sociological concept of interest' (Pickering 1992, p.6). The strong programme emphasised an empirical and naturalistic approach to scientific knowledge. It argued that beliefs ought to be seen as objects of study and should be treated with

methodological symmetry; beliefs judged to be true or false, rational or irrational, should be explained using the same type of resources. The insights of SSK, particularly the notion of methodological symmetry, were taken up by others studying science and technology; however, a number of scholars (Garfinkel et al. 1981; Gilbert & Mulkay 1984; Knorr-Cetina & Mulkay 1983; Latour 1987; Latour & Woolgar 1979; e.g. Lynch et al. 1983; Pickering 1993; Traweek 1992) questioned the positioning of the social in SSK work as a special organising and explanatory concept, instead seeing the social and material elements of scientific culture or technological development as co-produced. ANT is a key strand of this body of work.

Actor-network theory

The first point to note about ANT is that it is somewhat hard to pin down. Nevertheless, a few general themes can be suggested: ANT emerged in the 1980s, is a branch of STS, draws particularly on semiotics and ethnomethodology, is associated with the work of Michel Callon, Bruno Latour and John Law, and has a strong focus on the empirical. For this reason, in trying to get to grips with the body of work to which ANT relates, I will discuss its content and development through the examination of a range of empirical studies: for one thing that is very clear about ANT is that it is something to be used. As Latour (2005) emphasises, ANT is a way to access sites and methods. He suggests that it is not intended to be used as a framework through which to structure accounts of the world but rather as a tool to aid the researcher in describing the world that they are investigating. Therefore, it follows that the simplest and most productive way to explore the ideas ANT has generated is through exploring the descriptions it has produced. This exploration will progress from the earlier days of ANT – three classic studies by Callon (1986a), Law (1987) and Latour (1992) – through reactions to and criticisms of these, to more recent accounts in which a range of authors take up the ideas of ANT in their empirical studies and, in doing so, transform them.

To examine how ANT was deployed in earlier texts I have chosen three studies as my focus. Whilst this tactic necessarily excludes a variety of other interesting work, I choose here to sacrifice breadth for depth. I look at these three studies in particular because they are considered to be classic ANT accounts and are cited in much of the work that follows them. I have also chosen fairly short pieces (i.e. chapter rather than book-length) to enable a reasonable description of them to be provided in a short space. These papers are: Michel Callon's *Some Elements of Translation: Domestication of the Scallops*

& Fishermen of St Brieux Bay (1986a); John Law's *Technology and Heterogeneous Engineering: the Case of Portuguese Expansion* (1987); and Bruno Latour's *Where are the Missing Masses? The Sociology of a Few Mundane Artefacts* (1992). Each of these lays out some of the concepts central to ANT and applies them to a case study or a series of examples.

Callon and the Scallops of St Brieuc Bay

In the first of the three texts Michel Callon (1986a) begins with the identification of an asymmetry in previous accounts of science and technology: whilst sociologists take into account scientists' discussions of scientific and technical aspects they do not take into account those about society. In addressing this issue he asks: "What would happen if symmetry were maintained throughout the analysis between the negotiations which deal with the natural and social world?" (Callon 1986a, p.3). To answer the question he introduces three principles: agnosticism, generalised symmetry and free association. He then relates these to four 'moments' in a controversy about the decline of, and a possible conservation strategy for, a population of scallops.

His first principle, 'agnosticism', has to do with the outlook of the analyst:

> "Not only is the observer impartial towards the scientific and technological arguments used by the protagonists of the controversy, but he also abstains from censoring the actors when they speak about themselves or the social environment. He refrains from judging the way in which the actors analyse the society which surrounds them." (2005, p.3)

Next he introduces 'generalised symmetry', which refers not only to treating conflicting viewpoints in a controversy the same way but suggests that 'society is no more obvious or less controversial than Nature' (Callon 1986a, p.3); therefore, we ought to use the same vocabulary for talking about 'social' and 'technical' aspects of any situation being analysed. By the final principle, that of 'free association', the observer is asked to do away with the assumption of a boundary between the natural and the social, to 'abandon all a priori distinctions between natural and social events' (1986a, p.4). Instead she must follow the actors to see how they define a situation and to: "identify the manner in which they define and associate the different elements by which they build and explain their world, whether it be social or natural" (1986a, p.4). Having laid out these three principles, Callon moves on to apply them to his example.

The example begins with Callon (1986a) following his chosen actors – three researchers. He traces their attempts to enrol others into the network of relationships

they wish to build. He structures their activity into four 'moments' that relate to four sections of a process called translation, which he names 'problematisation', 'interessement', 'enrolment' and 'mobilisation' of actors. During the problematisation phase the researchers write a series of reports and articles describing their trip and ideas for future projects, which include a series of crucial questions about the development of scallop larvae. Callon (1986a) suggests that these reports not only outline questions but establish the researchers as 'obligatory passage points' in the network they are building. In other words they position themselves as crucial to the network. The reports outline a set of actors and a role for each. These actors are the fishermen of St Brieuc, scientific colleagues and the scallops of St Brieuc. Furthermore, they define themselves, what they want, and outline why each set of actors should also be interested in their goal.

Having set out their problematisation, Callon suggests that the researchers must then strengthen their definition of the actors by weakening any links with others who would define them differently; the entities defined in the problematisation need not accept these definitions. This stage, called interessement, is then: "the group of actions by which an entity (here the three researchers) attempts to impose and stabilize the identity of the other actors it defines through its problematisation." (1986a, p.8) Callon uses the domestication of scallops to illustrate interessement. The Japanese technique the researchers are trying to adopt entails immersing towlines made up of collectors in the sea, to which the larvae anchor and are then protected whilst they develop. Through the use of this 'interessement device' the scallops are physically removed from any other actors who may harm them. Callon suggests that this will 'extend and materialise the hypothesis made by the researchers' (1986a, p.9). For the fishermen and scientific colleagues the interessement devices used are meetings, articles and conferences during which the researchers lay out their arguments to representatives. However, these interessement devices may not necessarily lead to the next phase in translation, which Callon (1986a) calls enrolment. When actors are successfully enrolled in a network they accept the definitions and roles that have been laid out for them. For the scallops this definition is as an entity that anchors. Callon describes how the researchers must deal with various problems, or 'enemy forces', such as currents and parasites to persuade the scallop larvae to anchor and thereby enrol them into the network. He presents the researchers' attempts to resolve these problems as negotiations in which the researchers

try to figure out how best to get the larvae to anchor. The researchers are successful in this stage and manage to persuade some larvae to anchor.

Callon (1986a) suggests we see these larvae as representatives or spokesmen similar to the official representatives of the fishermen who have agreed to participate in the researchers' project. The problem the researchers face is whether 'the masses' will follow their representatives. Will other scallops anchor? Callon calls this final stage 'mobilisation of actors'. For the translation to be complete and the network built, for the researchers to speak for the other actors, the scallops, fishermen and scientists must do as their representatives have suggested they will. He describes how, during this process of mobilisation, the actors go through a series of displacements, for example the scallops become larvae, then numbers, then tables and curves. These are easy to transport (or mobilise) and are an important part of the process of speaking for other actors – of translating them. He ends his example with a demonstration of the fragility of the network: it turns out that the larvae do not follow their representatives; they do not go into the collectors and anchor and the stability of the network is questioned.

Law and Heterogeneous Engineering

In *Technology and Heterogeneous Engineering,* Law's (1987) preoccupation is with how objects or artefacts come to be stabilized. He addresses this question using a network approach[20] that he draws from Hughes' (1983; 1987) historical analyses of systems building. The three central concepts in his approach are the heterogeneity of the elements involved in a network, the complexity and contingency in the way these elements relate to each other and – the main difference from Hughes – that the elements in the network are difficult to hold in place. He takes up Callon's (1986a) argument that the social ought not to be privileged in explanation; instead '*the stability and form of artefacts should be seen as a function of the interaction of the heterogeneous elements as these are shaped and assimilated into a network*' (1987, p.113, emphasis in original). Law also emphasises the necessity of using the same analytical vocabulary to discuss the natural and the social. His approach is developed through an examination of the technology of

[20] Although, the use of the network as an analytical tool has older roots in anthropological work (see for example J. C. Mitchell & J. Mitchell 1969)

the fifteenth and sixteenth century Portuguese maritime expansion and particularly the establishment of the Portuguese spice trade.

Law (1987) turns first to the galley, describing what it is made of and what it does. He suggests that the galley is an 'emergent phenomenon' and details the entities that must be associated and held together to create a galley. He suggests that, although the galley was successful as a war vessel in the sheltered waters of the Mediterranean, it faced a number of problems if used as a vessel to sail to the Indies. Specifically, its cargo carrying capacity was extremely limited and its endurance was restricted by the size of its crew. He uses this example to emphasise the importance of struggle in the problems faced by 'systems engineers': "How to juxtapose and relate heterogeneous elements together such that they stay in place and are not dissociated by other actors in the environment in the course of the inevitable struggles." (1987, p.117) He goes on to describe how the Portuguese dealt with their struggle with the Atlantic and reached the Indies.

Three technological innovations proved to be important steps in making this struggle successful: the mixed-rigged seagoing vessel which was able to carry enough supplies to sail greater distances; the availability of the magnetic compass which allowed greater accuracy in navigation and with it the ability to sail further from the coastline; and, with the first two steps, the use of a new route called the *Volta*. Law suggests that the *Volta*:

> "Can be seen as a geographical expression of a struggle between heterogeneous bits and pieces assembled by the Portuguese systems builders and their adversaries, that is, the winds, the currents, and the capes. It traces on a map the solution available to the Portuguese." (1987, p.120)

Here he has adjusted the focus so we now see a network – of which the vessel is one part – made up of heterogeneous elements that systems builders have struggled to associate together against various challenges. Law then goes on to describe the use the Portuguese made of the Caravel type of vessel to explore the African coast once they had reached it. He notes that the Caravel was well adapted to this type of task. He uses this example to observe that the structure of a network reflects the power and type of forces available (the Caravel is long, light, does not draw water and is easy to handle) and the forces with which it collides (shallow water, reefs, winds). Therefore, to be well adapted is to be able to use forces and to transform them.

Next Law (1987) outlines the importance of developments in navigational techniques in further detail. The problem facing the Portuguese was the need to find a way to determine their position a long way from land when they were using larger *Voltas*. To address this, an astronomical method of navigation was developed. Firstly, devices used in universities were adapted to be simpler for mariners to use (although a reading from these instruments still had to go through a number of transformations before it could be converted into a latitude). As Law notes:

> "The construction of a network of artefacts and skills for converting the stars from irrelevant points of light in the night sky into formidable allies in the struggle to master the Atlantic is a good example of heterogeneous engineering." (1987, p.124)

This advance necessitated the development of both the production of a set of rules for the calculation of latitude by semi-educated mariners and a record of the measurements of important coastal latitudes, and for these to be made available to mariners. Law suggests that, even when this complex network had been put into place, mariners found the method difficult and did not always try to practice it. He writes:

> "Instruments, inscriptions and stars were not enough. Part of the association of elements to convert stars into latitudes lay in the practice of mariners, and it was this element that was the most prone to distortion." (1987, p.126)

The mariners were identified as the weakest link in this part of the network.

Even once the Portuguese had reached and explored India they still faced challenges. This time the hostility of the Muslim traders who controlled this section of the spice trade. In this instance, they gained and maintained control through their greater military power at sea. Law utilises this part of the story to demonstrate that the Portuguese came across social adversaries, as well as physical ones (such as the oceans), which they were also able to successfully associate in a way that rendered their network durable. Law underlines how in this type of explanation all the elements that make up the network – whether they are devices, natural forces or social groups – are treated in the same way and none are given preference in the explanation. He also insists that the network that is chosen to study is crucial. It is what exists within the network that forms the focus and this brings different structures into view.

Latour's missing masses

The piece by Latour (1992), with its lack of emphasis on network building, is at first glance rather different from those preceding it but I think it draws out some of the

interesting points about ANT nicely. Latour's account begins with a seatbelt. More precisely, he uses a description of how, if he does not fasten his seatbelt, his car flashes a red light and then sounds an alarm, to introduce the question of whether the morality in this situation is in the human user or the technology. This leads him to the main theme of his paper: that, like physicists, sociologists are searching for the mass – something 'strongly social and highly moral' – that is missing from their accounts:

> "To balance our accounts of society, we simply have to turn our exclusive attention away from humans and look also at nonhumans. Here they are, the hidden and despised social masses who make up our morality. They knock at the door of sociology, requesting a place in the accounts of society as stubbornly as the human masses did in the nineteenth century. What our ancestors, the founders of sociology, did a century ago to house the human masses in the fabric of social theory, we should do now to find a place in a new social theory for the nonhuman masses that beg us for our understanding." (Latour 1992, p.227)

With this, Latour goes on to investigate the part nonhumans play in society through a series of small accounts of everyday technologies.

The first of these begins with a small note on a door: "The Groom Is On Strike, For God's Sake Keep The Door Closed". Utilising a thought experiment where the reader is asked to imagine the work that would need to be done if a door (with its hinges, springs and hydraulic pistons) was not there to keep the outside out and the inside in, he notes that, 'techniques are always involved when asymmetry or irreversibility are the goal' (Latour 1992, p.228). He then describes the methods by which one might make sure the door was closed after people go through it. These are disciplining all the people who use the door, e.g. through signs[21], employ one human actor (a 'groom') to do this work, or use a nonhuman actor (here the 'groom' or automated door-closer). He calls the work that the door-closer does – the transformation of a major effort into a minor one – 'delegation'. Latour also points out that the door-closer (with its powerful spring mechanism) presupposes a skilled human user[22] and therefore discriminates against some users (i.e. the very old and very young.) He summarises the situation by saying that the groom:

> "Shows in its humble way how three non-human actants (hinges, springs and hydraulic pistons) replace, at least 90 percent of the time, either an undisciplined bellboy who is never there when needed or, for the general public, the program of

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[21] This 'set of written instructions that can be substituted by the analyst to any artefact' Latour terms a *programme of action* (Latour 1992, p.228).

[22] He calls this imposition of certain behaviour back onto human actors 'prescription'.

instructions that have to do with remembering-to-close-the-door-when-it-is-cold" (Latour 1992).

Latour then returns to the note, attending to the anthropomorphism present ('The Groom Is On Strike') to suggest that, whilst attributing human characteristics to objects is often seen as merely projection, 'the automatic groom is already anthropomorphic through and through' (Latour 1992, p.235). He notes, from the etymology of the word, that it means something which has human shape or gives shape to humans, and again questions the divide between the human and non-human. Latour next compares machines to texts in order to underline that the attributions of roles and action is a choice, that users/readers can ignore the prescribed definition of them and behave otherwise and also that: "The actors at any point may be human or nonhuman, and the displacement... makes impossible the easy reading out of one repertoire and into the next" (Latour 1992, p.239). He suggests that: "The distinctions between humans and nonhumans, embodied or disembodied skills, impersonation or 'machination', are less interesting than the compete chain along which competences and actions are distributed" (Latour 1992, p.243); further, that where you are along this chain decides whether you get 'classic moral humans' or 'efficient machines and mechanisms'. Continuing this machine as text metaphor, Latour compares the work of engineers to 'shifting out' (the displacement of a character to another space or time) in writing. However, he suggests that technical shifting out inscribes words into another matter, which allows us to ignore the silent delegated actors and explains why the 'masses' are usually excluded from accounts. He illustrates this through a story in which the purchase of a metal bar to secure his son (who is too old for a child's seat and too young for a seatbelt) delegates his shouting at the boy to a silent artefact: speech has been translated into steel.

Finally, Latour brings his account to a close with a look at the Berliner key. This is a key which forces people to lock a door behind them by making it necessary to push the key to the other side and relock it to retrieve it from the lock. The key is also oddly shaped and requires a special key holder. For Latour, this underlines that the key, or any artefact, is only part of the programme of action (which is also a fight against anti-programmes – conflicting programmes of action) because it requires a competent user who will relock the door. Here Latour makes the point that:

> "Students of technology are never faced with people on the one hand and things on the other, they are faced with programmes of action, sections of which are endowed to parts of humans, while other sections are entrusted to parts of nonhumans." (1992, p.254)

This brings him to a point familiar from our discussion of Callon (1986a) and Law's (1987) texts: "How a negotiation to associate dissident elements requires more and more elements to be tied together and more and more shifts to other matters" (Latour 1992, p.254).

Similarities

Although these three accounts take different questions as central, have at the centre of their analysis very different subjects, and approach their subject matter in some ways differently, they share many common preoccupations. Drawing out these preoccupations allows me to identify some of the main characteristics of ANT. Firstly, all three authors stress the importance of symmetry in explanation. They suggest that the social and technological, the human and non-human, must be accounted for through the same type of explanation. Consequently, their accounts pay attention to a range of heterogeneous elements and feature diverse actors; scallops, seatbelts, galleys, doors, sailors, scientists, fishermen and door-users all play their part. In ANT accounts attention is paid to who can be an actor and what it means to act. Attention is also paid to the vocabulary used to explore this action (Akrich 1992; Akrich & Latour 1992). All three accounts introduce a vocabulary that is used explicitly to ensure that their account is neutral and does not make a priori assumptions about what sort of actors it contains and how they act.

Furthermore, in ANT we see a focus on exploring the world from the point of view of the network or actors being studied[23]. The metaphor of the network is also very important in these texts[24]: all three are interested in how the diverse elements in these actors' worlds are brought together and kept together (or not) and in the associations, relations or interactions between entities. There is also an awareness of the work involved in keeping entities together: Law emphasises the conflict and struggle the Portuguese face; Callon notes the fragility of his scientists' network; Latour talks of

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[23] This is more prominent in Latour's book on Pasteur (1988).

[24] The importance of the network is more obvious in Latour (1988) and Callon (1986b)

conflicting anti-programmes. Moreover, the war metaphor, found running through the description of many of these processes, is particularly striking; Callon (1986a) talks of enemy forces and mobilising actors and Law's account (1987) is particularly full of conflict, struggles and adversaries, whilst in Latour's (1992) piece (where the metaphor is less noticeable, although Latour's (1988) investigation of Pasteur is full of victories over microbes, alliances and 'trials of strength') there are fights against anti-programmes.

Differences

In their call for analytical attention to be paid to non-human actors, these three studies, along with various other accounts of the ideas of ANT (Akrich 1992; Akrich & Latour 1992; Callon 1986b; Johnson 1988; Latour 1987, Latour 1988, Latour 1991; Latour & Woolgar 1979), were taken to constitute a fairly radical step in the analysis of science and technology. Inevitably, the ideas Callon, Law and Latour put forward attracted discussion and criticism. It is necessary to outline some of these criticisms here, because it was with these as a backdrop that these early ideas have been taken up and transformed. The focus of much of the critical attention towards ANT was the idea that non-humans actors ought to be granted agency in analyses along with human actors. This is one of Collins & Yearley's (1992) main critiques of Latour and Callon's work (see also Schaffer 1991), which they outline in a chapter accusing Latour and Callon of playing 'epistemological chicken'. Collins and Yearley's SSK approach (see for example Collins 1985) argued for a type of symmetry in analysis that sees the boundary between true and false as a construction; however, they find ANT's radical symmetry a move too far, and also regressive. They suggest that in giving agency to the scallops, Callon's account does not add anything to our understanding and in fact the way the story is told 'looks just like the account of a conventional historian of science' (1988, p.315). They suggest that the ability of the SSK approach to understand the construction of knowledge has come from the exploration of the difference between humans and things, and for this reason they find ANT to be a backward step. They argue that Callon and Latour's accounts offer useful descriptive language but are lacking in explanation.

Some rather more sympathetic criticisms of these early ANT accounts focussed on the way that the theory deals with difference and otherness. Linked to the previous concerns, Susan Leigh Star (1991) questions the political consequences of ANT's processes of delegation, and raises the issue of how some human perspectives win over

others[25]. Her concern is with how to foreground multiplicity in STS thinking about power. Using the example of being allergic to onions in McDonalds she brings up the issue of what happens to those who are excluded from a network. The point she is making is an important one; that a network looks different depending on where you stand in relation to it. Strathern (1996) also raises some points about the network metaphor, which she links to Euro-American ideas about relatedness. She suggests that it is useful for capturing links between entities without making assumptions about hierarchy and has 'properties of autolimitlessness; that it is a concept which works indigenously as a metaphor for the endless extension and intermeshing of phenomena' (1996, p.522). This raises the problem that the networks under study may be, theoretically, without limit.

Lee & Brown (1994) address a related point, which focuses around the concept of the other. Their main point is that ANT's inclusion of non-humans leaves nothing outside – no other – and risks the production of another grand narrative. Their argument suggests that the choice of vocabulary that is used – that the status of 'actant' is granted to non-humans within a liberal-democratic political discourse of universal enfranchisement – takes to its limit the post enlightenment ambition and leaves nothing outside of the network. They maintain that ANT 'offers no critique & countenances neither alternative nor supplement' (1994, p.781) and suggest that in analysis something always remains unmapped. For them, there is a need to tackle movement, difference and uncertainty through 'fractal strategies' that preserve 'a place for an irreducible otherness at work in the very heart of every multiplicity' (1994, p.787).

'More than one and less than many'[26]

In the last couple of decades, since these accounts were written and written about, something has happened to ANT. ANT has started telling many different stories; stories that are often not about networks and enrolment; stories that complexify the question of what exactly ANT is. To illustrate the ways that ANT has developed I will consider several more recent studies that put ANT into practice, both maintaining some

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[25] Law also discusses this point in his introduction to *A sociology of monsters* (1991)

[26] I borrow this rather apt idea from Law's (2002a) *Aircraft Stories* in which he is concerned with 'fractionality' and the way that objects are multiple – more than one and less than many.

similarities with ANT as it was in the classic studies of Callon (1986a), Latour (1992) and Law (1987) and taking it in different and unexpected directions[27].

Ambivalence is not necessarily a problem

Vicky Singleton and Mike Michael's (1993) account of the Cervical Screening Programme in the UK provides an example of using ANT to explore a case study, and the case study to rethink ANT. They are particularly interested in the process through which, when telling an ANT story, a coherent narrative is produced and whether in this process any other aspects of the story lose out. Their account begins with an outline of ANT that encompasses Callon's (1986a) three principles and the processes of interessement, enrolment and translation, and introduces their critique of the perspective. They observe that:

> "The networks of Callon and Latour are clean and clear. What, at first seem, to be complexly constituted actors often emerge as a unitary entity (though this is always a provisional state); this is not simply a product of the state and configuration of the network being studied, but is rendered singular by the flow of the narrative." (1993, p.232)

They suggest this process may be influenced by the recurrent metaphor of war which could be replaced by one of 'permanent reform' to emphasise the multiplicity of actors and inherent instability in a network.

In Singleton and Michael's (1993) account, the Cervical Screening Programme emerges as a network that – unlike the picture painted in the government reports of a clearly defined medial process – is pervaded by uncertain and ambiguous roles and associations, but is durable nonetheless. In this paper, they focus on the role of the GP as an important link between a number of other entities: women, laboratory, and cervical cells. They suggest that the GPs simultaneously problematise and de-problematise their role, whilst maintaining the 'black-boxed' Cervical Screening Programme network as that of a straightforward procedure. They are found, for example, to raise uncertainties about parts of their own role, e.g. the process of obtaining an adequate specimen, and that of others – making the cervix visible and the reliability of laboratory diagnoses. In the first example, the GPs are found to highlight a

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[27] It should be noted here that Callon, Latour and Law's ANT work does not end with these classic studies, nor has it been static. All three writers' later work has played an important in re-articulating what ANT does (see for example Callon 1999; Latour 2010; Law 2002a, Law 2004).

number of uncertainties in the supposedly simple procedure of obtaining an adequate specimen, such as difficulties locating the cervix and the amount and type of cells obtained. These are defined by reference to the multiple identities of the actors involved i.e. the variety of positions a cervix can adopt. The GPs de-problematise this difficulty by emphasising that by utilising their skill and experience it is still possible to obtain an adequate sample.

Singleton and Michael (1993) go on to suggest that this indeterminacy allows the GPs to negotiate their identities in the Cervical Screening Programme by complexifying their role and underlining their importance within the Cervical Screening Programme, whilst still remaining committed to this role. They suggest that within this process the black-boxed entity that is the GP is opened and 'its own network-ness' (1993, p.258) and multiple identities are revealed; however, rather than betraying the network this ambivalence is an integral part of it. The GPs continue to carry out their assigned roles. In conclusion, they suggest that:

> "Betrayal and defeat are no longer a dramatic and mysterious event, as is so often portrayed in actor-network narratives, rather, it can be conceptualised as the congealment of a disparate array of ambivalences into a focused pattern of resistances." (1993, p.259)

Singleton underlines this conclusion in a later article (1998) where she describes the role of the laboratory in the Cervical Screening Programme, and again underlines the fact that it is not necessary for the entities that are associated into a stable network to have stable identities. She shows that, in a similar way to the GPs, the laboratory workers complexify and destabilise their own role and that of others, such as the cervical cells; however, the laboratory workers also de-problematise their role by redefining their identity and therefore the laboratory still plays its assigned role in the programme. Here, Singleton emphasises the importance of this incorporation of multiple identities and instability into the network: the ability of the laboratory to redefine its role actually allows it to continue carrying out that role. She also suggests that this focus makes the negotiation inherent to work practices visible.

Fluidity as well as durability

Like Singleton and Michael, Marianne de Laet and Annemarie Mol (2000) dispense with the need for stability in their account of the Zimbabwe Bush Pump: in fact they describe an object that is fluid yet holds together, whose fluidity is its strength. Their account of

the bush pump begins by describing the boundaries of the pump, next considers whether it is a successful technology, and then focuses on its maker. The first section deals with questions about how best to describe the pump. They note its colour (bright blue), the different parts that make up the pump (pump head, pump stand and lever), the parts that make up these parts, and how they work. They provide a drawing of it. They go on to describe the parts under the ground (its hydraulic components), how it differs from other pumps (it is hydraulic, on top of this it also has a greater capacity and durability) and its health giving properties that come from its concrete headworks (it provides fresh, clean water). Yet this is not everything that defines the pump: it also needs a hole. For the hole to be drilled it needs to 'collaborate' with another piece of technology; however, this technology also needs the participation of the village. As well as all this, de Laet and Mol (2000) suggest that the bush pump – as part of national policy of providing clean water and developing an infrastructure for water, and as a national standard – helps build the Zimbabwean nation. This account demonstrates that the boundaries of the Zimbabwe bush pump can be drawn in many ways: it can include other devices, other materials, even the village or the nation. It is not clear where the pump ends or what exactly it is.

This is not, however, the only thing that is fluid about the pump. It is also difficult to judge when the pump is and is not working. In this section de Laet and Mol (2000) describe all the things that can go wrong with all the different parts of the pump. They find that it is designed to be easy to repair and can often continue to work despite the failure or even absence of some parts. They also suggest that the judgement of whether the pump is 'working' is relative: that, for example, a high *E.coli* count in the pump water does not necessarily mean it is not properly promoting health, as it may be the best alternative available. So, for de Laet and Mol, the Zimbabwe bush pump is a 'fluid actor'; the pump does things, it acts, although it is often not clear when it stops acting. Their final examination of the pump concerns the man who designed it. De Laet and Mol describe how Dr Morgan has never claimed authorship over it and maintains that its development is collective and collaborative. They suggest that he has in fact worked hard to 'manage his own dissolution' (2000, p.246). He is not an actor, but he is not passive either.

In juxtaposition to accounts of centred networks and managerialist creators, de Laet and Mol (2000) have placed fluidity, fluid objects and fluid actors. Here fluidity, like ambiguity, far from being a problem for the network is the very reason for an artefact's success. Yet they warn against setting up fluidity as a new standard to replace durability or strength. Moreover, they are interested in developing an issue of particular centrality to ANT: in their account of a pump that acts and an inventor who dissolves, they are concerned with extending the notion of the actor: "Our actor, the Bush Pump, goes to show, once again, that actors do not have to be humans" (2000, p.253).

Ontological choreography instead of network building

Charis Cussins (1996) takes a rather different central question as the focus of her article on reproductive techniques: an account that is perhaps not exactly an ANT account but is recognised (Law 1999b) to have ANT-like qualities, as well as implications for ANT. In her study she addresses the notion that objectification is always opposed to personhood and, as a consequence, alienating. She is also interested in exploring the dependence of selves on technology. She notes the tension between conceptualising identity as an ongoing process and the ability to account for agency. As well as, in infertility medicine, between the patient as disciplined subject and as agent, suggesting that 'the subject is dependent on the constant ontological exchange between ourselves and our environments' (Cussins 1996, p.578). It is this exchange, named 'ontological choreography', that she explores in her descriptions of infertility treatment.

Cussins' (1996) text begins by describing some of the techniques of infertility treatment – the pelvic exam, the ultrasound, diagnostic surgery, the manipulation of gametes and embryos in the laboratory – in order to 'show what is made to appear by the different equipment and procedures' (1996, p.581). For Cussins each procedure objectifies the body of the woman in different ways and provides the opportunity to focus on an aspect of ontological choreography: the body's parts are 'unblack-boxed' (the pelvic exam), made visible (surgery), separated (work in the laboratory on embryos and gametes), and the diversity of the different steps and the tenuousness of their relatedness is demonstrated (the ultrasound and the information it gives). In thinking about the pelvic exam, she describes the way the woman has already started thinking about the different parts of her body (un-black-boxing it) before embarking on the process (the phases of the menstrual cycle and things that can go wrong in trying to conceive), how the patient is situated in the clinic (on the examination table) the

instruments used (speculum, cleaning swabs), and the dialogue with the patient (about what hurts and her fertility history). Cussins suggests that these steps, which render the body and instruments compatible, are at the heart of objectifying the woman. However, the women are also active in this process.

As the treatment continues and the phases of treatment take the women's body parts further from her, the importance of 'trails of instruments, technicians and objectified patient' (1996, p.585) that can be linked back to patient (or of the ability of parts to be able to stand in for the whole) are emphasised. Cussins (1996) suggests that it is these trails that ensure the objectification of the patient is not opposed to her subjectivity. From this point, the next section moves on to show the ways the patients deal with this objectification emphasising the ways that women participate actively in their objectification. She notes the difference in the ways the women talked about successful and failed procedures, and suggests that there is a loss of subjectivity after a procedure has failed; therefore, it is not objectification itself that is problematic but the outcome of the objectification. As opposed to the way a network is formed and held together, here, what Cussins (1996) has described is the way a patient is broken down into different elements and links maintained between the elements; the work that is involved in maintaining the relationships between many different heterogeneous elements and the patient.

Performance and multiplicity

The attention that Cussins' (1996) ontological choreography draws to the work that goes into linking and holding things together and the fragility and movement within this process is echoed in the way that Mol (1998) approaches her account of atherosclerosis. For Mol, atherosclerosis is composed of stories and activities. Her aim is to "begin to unravel the patterns in the coexistence of a variety of "atherosclerоses"" (1998, p.145). She begins her series of 'empirical stories' with the textbook, which tells a story linking patient complaints with a picture of the 'thickened intima of a vessel wall', making links easily. She moves on to investigate how these links are made in hospital practice: the vascular surgeon eliciting complaints about pain from the patient which are identified as the condition 'intermittent claudication'; the pathologist looking at a slide through the microscope identifying thickened cell wall. She notes that these constitute two performances of atherosclerosis, which it is sometimes possible to 'move practically'

(1998, p.147) between, for example using a form connecting them to a patient, taking them as 'aspects of a single entity' (1998, p.150).

However, Mol (1998) goes on to say that making these links is not always simple. Sometimes ways of measuring the atherosclerosis (she gives an example of pressure measurement and the complaints of the patient) do not map onto each other, then:

> "When several 'atherosclerosis' in a single patient do not coincide, it becomes difficult to believe that they can all be trusted and yet be about a single object. At that point there are several ways to go. The first is to make a decision to trust one of them – in which case the practitioners can hold on to the idea that there is a single object-out-there." (Mol 1998, p.151)

In this case, she finds the differences are seen as a controversy about the object, and negotiation about practicalities is the outcome (on the other hand, sometimes they are seen as outcomes of different techniques and interpretations involved). She goes on to give a variety of examples where atherosclerosis is performed in different ways in different settings (i.e. in a GPs office as a process over time) with different links needing to be made (such as making links between events within research practice).

In Mol's (1998) account, the doctors dealing with atherosclerosis are engaged in making links between different performances of the disease in practice. She shows that these links can prove difficult to make and emphasises the work that is needed to turn these performances from a practical matter to a characteristic of objects inside a body. She concludes that atherosclerosis is many and is performed in a variety of ways. Atherosclerosis is a name given to different objects: "The ontology incorporated and enacted in the diagnosis, treatment and prevention of atherosclerosis is multiple." (Mol 1998, p.162)

Actors and action

Emilie Gomart's writing (Gomart 2002a, 2002b, 2004) addresses issues of actors and action in relation to drugs and drug users[28]. In *Methadone: six effects in search of a substance* (Gomart 2002a) she explores the difference in the action of two drugs – methadone and heroin – during a drug substitution trial. Gomart begins with a problem she identifies in the historical treatment of drugs. She suggests that an essentialist/social constructivist

[28] See (Willems 1998) for an argument in a similar vein on the ways that drugs are productive – as playing a part in defining diseases and reorganising the body.

dichotomy is set up where diverse accounts of a drug's properties are due either to: new discoveries about the drug, or different social interpretations of a drug. In each case the drug is seen as something that is invariable. Her answer is that we must rework 'anew and head-on the question of how the drug and its user, nonhuman and human, *act*' (2002a, p.96). To do this she draws on two different accounts of the 'question of the nature of action of humans and substances' (2002a, p.96). One is pharmacologists studying drug effects who do not in practice begin with a pre-defined substance but pose this question in their experiments. The other is science studies authors working on a new vocabulary to describe action. For her, the important move that science studies authors have made is describing entities as inseparable from the techniques that discover them and as performed or constituted through these practices or, as she puts it drawing on Foucault, produced through a *dispositif*.

In Gomart's (2002a) study of two methadone substitution experiments, her focus is therefore on *dispositifs* and actions. She suggests that these experimenters start with an 'effect' and search for the substance. From her analysis of the American experimental report, she proposes that instead of describing the effects of methadone the authors describe the: 'medical benefit of a methadone *treatment*' (2002a, p.106), and in doing so describe a heterogeneous network of practices. Moreover, the methadone cannot be detached from the trials and techniques of the treatment for its properties 'emerge as relevant only in the course of treatment' (2002a, p.107): it is a performance and a competence. When methadone was transferred to the French trial, Gomart suggests the aim was to 'construct a specifically and 'originally' *French* methadone' (2002a, p.114) by altering the treatment procedures. She says of this alteration, that the methadone is: "Described as the performance of a collective, a drug which acts like a medication when it is inserted into a diversity of medical practices. However, this performance mobilizes very different actants." The former begin with an induction in which the methadone dosage is increased until cravings ceased, whilst the latter begin with the selection of the patient. Gomart notes that this moves the focus to the patient rather than the drug.

In this paper, Gomart (2002a) insists that methadone is bound up with the *dispositif* and cannot, therefore, be described without referring to its specific setting: in her description the trials 'make' the two different methadones. She says that: "Methadone endures as a shaky chain of actants, preferred techniques, tentatively and for the time

being crystallizing a certain mode of action." (Gomart 2002a, p.125) Her paper is an important extension of ANT ideas about what it entails to be an actor and to act, that shifts the focus to performances and the *dispositif.*

On how to be ANT-like

I have presented this selection of ANT-like stories to give clarity to what it is that ANT as a body of work does and, more specifically, what it can do for my questions. My narrative has been broadly historical to give a feel for the movement and breadth in the field, and descriptive rather than analytical in order to explore not just the themes ANT raises but the specific instances in which it has been deployed. It is clear from the former point that these three letters – A, N, T – stand in for work that is immensely varied in both subject matter and approach, which draws on and combines ideas from a wide range of other literature and is neither stable nor fixed. From the latter it is possible to draw out the ways that ANT has changed and, more importantly, the ideas that characterise ANT accounts and how these can inform my approach.

Singleton & Michael (1993) and de Laet & Mol's (2000) stories shift ANT away from the focus on the formation of networks and how they are made durable. They suggest that ambiguity, instability and fluidity cannot always be seen as the reason that a network fails: sometimes these things are integral to the network, the aspect that makes an artefact work; therefore suggesting that maybe sometimes we need different metaphors[29]. The stories of Mol (1998), Cussins (1996) and Gomart (2002a) do not tell of network building, but of choreography, trails, making links and enacting through *dispositifs.* Mol (1998) and Cussins (1996) shift attention to questions of ontology and the work that goes into maintaining links between entities, whilst Gomart (2002a) highlights the importance of attending to practice and performances[30].

However, these new stories do not just tell us about the ways that ANT has changed: they also tell us something about links and trails that abound within ANT and about the themes and preoccupations that are common to many ANT accounts. One interest that runs through the work of all of these authors is in understanding the relations between

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[29] See also Law (2000) on hegemonic networks and the possibility of relational orderings which perform other logics and (1994) on fluid space.
[30] See also mol and Law (2004) on the ways that body is enacted.

heterogeneous entities. At first this point sounds rather banal, but it focuses our attention on two major ANT preoccupations. First that it is not enough to study only humans or society: attention must be paid to the role non-humans and technology play. ANT studies give non-humans a type of agency that is more open than traditional natural causality (Latour 2005). Second, ANT states that it is the relations, interactions and links between these entities that are important, as opposed to the people/things in themselves: actors are constituted through these relations and interactions. Similarly, these studies share a concern with questions about actors and action. They pay close attention to who is acting and what is means to act. They stress that it is not only people who can be actors, and therefore that classic theories of action need to be re-thought[31].

This interest in actors also impacts on the viewpoint of the ANT researcher who, as Latour often underlines, must 'follow the actors themselves'. For example, in the texts outlined we see that Callon follows his three scientists as they attempt to construct a network; de Laet and Mol (2000) follow the bush pump, observing the various things it does; Mol (1998) follows medical practitioners and notes they ways that they perform atherosclerosis; and Gomart (2002b) follows her experimenters in their search for substance. The emphasis is on allowing the actors you are studying space to define their world and to watch for the other entities they bring into view and the links that they create. Moreover, as Mol (1998) and Cussins (1996) bring to the fore most clearly, ANT studies have questions of ontology at their centre rather than epistemology: they explore the way the world of their actors is assembled, rather than how they know about the world.

Tracing legal connections

Finally, in addition to considering how ANT will be used in my study it is necessary to think through how the socio-legal dimension can be incorporated into ANT, and specifically how regulation might be conceptualised within an ANT approach. Whilst STS as a whole has paid some attention to law, particularly the relationship it has with science[32], it is interesting to note that ANT scholars have generally been rather silent on

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[31] See particularly (Callon & Law 1995) on the 'hybrid collectif'.
[32] see for example (Jasanoff 2008)

the subject of the legal in their studies[33], and that this is not necessarily because the legal would be uninteresting or irrelevant. For example, in de Laet and Mol's account of the pump there is a socio-legal story to be told about the decision not to patent the pump – to keep the pump out of this type of legal network and not establish this type of legal connection – which was crucial in enabling its fluidity. Although ANT has been mainly focussed on the scientific and medical, there seems no reason why it should not be useful in other areas such as Socio-Legal Studies. As Latour (2005) emphasises, ANT is about how to do sociology rather than just the sociology of science and technology.

More recently, some researchers have begun to consider the utility of ANT in socio-legal research. I utilise Emilie Cloatre's (2008) work on *TRIPS and pharmaceutical patents in Djibouti,* in particular the idea of the 'socio-legal object' and 'legal/technical hybrid', to address this point. Cloatre (2008) sets out to examine both the impact of trade-related aspects of intellectual property rights (TRIPS) and pharmaceutical patents on health in a particular setting, and the utility of ANT to socio-legal studies. She uses the concept 'socio-legal objects' – defined as: "Objects with a legal origin/dimension studied in their social action through networks and connections" – to investigate the links between written legal rules and their social actions. This concept enables her to explore the networks through which TRIPS circulate and the actors they mobilise in the particular context of Djibouti. Utilising the ANT notion of the hybrid she suggests that patented drugs may be understood as legal/technological hybrids: "Patented drugs can therefore be understood as a particular type of hybrid, made up both from the complexity of pharmaceutical patents and of drugs" (2008, p.273). This allows her to understand how, in the absence of written patent laws, generic medicines were little used and patents could still be present in Djibouti's pharmaceutical market.

Both of these concepts seem highly useful for the investigation of NRTs. Conceptualising pharmaceutical regulation as a socio-legal object allows the focus to move from considering regulation as it is written, to asking about the way that it circulates and the actors that it mobilises in the specific example of NRTs and in specific settings where innovation and harm reduction are issues. The idea of the

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[33] With the expectation of Latour (2004, 2010) who has turned his attention to law and its activities in a comparison of a laboratory (Ecole de physique-Chimie) and the Conseil d'Etat.

legal/technological hybrid is particularly apt as it encapsulates the character of NRTs as made up both of drugs and of regulations. It focuses attention on tracing the ways in which pharmaceutical regulations are embedded within NRTs. However, Cloatre does also draw attention to a possible limitation of ANT for socio-legal research:

> "The extent to which ANT offers scope to theorise the immaterial... Socio-legal objects can become elusive and while their presence remains identifiable – and while ANT is actually a useful approach to conceptualise their presence – their modes of action can remain difficult to seize." (2008, p.278)

Moreover, Cowan and Carr (2008) raise the issue of what other possible focal points may have become blurred in their use of ANT. Both criticisms suggest a need to be aware of the limitations of ANT and what it draws attention away from, as well as what it uncovers. Both papers also note the similarities ANT has to some more typical socio-legal approaches, particularly Implementation Studies, which suggests a need to consider where ANT connects to what has gone before, as well as when it is innovative.

Central concepts; potential problems

Having identified some of the core characteristics, as well as many divergences, within ANT and considered the tracing of legal connections, I will conclude this chapter by sketching out how these characteristics will be carried into my work and further elucidate some of the key concepts that will used throughout this thesis to understand nicotine regulation, as well as some of the issues that they raise. Firstly, of course, it is important to *follow the actors* and describe their understandings, actions and interactions. This pushes the analyst to trace associations and look for links rather than imposing a framework on the world being investigated. Similarly, ANT allows an approach to a topic that is open as to what will count in the world: entities such as technologies and drugs can play as active a role as scientists. It allows the researcher to adopt an open approach to what counts as data. Moreover, it has become clear throughout this investigation of ANT studies that ANT is very fluid and flexible. The accounts related here use ANT to understand their studies and, through these studies, reinterpret ANT by developing it in different directions and mingling it with a variety of complementary ideas. This suggests a certain flexibility for ANT to be adapted for, and through, my study. However, this approach raises a related set of problems: how do you, the researcher, decide which actors to follow? How do you establish what will count in the world and what is and is not data? Moreover, following the actors may make it more

challenging to maintain analytical distance: you may start to see the world through their constructs and experience their practices (McLean & Hassard 2004).

Translations

The central ANT process of ***translation*** describes the 'dynamic process through which facts, concepts, and physical entities move from site to site and are either reinforced and solidified or else contradicted or undermined' (Valverde et al. 2005, p.86). Translation is the process by which entities enrol and order each other and come to speak for and configure other entities; it is 'the process or the work of making two things that are not the same, equivalent' (Law 1999a, p.8). Translations can be inscribed into a medium and, as Law (1992) notes, embodying relations in inanimate materials – such as texts or buildings – renders them more durable. In addition, Law (1999b) underlines that to translate is also to betray, that it implies both similarity and difference: entities are both the same and changed in the process.

Networks

Whilst the ***network*** metaphor has come under criticism and more recently been replaced with a variety of other concepts, it seems to me to be a useful analytical starting point. Latour suggests networks be seen as 'the summing up of interactions through various kinds of devices, inscriptions, forms and formulae, into a very local, very practical, very tiny locus' (Latour 1999a, p.17). He suggests it helps to flatten the social and investigate the associations between elements (Latour 2005). Using the network as an analytical tool allows the tracing of the elements a technology incorporates and how it is enrolled in, shapes and shaped by the different networks of which it is part. Along with the network metaphor, I use the term *assemblage* in a similar way to describe a, perhaps more tentative, collection of heterogeneous elements. It is, nevertheless, also important to keep in mind the criticisms that have been made of the network as analytical tool, and the potential alternatives. Being aware of the potential limitlessness of networks, their lack of outside, issues of who is included in and excluded from network arrangements, and the tendency focus on construction and stability will hopefully help to avoid them; whilst openness to ideas of ambiguity, fluidity and choreography provides an awareness of alternatives. The practical issue of where and when to *cut the network* (Strathern 1996) remains one of the most central in a research project.

Punctualisation

Law points out that we are 'only sometimes aware of the networks that lie behind and make up an actor, an object or an institution' (Law 1992, p.4). This, then, is another quality of networks – they often become simplified or in ANT terms *punctualised* or *black-boxed* – so that complex webs of relations come to appear as a single entity. When a network is translated into a 'black box', it is treated as a stable, unproblematic, taken for granted actor, and treating this as a fact strengthens the translation (Latour 1987). As Prout notes:

> "A device, therefore, can be seen as packaging a network and extending it through time and space; it can 'delegate' a network, standing in for it, repeating it and performing its work in times and places remote from its origination." (1996, p.202)

The researcher must, therefore, return to a point in time before the networks under investigation were punctualised and where many possibilities still existed (Latour 1987) – where technoscience is being made. Further, an important practical question this discussion raises for the ANT researcher is of when entities ought to be treated as black boxes and when the networks behind them ought to be unpicked.

These important questions of which actors to follow, when to unpick black boxes and where to cut the network and will be discussed further in the next chapter, which examines the practicalities of using ANT to examine nicotine regulation.

Chapter Three: Research Design and Methods

Introduction

The previous chapter provided an overview of some of the key characteristics of ANT accounts. I introduced commonly used concepts and shifting emphases in the production of ANT accounts. At the end of Chapter two, I also began to investigate how an ANT study might be done: we were told that it is important not to judge a priori what sort of actors we will find in the world we are studying; it was suggested that we focus on relations and associations rather than things or people in themselves and the network metaphor was proffered as a tool with which to 'flatten the social'; we saw that ANT is interested in questions of ontology, that we should investigate how the world of our actors is assembled or produced; finally, we were directed to follow the actors, to allow our actors to define their world rather than imposing a pre-determined framework onto our account. However, as Gad and Jensen observe: "...reading ANT texts for their methodology is often quite disappointing. Most texts by Mol and Strathern, Law and Latour do not say much about how to go about doing ANT, practically speaking" (2010, p.19). This was one of the initial problems I was faced with in undertaking this research. Unlike approaches such as conversation analysis or grounded theory where research procedures and practices are explicated in a great deal of detail, there is little in ANT writings on how the researcher might actually go about investigating the world. How exactly, in practice, does one go about following the actors? And which actors ought one to choose to follow in the first place? Chapter two also introduced some potential problems to bear in mind when undertaking an ANT study: how to avoid the tendency to focus on construction and stability and ignore ambiguity and fluidity? How to account for otherness and exclusion? How does one deal with the limitless tendencies of networks? How do you know where to cut the network? It is important when collecting and dealing with data to consider the assumptions your approach makes about the nature of reality and the relation of the accounts produced to reality. This chapter attempts to provide a working answer to these questions. I begin by outlining some the key debates in qualitative research about ontology, epistemology and the position of different kinds of data, and try to locate ANT's position within these. I then discuss how I answered the question of how to deploy ANT. First I discuss this issue generally, and then I move to on to provide an account of this question was answered practically in my research design, collection and analysis of data.

Methodological questions

Realism or constructivism?

The centrality of the relationship between analytic perspectives and methodological issues is commonly emphasised in the methodological literature (e.g. Hammersley 1992; Silverman 2006). As Hammersley underlines: "...there is no escape from philosophical assumptions for researchers. Whether we like it not, and whether we are aware of them or not, we cannot avoid such assumptions." (1992, p.43) From the very beginning of the research process, in the questions that are asked, the way they are formulated and the ways that are chosen to collect data, the researcher makes assumptions about the nature of the world being studied and the relationship between it and accounts of that world. Paying attention to the philosophical underpinnings of research methods brings us to one of the most fundamental debates in many social science disciplines, that between realist and constructivist positions on what is 'out there' to know about. These have taken different shapes in different disciplines: in anthropology as a 'crisis of representation' (Clifford & Marcus 1986); in sociology as approaches that examine the socially constructed nature of reality; and in STS as a focus on the role of the social in the construction of scientific accounts and the development of technologies. What follows is necessarily an oversimplification of far more complex and subtle positions, but hopefully it will give an overview of some of the key concerns so ANT's position may be located.

Qualitative and quantitative methods had commonly been used side by side and ethnographic methods had been developing within anthropology and sociology during the early twentieth century (Murphy et al. 1998). In the 1930s and 40s the dominant methodological model in the natural sciences was increasingly seen as the proper model for the social sciences, and experimental and survey research were emphasised (Hammersley & Atkinson 1995). The dominant model of 'positivism'[34] saw knowledge acquisition as progressive, science as an ongoing cumulative process of discovery, and scientific endeavour as requiring disinterested objectivity (López & Potter 2001). In this model, experimental logic, empiricism and the development of universal laws were

[34] It has been pointed out that 'positivism' is often used as a term of abuse or 'straw man' by qualitative researchers and a caricatured position painted (Hammersley 1992; Hammersley & Atkinson 1995; Silverman 2006)

emphasised. In reaction to this prioritisation of quantitative methods, some ethnographers questioned whether social phenomena can be studied in the same way as natural phenomena. They argued that, as social action is meaningful, a different model, often referred to as 'naturalism', is required for social science research (Blumer 1986; Lofland 1967; Schatzman 1973). Naturalism prioritises studying the social world in its 'natural' state; therefore, direct observation, familiarity with the social world being studied and the understandings and actions of people within it, and producing accurate and detailed descriptions are essential. This approach is particularly identified with the urban ethnographies of Chicago school sociology and draws on approaches such as symbolic interactionism, phenomenology and hermeneutics that:

> "...argue that the social world cannot be understood in terms of simple causal relationships or by the subsumption of social events under universal laws. This is because human actions are based upon, or infused by, social or cultural meanings: this is, by intentions, motives, beliefs, rules, discourses and values." (Hammersley & Atkinson 1995, p.7)

Nevertheless, it is suggested that observational methods were part of an attempt to create a more scientific and professional way to do social research (Murphy et al. 1998).

The naturalist approach to ethnography adopts a 'realist' approach to the social world. The 'doctrine of realism' is the idea that the external world exists independently of our representations of it; that: "There is a reality independent of the researcher whose nature can be known, and that the aim of research is to produce accounts that correspond to this reality" (Murphy et al. 1998). In the eyes of realists, discovering the truth about the way the world operates is seen as the aim for both social and natural sciences. Hammersley has pointed out that:

> "Despite this commitment to realism, however, there is an important strand in ethnography that pushes in a contrary direction. Central to the way in which ethnographers think about human social action is the idea that people construct the social world, both through their interpretations of it and through the actions based on those interpretations." (Hammersley 1992, p.44)

He suggests that once this stance is applied to the work of the ethnographer the realist position becomes more problematic. As Gubrium and Holstein note (1997), since the 1960s some qualitative approaches have been arguing that everyday reality is 'in one way or another produced by those engaging in it' (1997, p.38). They include social phenomenology, ethnomethodology, social constructionism and some versions of

symbolic interactionism and labelling theory in this 'family' of approaches. These 'constructionist' approaches[35] have in common the premise that reality is constructed or accomplished through human interaction and understandings. Constructionist approaches suggest that positivism and realism fail to take into account the fact that social researchers are part of the social world they study (Hammersley & Atkinson 1995). For many researchers in these traditions there is a need to be more reflexive about the role of the researcher in the production of knowledge.

These doubts about realism are commonly traced (e.g. Hammersley 1992; Hammersley & Atkinson 1995), at least partly, to shifting ideas in the philosophy of science about the nature of the scientific method and particularly Kuhn's *Structure of Scientific Revolutions* (1962). Kuhn highlighted the influence of theoretical suppositions about the world in scientific method as opposed to science as a process of cumulative development towards the truth. This opened the door for work in SSK and STS looking at the practices of science and the role of the social in the production of scientific knowledge. More recently, post-structuralism and the 'linguistic turn', and postmodernist ideas have presented more radical challenges to realist approaches. The linguistic turn describes an increasing interest in the way that language constructs rather than just reflects on reality, and an understanding of language as social (Seale et al. 2004). Postmodernism, drawing on this changing understanding of language and the nature of knowledge, describes a variety of approaches that have in common a rejection of grand narratives (e.g. Lyotard 1984) and a view of knowledge as historically and culturally relative. More radical constructionist approaches argue that the external world consists merely of representations; therefore, there are multiple realities and multiple truths. Research accounts are seen as one representation amongst many rather than representing an independent reality, and therefore equally valid.

One attempt to move beyond the extreme realist and constructionist positions is Martyn Hammersley's 'subtle realism' (1992, 2008). Hammersley's position requires: a shift from a definition of knowledge as beliefs whose validity is known to beliefs whose validity we can be reasonably confident about; that there are independent phenomena in the sense

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[35] Also termed idealist, interpretive or relativist, although these terms all have slightly different meanings and would vary in the approaches they encompass.

that making a claim about them does not change aspects of reality in such a way as to make them true; and, the acceptance that representation is from a point of view and it is possible to have multiple, non-contradictory, valid descriptions of a phenomenon. Subtle realism, therefore, accepts that material reality can be a constraint on the possibility of definition.

ANT's construction

Although, with their post-humanist, constructionist stance, material-semiotic approaches have some commonalities with postmodern approaches, they come at these debates from a rather different angle, as Mol suggests:

> "The western philosophical tradition has it that ontology precedes everything else, and thus to locate it inside practices (robbing it of its universal and unified character in the process) is the interference with philosophy that is sought..." (Mol in Woolgar et al, 2008: p4)

As outlined in the last chapter, early ANT accounts were trying to move beyond descriptions of science and technology that explained change by reference to either the natural/technical (technological determinism) or the social (social constructionism); therefore, attempting to move beyond nature/culture dualisms. In common with ethnomethodology, ANT sees reality as something that is locally accomplished or produced through interaction; however for ANT it is produced not just by humans but also by material actors. In addition, ANT is a form of 'relationalism'; entities are constituted through relationships rather than as having intrinsic properties. Although ANT argues for a view of the world as constructed, it also emphasises the reality of what is constructed through its focus on materiality – not any version of reality can be produced. As in subtle realism, the material properties of objects restrict the descriptions that can be made of them. As Lee and Hassard observe:

> "In short, ANT is ontologically relativist in that it allowed that the world may be organised in many different ways, but also empirically realist in that it finds no insurmountable difficulty in producing descriptions of organizational processes." (1999, p.392)

In fact it has been suggested that in STS more broadly there has been a 'turn to ontology' (Woolgar et al. 2008) – that many STS approaches are more concerned with the various ways the world is constructed, whether this is a focus on practices, performance or co-production, than how it can be known.

How to deploy ANT?

Having considered some of the common observational and analytical positions that shape social research and how ANT approaches fit into (or perhaps reframe would be more accurate) these debates, I want to turn my attention back to the practical question of how one might go about doing ANT. Gad and Jensen (2010) present a helpful analysis of how, what they call, 'post-ANT' might be thought about. They suggest that:

> "...while it might ally with specific methods, it is not itself one... we read ANT texts neither as sociological theories or methodological guides but as additions to and transformations of the study of various networks. This is why we find notions such as a "postplural attitude" or a "nonhumanist disposition" to better characterize ANT and post-ANT..." (2010, pp.19-20)

It is in this spirit that I conducted my research[36]. Refusing to 'know in advance who the relevant actors are in any given situation and what comprises a network' (Gad & Bruun Jensen 2010, p.22) are clearly central to the ANT disposition. This pushes one to conduct ANT research in an emergent and iterative fashion. For this reason, I will discuss the questions of how one might go about doing ANT and the problems this raises alongside a description of how I answered these questions in practice. However, whilst a commitment to not making a priori assumptions about which actors are relevant is a useful tool, it does leave one with the tricky question of where exactly to start, as Gad and Jensen note 'there are no a priori limits as to where the empirical can be found or to what kind of settings will enable insights about a given theme'. They suggest of Mol's (2002) study of arteriosclerosis in a hospital setting:

> "While clinical practice is an obvious site to begin an investigation of a medical issue, the self-evidence of this choice should not lead the researcher to forget that any phenomenon is always part of much larger networks, which participate in defining the qualities and characteristics encountered in the clinic. For this reason, it should never be automatically assumed that that one comes closer to medical reality by engaging with a clinical situation than, for example, by examining performance art, newspaper clips, or patient diaries." (Gad & Bruun Jensen 2010, p.20)

Gad and Jensen go on to underline that knowing which aspects of reality it is important to grasp:

> "...depends on answering the central question, 'crucial with respect to what?' – a question that must be answered by the researcher as much as the 'field.' Indeed, the insistence that this question be answered in each case is to take seriously that if everything is empirical, then researcher is inevitably part of the field. In addition,

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[36] As I am sure is clear from the publication date, this paper did not inform my research strategy; however it did help me think more clearly about many key issues afterwards.

> what this means is that, even if one claims to 'follow the actor,' one cannot shy away from the fact that one is doing so hoping to achieve certain effects..." (2010, p.20)

Clearly one must start with at least some preliminary assumptions about what is important and what to follow. I will, therefore, try to make the assumptions I started with and the decisions I made explicit in the next section.

Ethical considerations

It is argued that whilst the principles of autonomy, protection of the research participant from harm and justice apply to all types of research (Murphy et al. 1998), ethical issues within qualitative research should be seen as processual and embedded in relationships. Murphy and Dingwall suggest that ethical research practice:

> "...depends on the conscientious and reflective commitment of individual researchers and research teams to identifying and minimizing potential harm to participants, to negotiating fully informed consent at the outset and throughout the research process, and to treating all those under study with disinterested even-handedness." (2003, p.167)

Consequently, they argue that informed consent ought to be conceptualised as open ended, relational and based on trust (Murphy & Dingwall 2003). As Miller and Boulton highlight:

> "...while informed consent is often conceptualised as a one-off act – and gaining written consent can be just that – in practice it includes weighing up risk, privacy and protection, safety and potential harm, trust and responsibility and demonstrating that this has been done in a systematic and auditable manner." (2007, p.2208)

Bearing this in mind, ethical considerations will be discussed along with the review of practical issues and decisions that follows. Professional ethical guidelines produced by the British Sociological Association, the Economic and Social Research Council's Framework for Research Ethics and the University of Nottingham Code of Research Conduct and Research Ethics were adhered to whilst conducting this research, which has gone through my School's ethics review procedure.

Designing the study

Developing the research questions and focus

As outlined in the introduction, the idea for the study developed out of growing concerns within the public health community that the division of regulatory responsibility for conventional tobacco products and for alternative modes of nicotine delivery is having perverse effects on the reduction of smoking rates in industrialised

countries. As previously noted two of my supervisors, Ann McNeill, at the University of Nottingham, and Deborah Arnott, at ASH, shared these concerns and had participated in discussions about how the regulation of nicotine products might be improved. They felt that little progress was being made in these discussions and hoped that research into the development and effects of regulation might produce new ideas on this problem. They approached Robert Dingwall, then Director of Institute for Science and Society, to bring his knowledge of socio-legal approaches to regulation and social science research methods to the project and together applied for an Economic and Social Research Council CASE studentship. The project, as developed by my supervisors, began with three preliminary research questions:

i) How did different nicotine products come to be regulated in different ways: in particular, how did NRT fall primarily within the scope of pharmaceutical regulation?
ii) Does the current approach to regulation constitute a barrier to innovation and impede the effectiveness of cessation programmes?
iii) Are there alternative approaches to regulation that might be more efficient and effective?

The project was conceptualised as:

> "...part of a programme within Institute for Science and Society on the boundary between STS, socio-legal studies and public health reflected in the supervision arrangements. It combines elements from the socio-legal studies study of regulation and the STS and public health concern for understanding risk and its implications for innovation. The outcome will contribute to Institute for Science and Society interest in synthesising these traditions, to ASH's policy goals, which identify the need for a variety of approaches to achieve reductions in the consumption of tobacco products and to improving public health. By linking traditional public health approaches to the different resources of STS and socio-legal studies, ASH will extend their portfolio of strategic options in innovative ways. At the same time, the STS and socio-legal studies literatures on regulation will be enhanced by this case study in the consequences of divided responsibility for the oversight of potentially substitutable products."

The project then needed a student.

I came to this project in autumn 2007 with training in sociology and social research methods and a general interest in medical sociology, STS, drug use and qualitative research. I was particularly interested in the bringing together of STS and socio-legal studies ideas to look at a public health problem. I did not, at that point, have any specific interest in, or strong feelings about, tobacco control. Consequently, in contrast to many social science PhDs where the student has developed a project themselves, working with a supervisor, out of their particular interests, I knew little about the subject

matter I was to study but had fairly well-defined research questions. Many PhD projects change their focus quite substantially after the initial investigation. Although I was able to shape the development of the project a great deal, as I had a non-academic stakeholder with an interest in the research and its outcomes the research questions themselves remained fairly fixed. I was, therefore, able to approach 'the field' with relatively few preconceptions about what is important but I was always doing so hoping to achieve certain effects – my gaze was directed by my research questions towards nicotine products and regulations. Additionally, when asked by friends or acquaintances in everyday situations about my research, I found people were often interested in whether I smoked or ever had, and smokers sometimes seemed a little put off by my topic: as if by studying this area, I would automatically take stance on their smoking. I am not sure whether it has influenced my understanding of smoking more broadly, but I come to the subject as someone who had smoked casually in her late teens and early twenties, a 'social smoker', and was able to stop with little difficulty. The initial stages of my research involved a familiarisation with the relevant literatures, with a particular emphasis on the public health literature on tobacco and the multi-disciplinary literature on regulation, as I already had some knowledge of medical sociology and STS writing.

Methods for answering the research questions

The objects of my study are nicotine products, particularly NRTs, and the impacts regulatory governance has on them. As such, it is somewhat abstract and multi-sited. It was clear from my preliminary reading that NRTs circulate through countless local sites and many different types of network – laboratories, factories, supermarkets, pharmacies, clinics, homes, conferences, meetings, journal articles, and reports – and interact with all manner of different actors. The three main methods for exploring the social world are generally taken to be the use of observational methods, interviewing and documentary analysis, or 'hanging out', 'asking questions' and 'reading the papers' as Dingwall (1997) describes them. Dingwall argues that: "If our objective is to understand the foundations of social order, the constitution of society, the organisation of settings or any of the classic questions of sociology, observation must be the method of choice" (1997, p.61). He suggests that because observation enables the documentation of members of a community accounting to each other in natural settings, that observers find rather than construct data. Moreover, ANT studies, highlighting as they do the observation of actors in order to follow the various associations that they make, tend to have an affinity for ethnographic methods.

However, observation generally relies upon having a primary site (or at least multiple central sites (Marcus 1995)) where interaction can be observed: where the ethnographer is able to go and hang out. Moreover, ANT's 'disposition' suggests that there are no a priori limits about where the empirical can be found. Whilst associations formed around NRTs within a clinic setting would likely be a fascinating study, this would not have allowed me to trace the wider networks through which NRTs circulate and are constituted. As Prior (2008) notes for the drug imipramine:

> "Thus, if we were to take the object called imipramine... we could not only trace its singular biography, but also note how that biography is necessarily defined in terms other than its chemical composition. Indeed, its changing identity would have to be grasped via a study of the networks of institutions, corporations, researchers, and concepts in which it has been variously positioned. For the very same chemical compound (imipramine) has been variously regarded as an antipsychotic, a 'sedative', a euphoric, an antidepressant, and nowadays a pharmacogenetic object, depending on what network it is located in." (2008, p.832)

How else might I follow nicotine products? Atkinson & Coffrey (1997) underline the 'pervasive significance of documentary records, written or otherwise, in contemporary social settings'. They note the central role that documents play in contemporary organisations and go on to highlight the need for a 'clear understanding of how documents are produced, circulated, read, stored and used for a wide variety of purposes' (1997, p.46). Similarly, Murphy et al state that 'it is clear that documents are a major feature of contemporary society and, as such, an important source of data' (1998, p.124). In relation to science, Weiner notes that scientists leave behind them, in journals and books, an 'impressive paper trail' (Weiner 1988, p.548), whilst Kerr suggests that journal articles are, 'potent markers of the state of knowledge in a particular field' (2000, p.854). Furthermore, Latour has demonstrated that documents are an important way in which scientific objects are constituted and translated to widespread settings (e.g. 1987, 1999b). Drawing on Foucault, Prior (1997) similarly highlights the way that texts structure the world:

> "Textually ordered knowledge packages and stabilises the order of things as they appear within a wider realm of discourse. Indeed, a text instructs us how to see the world, how to differentiate the parts within it, and thereby provides the means by which we can engage with the world." (Prior 1997, p.67)

He notes that documents are 'active agents in episodes of interaction and schemes of social organisation' and suggests that we need to examine what documents do, not just what they contain. Following Prior, I propose to examine both the positioning of documents within the networks I am studying and the ways that documents enable me

to trace the links in these networks. In this way an 'ethnography of documents' can be undertaken.

What of the other method for qualitative social research; asking questions? Interviews are a very commonly used method in social science broadly and interviews with scientists, clinicians and other experts are often used in STS studies (e.g. N. Brown & Michael 2003; Faulkner et al. 2006; Hedgecoe 2006; Pickersgill 2009). They have various pragmatic advantages over observational methods. Interviews provide a means for exploring topics that are not amenable to observation, including those that lack a clearly defined, physical site where action can be observed or where the site may be difficult to gain access to, for example private locations or where an activity is stigmatised (Murphy & Dingwall 2003). It is generally easier to negotiate access for an hour of an informant's time than the ongoing access required for observation. Interviews are less time-consuming and perceived to give more control to the interviewee over the information to be revealed. However, a range of potential problems have been raised with interviews. What is meant by 'an interview' varies quite broadly: from the very structured standardised quantitative survey interview to the very unstructured interview as conversation approach. Survey interviews, as part of the more general critique of 'positivist' quantitative social science methods, have been criticised for their ideal of the standardised interview which aims to gather facts about reality (Murphy et al. 1998). As Miller and Glassner put it: "...positivists have as a goal the creation of the 'pure' interview – enacted in a sterilised context, in such a way that it comes as close as possible to providing a 'mirror reflection' of the reality that exists in the social world." (2004, p.99) This standardisation of the interview approach is seen as neither possible, as interviewees may have different reactions to the same interviewer, bring different 'framings' to the interview or interpret questions differently, nor desirable, as they do not allow us to grasp the interviewees own meanings (e.g. Cicourel 1964). In contrast, it is argued that the less standardised, more conversational 'qualitative' interview: "...allows the interviewee freedom to talk and ascribe meanings while bearing in mind the broader aims of the project" (Silverman 2006, p.110). The qualitative interview is seen as allowing the researcher to better develop rapport with the interviewee, grasp how informants define their experiences, avoid imposing their own structures and views on the data: to access the subject behind the person.

This 'emotionalist' conceptualisation of the interview has also been critiqued for its lack of recognition that some of the problems of the standardised interview apply to all interviews (Holstein & Gubrium 2004; Silverman 2006). Holstein and Gubrium (2004), drawing on Foucault, suggest that the interview is predicated on a culturally and historically contingent type of subject – the individualised self, '...the bounded, unique self, more or less integrated as the centre of awareness, emotion, judgement and action' (1995, pp.7-8). Moreover, they suggest that interviews are 'part and parcel of our society and culture' and are central to making sense of our lives. Murphy and Dingwall underline that: "The important point here is that *all* interview talk, like all other naturally occurring talk, is *always* socially and contextually constrained." (2003, p.85) Dingwall (1997) argues that this view developed from the symbolic interactionist and ethnomethodological understanding of interaction as a 'dance of expectations':

> "I produce my actions in the expectation that you will understand them in a particular way. Your understanding reflects your expectation of what would be a proper action for me in these particular circumstances which, in turn, becomes the basis of your response which, itself reflects your expectations of how I will respond." (1997, p.56)

When applied to the research interview, it can be seen as 'an occasion for the elicitation of *accounts*' (Dingwall 1997) and as a site of the production of knowledge (Holstein & Gubrium 2004). The interview is understood as a social situation and those participating in the interview, both interviewer and interviewee, as actively making meaning (Dingwall 1997; Holstein & Gubrium 2004; Murphy & Dingwall 2003; Silverman 2006). The interview is a situation in which the interviewee is 'required to demonstrate their competence in the role in which the interview casts them' (Dingwall 1997, p.58). This emphasises the role of the interviewer in shaping the interaction. Accounts are constrained by participants' 'need to present themselves as moral, rational, reasonable people' (Murphy & Dingwall 2003, p.97). It is, therefore, suggested that 'analyses should start from the question of what informants can be seen to be doing with their interview talk' (Murphy & Dingwall 2003, p.97). Whilst in some approaches, particularly ethnomethodology and conversation analysis, the interview is not seen as able to tell us anything about the social world beyond it, others argue that it is possible to examine both the 'inside' and the 'outside' of the interview (Holstein & Gubrium 2004; J. Miller & Glassner 2004; Murphy & Dingwall 2003). Murphy and Dingwall (2003) see interviews as 'potentially accurate descriptions' created by the interaction between what happened and the frameworks available for describing it, whilst Holstein and Gubrium suggest that 'active interview data require disciplined sensitivity to both process and

substance' (2004, p.126). Taking these considerations into account, we might see the interview in an actor-network study as an instance of talking the network into being in a similar way as when Manning describes the flow of information about finding an abortion through social networks:

> "It is my alternative contention that the network itself is created by the search, located by the searching, defined via the transactions carried on between the knowledgeable informants (referees), the abortionists and self-defined candidates, and begins to function as a result of the actor's involvement in it." (1971, p.144)

Using Manning's (1971) conceptualisation, we can think of the network as created, located and defined by the interview talk.

Carrying out the study

Having considered the methods through which I might investigate my research questions and decided on the appropriateness of the use of interviews and documents, I decided to undertake an initial investigation, or 'mapping', of the field. This was to gain a rough picture of what actors (human, material, institutional and conceptual) were involved in this network, what ideas were commonly held or argued over and what (and who) was taken to be important, in order to direct my interviewing and document collection. I did this initially by reading publications seen as key (as recommended by my supervisors). The most recent (at that point) report by the RCP on *Harm Reduction* (2007), which outlines the regulatory situation, was a key resource. To continue this mapping, as well as to begin to tackle the first research question, focussing as it does on how nicotine products were positioned within regulatory networks, and particularly how NRTs came to circulate within networks of medical regulation, some sort of historical investigation seemed appropriate. By undertaking historically-oriented research, I hoped to understand how networks came to be constituted, how some associations came to be made rather than others and to better understand what actors are involved in the network and how they came to be a part of it, as well as what actors have been excluded.

Tracing networks through history

I began this section of my research with an investigation of the secondary literature on tobacco control policy and the development of NRT to establish what further research might be required to answer my questions. As noted in the introduction, tobacco control since the 1950s, particularly the discovery of the link between tobacco smoking and lung cancer and developments in the US, are well covered in the historical literature

(e.g. Brandt 1990; Doll 1999; Lock et al. 1998; Berridge 2006; Feldman & Bayer 2004; Read 1996; Glantz et al. 1998; Rabin & Sugarman 1993; P. Taylor 1984). My starting point for the UK history was Professor Virginia Berridge's (2007) detailed exploration of tobacco control policy in the second half of the twentieth century. From reading Berridge's account, it became clear that Professor Michael Russell in the UK, Dr Ove Fernö in Sweden and Professor Murray Jarvik in the US were important actors in the development of nicotine gum and the concept of nicotine addiction. The journal *Addiction* has published a series of interviews which record 'the views and personal experiences of people who have especially contributed to the evolution of ideas and practices in the journal's field of interest' (Addiction 1994). This includes interviews with Ove Fernö (1994), Murray Jarvik (2001) and Michael Russell (2004), which cover their work on the role of nicotine in smoking and NRTs and provided a valuable resource for this thesis. To establish how tobacco regulation developed, I decided to trace the history of tobacco use and control, which is fairly well covered in the secondary literature (Borio 2007; Gabb 1990; Leavey 1998; Rudgley 1998; Rogozinski 1990; Wagner 1971). Jordan Goodman's (1993) account of the culture and economics of tobacco use from its use in Amerindian cultures to the twentieth century was particularly valuable in tracing the different networks which tobacco has been part of.

The period that emerged from this review of the literature as requiring more detailed examination was during the late 1970s and early 80s when nicotine gum was developed in Sweden and came to market in the UK. Although Berridge (2007) does cover this period in her book, as do the *Addiction* interviews, I wanted to explore the development of nicotine gum in greater detail, particularly how it came to be enrolled in networks regulating the production and sale of medicines. For this reason I decided to pursue a limited amount of primary historical research. I followed Berridge's research to the ASH archive at the Wellcome Library for the History of Medicine and the UK National Archives. I examined documents Berridge had referenced, searched for references to both material and human actors: *Nicorette*; nicotine gum; nicotine; Michael Russell; Ove Fernö, and browsed documents that I thought might be relevant. The National Archive's Ministry of Health papers between 1975 and 1985 contain documents from the Advisory Committee on Borderline Substances (ACBS) which discuss anti-smoking products including *Nicorette*. These included agendas and documents for, and minutes of, committee meetings, and letters to and from committee members. There are also

documents (mainly letters and memos) from the Social Services Committee dealing with possible legislation on tobacco, and agendas and minutes of the Independent Scientific Committee on Smoking and Health (ISCSH). Papers from this period in the ASH archive that were of interest included correspondence of Mike Daube's; documents and notes from various conferences; documents dealing with possible legislation on tobacco and interview transcripts of interviews conducted by journalist William Norman, while researching a book on the political aspects of smoking (Wellcome catalogue), with Lord David Owen and Sir George Godber. In addition, the House of Commons parliamentary papers were searched for references to 'nicotine' or 'tobacco' and the Hansard Commons debates for '*Nicorette*', 'nicotine gum' or 'borderline substances committee'. I also collected various official documents, mainly reports from the RCP and the ISCSH.

This research led to the decision to try to conduct a small number of partially oral-history type interviews to learn more about the regulatory decisions made at this time: in order to better trace how nicotine gum was enrolled into some networks and not others. Colleagues of Ove Fernö and Michael Russell during the late 1970s and early 1980s were identified as potential participants. It should be noted here that document collection, historical investigation and interviewing were, in reality, an intertwined and non-linear process and there was no clearly defined boundary between the historical and 'contemporary' research. Most of those interviews undertaken to better understand the historical situation, addressed the topics covered in the other interviews. The interview process will be covered in more detail in the section on the interviews below. In addition, I searched for scientific papers produced during the late 1970s and early 1980s to understand how ideas about smoking, and particularly the role of nicotine in smoking and the utility of nicotine gum, were changing during this period. Mainly, I located papers mentioned as important by other sources (secondary literature; interviewees).

During this process of historical research and mapping the field, I modified the initial research questions slightly. I separated the second question out into its two parts to reflect that they are different, if somewhat intertwined, issues: ii a) *Does the current approach to regulation constitute a barrier to the innovation of a greater variety of, and more effective, products?* And ii b) *Does the current approach to regulation impede the effectiveness of harm reduction goals?* I shifted to looking at the broader issue of harm reduction rather than smoking

cessation programmes, as it became clear during my reading that harm reduction is becoming an increasingly important and common way of thinking within the field.

Collection of documents

The collection of documents extended from the historical research throughout the data collection process. Documents were collected continuously alongside other aspects of the data. Various sorts of documents were part of the networks I examined. As noted earlier, journal articles play an important role in scientific networks. In addition to journal articles, I collected official documents, mainly reports, produced by various key actors in discussions on tobacco policy including the RCP, ASH, the DH, the WHO, the MHRA, the National Institute for health and Clinical Excellence (NICE) and the EU. Reading tobacco control literature broadly formed a background to my research. Aside from scientific papers collected for the historical research, journal articles were collected in two main areas: those on harm reduction and on nicotine/tobacco regulation. As with the choice of interviewees, sampling of documents was purposive and guided by the notion of following the actors and allowing them to define what is important. Although I read a broader selection of literature, accessed through key word (e.g. "harm reduction", "harm minimisation", "nicotine regulation", "tobacco regulation") online bibliographic searches using PubMed and Google Scholar, I focussed my analysis on documents that were mentioned by informants as key, documents highlighted within these documents, and documents that were commonly cited within the literature. Therefore, the process of document collection and historical investigation can both be seen more as an emergent, iterative process rather that than a straightforward, linear sampling.

Additional opportunistic observational work

Although this study was primarily based on the analysis of documentary and interview data, I also had the opportunity to conduct a small quantity of observation. I attended the joint Society for Research on Nicotine and Tobacco and Society for Research on Nicotine & Tobacco-Europe annual meeting in April 2009 in Dublin. At the conference I was able to conduct three interviews as well as attend private meetings between representatives of various pharmaceutical companies and members of the tobacco control community to discuss progress in NRT development. I was also able to attend a meeting between members of the tobacco control community and the MHRA in November 2009 to discuss the regulation of NRTs. I took minutes at round tables on

harm reduction and plain packaging set up by ASH for the DH. This took place during a period of around six weeks spent working with ASH during the summer of 2009 which was a planned element of the CASE studentship. These opportunities to observe occasions where current regulatory issues were debated allowed me to gain an impression of what actors are seen as important in the field. It helped me to identify and make myself known to possible informants and in some cases this previous contact facilitated the arrangement of interviews.

Interview process

Interviews took place between February 2009 and May 2010. As mentioned in the introduction, all data collection took place prior to the change of government; however, in the later interviews, participants were oriented towards and had started preparing for a possible change of government so this change was by no means entirely absent from the data.

Sampling

The sampling for the interviews was purposive and pragmatic. I wanted to interview actors who themselves, or as part of an organisation, play a role, or have a stake, in nicotine regulation. I identified different categories of actor involved with nicotine regulation: pharmaceutical companies, tobacco and nicotine researchers, NGOs and government bodies. An initial list of key stakeholders was identified from my reading, historical research, conference and meeting attendance, and in discussion with Ann and Deborah, who are very well networked within tobacco control. A list of around thirty potential participants was initially drawn up. Of these, twenty four were eventually approached. Interviews were conducted in stages with themes emerging from each interview, or set of interviews, informing further interviews. As outlined above, the first six interviews conducted were partially directed towards the historical section of this thesis. As nicotine gum was developed in Sweden, two of these interviews were with participants based in Sweden, who had some involvement in the development of nicotine gum. The primarily historically focussed interviews were conducted with experts who had worked in their area for some time and could talk about changes in the field. Key actors within discussions on product regulation and harm reduction were identified: important actors in academic and policy debates (with a UK focus but key stakeholders in the US and Canada whose voices are influential were also identified); a representative of the DH and the MHRA who are clearly key organisations within this

network; representatives of two of the three major pharmaceutical companies involved in the NRT market were identified.

Twenty out of the twenty four people approached were interviewed (a response rate of 83%). One, a politician I had wanted to interview regarding the history of tobacco policy did not respond; another politician I wanted to interview on this subject felt insufficiently knowledgeable about the area to participate; a researcher I had hoped to interview also felt that they would not have much to contribute to the subject; and the final researcher agreed to take part but in the end was not able to find time whilst the interviews were ongoing. Timing of interviews was both pragmatic and theoretical. I began with the more historically focussed interviews in order to trace the development of networks of regulation. Most of these interviews also addressed at least two of the three other research questions and fed into the refinement of my topic guide. In summer of 2009, I turned my focus to the second question on product development, which flowed quite naturally out of my data collection on nicotine gum, and sought to interview representatives of pharmaceutical companies. In autumn of that year a Universitas 21 scholarship enabled me to access some influential US actors. On my return, during winter 2009 and spring of 2010 I was able to follow up any participants I had not been able to meet with prior to my US trip and also approached representatives of two key institutions: the DH and MHRA. I had wanted to leave these interviews until later in the process to allow me to further refine the topic guide and get the most out of these interviews. Harm reduction emerged from my reading and interviews as an important and divisive concept and, as the majority of my interviewees were positive about the idea I sought to interview someone who could give me the opposite perspective.

Access and recruitment

Potential participants were mostly approached by email, with two approached by letter where email addresses could not be found. Where possible I was introduced to the potential participants by email or in person during a meeting or conference by Ann or Deborah, prior to, or as part of, approaching them for an interview. Only three of the eventual participants were approached without prior contact, whilst two of those who declined to participate were. It was felt that approaching potential participants through a mutual colleague would help facilitate their willingness to participate in the project, although it also had the effect of positioning me as a member of the tobacco control

community – a consideration I will come back to shortly. Contact communications explained that I was conducting a research project exploring the regulation of nicotine containing products in the UK. They named my supervisors and gave a brief description of the aims of the project, explained that I was interviewing 'key stakeholders in the field' and outlined briefly why I wanted to interview them in particular, and reassured the recipient that interviews would last no more than an hour and that, 'the interview and all research output would be anonymised, as far as is possible, consistent with the best ethical research practice'. They concluded by suggesting a timeframe for an interview and asking the recipient to reply to the email if they would be willing to participate or for more information. Interview dates and locations were negotiated via email for the most part and arranged to suit the participants.

Development of the interview schedule

As noted above, the interview schedule was developed alongside the historical research. Having settled on the use of qualitative interviews, it was still necessary to determine where on the 'continuum of standardisation' (as Murphy & Dingwall 2003 put it) I wanted my interviews to be located. The 'semi-structured' interview is commonly used in social studies of science and medicine, as well as other contexts where 'elites'[37] are interviewed, to examine the perspectives of scientists and clinicians. This type of interview, which tends to follow a list of broad questions or topics, allows a balance between focussing on the main themes and questions of the research and allowing informants space to define what is relevant and offer their own conceptualisations. The initial interview schedules were designed to tackle the initial question of how NRTs came to be regulated as pharmaceuticals, to examine the process of developing and marketing nicotine gum, then to move towards current issues in the development of new products, the negotiation of regulatory hurdles and the idea and context of harm reduction more broadly.

At an early stage in developing the schedule, it was suggested in a meeting with supervisors that I begin with the question of how my participants came to be working in the field of tobacco control or with NRT products. In nearly all of the interviews this

[37] In the sense of any informant 'who in terms of the current purposes of the interviewer is given special, non-standardised treatment.' (Dexter 2006)

strategy was very effective: it tended to put participants at their ease, helped begin building rapport and facilitated the development of a narrative. It also produced very interesting accounts of how people came to positions that they are now in, which almost unanimously stressed chance and luck in the development of, what was often a long and successful, career in the field of tobacco control. This question, along with the initial concern with historical developments tended to shape the interviews into a historical narrative. Rather than one standardised list of questions, the interview schedule was designed for each participant; moreover, topic guides were adapted in light of previous interviews, with questions that had not worked altered and new ideas investigated. Nevertheless, in general they followed a similar structure of: background questions on how they came to be in tobacco control, historical developments in NRT and ideas about the role of nicotine in smoking and changes in the field; questions examining the concept of harm reduction and its role in tobacco control, views on treatment; whether current NRT products needed to be improved; their views on what a more effective product might look like and whether there are barriers to innovating these products, their views on the impact of regulation and visions of future regulation.

I conducted three interviews at the Society for Research on Nicotine & Tobacco annual conference in April 2009 in Dublin in the conference hotel bar. For the most part, the rest of the interviews took place in offices or meeting rooms at the participant's workplace, with the exception of one in the lobby of the hotel the participant was staying in and one in a meeting room at the University of Nottingham. Two interviews took place over the telephone, which I was initially concerned about due to the lack of face-to-face interaction and cues, and the possibility that these would flow less well; however there was no great difference observed between these and the face-to-face interviews and they were of a similar duration. Interviews lasted between 29 minutes and two hours with a mean length of approximately one hour. Most of the interviews were digitally recorded, with the exception of two who preferred not to be recorded. In these cases notes were taken during the interview and written up as soon as possible afterwards. Reflections on interviews and any informal discussions prior to, or after, interviews were also written up as soon as possible afterwards. This type of 'off the record' discussion was seen as separate from the formal interviews and was not drawn on or quoted as part of the interview data but contributed to the project as background information (see Warren et al. 2003 for a discussion).

Bearing in mind that interviews are at the same time social interactions, another aspect of interviewing experts or elites is the roles taken within the interview. My initial approaches to informants cast them as a member of a particular community – for instance the pharmaceutical industry or tobacco control community – who had specialist knowledge. I found that the interviews cast me in the role of a student keen to learn from the informant's experience. The fact that these elite informants would be, for the most part, used to imparting information to students or colleagues and that I was younger than and, for most interviews, introduced as a student of a colleague seem likely to have contributed to this dynamic, which generally seemed helpful to the flow of the interviews. In fact, in some cases broad questions elicited a lengthy narrative flow with little prompting. In elite interviewing the importance of preparation and familiarity with your material in order to make a good impression is highlighted (Odendahl & Shaw 2001; Richards 1996). In addition to my familiarity with key issues from my ongoing historical work, prior to the interview I made sure to familiarise myself with the career path and any academic output of each interviewee as far as possible. The semi-structured nature of the interview and the presence of the topic guide also served as a way of demonstrating that I was well-prepared for, and valued, the meeting. Moreover, a minority of interviewees, particularly those speaking on behalf of an organisation, requested a list of topics in advance of the interview. Miller and Glassner (2004) note that 'In our experience, interviewees will tell us, given the chance, which of our interests and formulations make sense and non-sense to them' (2004, p.103). I would suggest that this is particularly the case in forms of elite interviewing, where the informant is in a fairly dominant position. There were certainly occasions in my interviews where my informants challenged a category I used or the way that a question was formulated, for instance:

> Int.: *Following on from that, what was the relationship of the ARU* [Addiction Research Unit] *like with the wider tobacco control community?*
> UK-RES-03: *That's a good question. ASH was created in 1971 and Mike Daube became the director in 1973, and before that it was a half time GP who was director of ASH, so Mike Daube was the first real campaigner of ASH. He was appointed to be an advocate, a leader, so that was 72/73, so ASH was just starting in 1973. So the answer to your question was there wasn't a wider tobacco control community, or rather it was really small.*

This led me to be more sensitive to when the 'tobacco control community' actually stabilised as a network.

Likewise, with this form of elite interviewing, I did not consider it necessary to introduce formal informed consent procedures such as consent forms. In fact this sort of procedure might have seemed somewhat patronising when presented to an influential academic researcher. I did, however, consider issues of informed consent, confidentiality and anonymity throughout the process of seeking access to participants and the interviews themselves. Brief information about the project was included when I contacted participants and they were encouraged to get in touch if they required more detail. Before starting the interviews, I reiterated the main aims of the project and asked if there was anything else they wanted to know; I asked if they would be happy for me to record our conversation and explained that the recording would be transcribed, kept securely and was for my use only, and that this was to enable me to focus better on the interview conversation; I also assured them that their views would be anonymised in any research output. To do this, each participant was given an ID that gave them a number, a code for what country they were based in (UK for the United Kingdom, SW for Sweden and NA for North America) and whether they were broadly in the research (RES) or policy (POL) community or the pharmaceutical industry (PHA) (see Table 1 below).

Table 1: Table of interview participants

ID	Interview Date	Participant location	Primary area
UK-POL-01	19/02/09	UK	Policy
SW-RES-02	28/04/09	Sweden	Research
UK-RES-03	28/04/09	UK	Research
SW-PHA-04	29/04/09	Sweden	Pharmaceutical industry
UK-POL-05	21/07/09	UK	Policy
UK-RES-06	31/07/09	UK	Research
UK-PHA-07	20/08/09	UK	Pharmaceutical industry
UK-PHA-08	20/08/09	UK	Pharmaceutical industry
SW-PHA-09	07/09/09	Sweden (Tel.)	Pharmaceutical industry
NA-POL-10	22/09/09	North America	Policy
NA-RES-11	14/01/09	North America	Research
NA-POL-12	27/10/09	North America	Policy
NA-POL-13	28/10/09	North America	Policy
NA-POL-14	28/10/09	North America	Policy
NA-POL-15	13/11/09	UK	Regulatory agency
UK-PHA-16	20/11/09	UK (Tel.)	Pharmaceutical industry
UK-POL-17	17/03/10	UK	Department of health
UK-RES-18	31/03/10	UK	Research
UK-POL-19	13/04/10	UK	Regulatory agency
UK-POL-20	25/05/10	UK	Department of health

Files (recordings and transcripts) were named using these identifiers and any names/identifying data were removed from the transcripts. Participants will be referred

to by these identifiers in any research output including in all following discussion. Other details, for example 'colleague of Michael Russell' are given throughout the text where they are deemed important to understanding particular interview extracts.

Data analysis

Before providing a description of the practical data analysis procedures, it is necessary to return to the issues discussed at the beginning of this chapter in order to elaborate on their implications for the status of the data, and what an analysis can and cannot reveal. Lee and Hassard's (1999) identification of ANT as ontologically relativist and empirically realist underlines ANT's view of reality as performative – as continually being made, but as real nonetheless and amenable to description. As Law and Urry note:

> "...the real is produced in thoroughly non-arbitrary ways, in dense and extended sets of relations. It is produced with considerable effort, and it is much easier to produce some realities than others. In sum, we are saying the world we know in social science is both real and it is produced." (2002, p.5)

They go on to underline that 'methods are protocols for modes of questioning or interacting which also produce realities as they interact with other kinds of interactions' (2002, p.5). Following from this understanding, data are neither literal descriptions of reality nor wholly subjective understandings with no connection to an external reality. Instead, the texts I analysed – interview transcripts, journal articles, reports – are themselves translations: in ANT all representations transform the phenomenon they describe. They are performative, but what is performed is limited both by what the tools the researcher uses are able to enact and by the reality they describe. Therefore, it is important to bear in mind how accounts were constructed and what they were constructed for, as well as the relations they enact, because some elements of reality will be reordered in the production of data. My data allow me to see some aspects of the networks they act in and enact, but not others. Data were viewed, then, as both resource and topic. I see my analysis as aiming at description and explanation of the emergence and ordering of a particular network.

Prior to analysis, the recordings of interviews were transcribed. I carried out the majority of the transcription in order to familiarise myself with the material, although some recordings were transcribed by a professional transcription service to save time. The transcriptions that I did not produce myself were checked through carefully whilst listening to the recording both for familiarity and to check accuracy. Transcription was

limited to the spoken material without the detail of pauses, hesitations etc which were not considered necessary for this project. The decision was made to carry out analysis of the material manually rather than use a data analysis package. The use of NVivo, a package I was already familiar with, was considered but rejected. I felt that NVivo was less useful for my relatively small but diverse data set than it might be for analysing a large set of more standardised interviews and that it might limit openness and flexibility in following actors with its focus on constructing hierarchical nodes.

Data analysis was an ongoing, iterative process that continued throughout the project rather than a delimited segment in the research process. There was a period, once data collection had stopped, when analysis was more intensive; however, prior to this I had begun making sense of the data I was collecting through more informal processes: drawing on it to inform my ongoing research strategy and data collection, reading, rereading, transcribing and noting tentative thoughts and ideas, to the point where I was very familiar with the data set by the time I embarked upon more formal data analysis. Initially, I borrowed some tools and ideas from grounded theory analysis (Charmaz 2006; Glaser & Strauss 1967; Strauss & Corbin 1990), particularly: grounding analysis in the data, 'open' and 'focussed' coding and comparison. My initial coding involved creating concepts to fit the data – identifying, naming, categorizing and describing phenomena found in the text, then categorising and sorting the data into themes using codes that appear frequently to sort large amounts of data (Charmaz 2006). I compared these concepts or themes with previous instances coded in the same category and reflected on the fit between the data and concepts, trying not to force the data into preconceived categories, as I went along. My analysis involved both inductive and deductive elements. I worked to ground my concepts and themes in the data, yet the data were already shaped by the topics I had deemed important and questions I had asked based on my earlier mapping of the field. Departing from Grounded Theory, to refine my analysis I focussed my attention on the ways in which networks were being enacted within 'accounts' (drawing inspiration from the mapping techniques in Clarke's 2005 "situational analysis"), for example: what actors appeared in accounts? How were they positioned? What other actors were they related to? Which actors kept reappearing in accounts as key?

Discussion

In the concluding section of this chapter I will discuss some of the key problems I encountered during the research process, particularly as relates to ANT, as well as considering some of the limitations of this research. One of the issues raised in the last chapter was that of maintaining analytical distance when following actors. In this chapter I also highlighted my frequent positioning as a tobacco control insider within interview situations. It is difficult to know exactly what impact this 'closeness' has on the data. On the one hand it seemed to be an advantage: my positioning as a sympathetic collaborator aided me in gaining access to settings and people within the network and appeared to facilitate openness in many of the interviews. However it probably shaped the way interviewees responded to me, particularly those speaking for organisations, such as pharmaceutical companies or the DH. In one particular interview with a participant who was not linked to the tobacco control community, I found this positioning as an insider, particularly through my connection with Ann and Deborah, had a negative impact on the interview. The interviewee made it clear that he thought I was not asking the 'right' questions – questioning their relevance and my knowledge – and gave quite defensive or dismissive answers to some of my questions. Ann and Deborah were mentioned a few times in answers, sometimes with comments about what they would have told me or said about a topic. This was a difficult interview; however, the data gave me a useful insight into a very different view of nicotine regulation. My position may also have led me, to some extent, to see issues through the concepts and concerns of the tobacco control community and particularly those of Ann and Deborah. This has been very useful in helping me to understand and explore the field. Whilst I have sought out contradicting and divergent views in order to maintain some analytical distance; a view of any network will always be partial.

Two interrelated questions I previously highlighted are: when should the analyst treat a network as a black-box and when should it be unpicked? And, where should the analyst 'cut the network'? As McLean and Hassard highlight:

> "Many of the criticisms expressed by writers dissatisfied with ANT accounting relate to the decision of who to include and who to exclude in ANT studies. Strathern (1996) has suggested this is essentially a question of where and when to 'cut the network'. It involves a continual process of deciding which actors to follow and how to represent them." (2004, p.499)

To make a project manageable, choices and selections are inevitable. Not every black box can be opened and it is neither possible nor practical to attempt to trace a network in its entirety. As McLean and Hassard (2004) imply this is an issue that runs through the collection of data, its analysis and the writing of accounts. As directed by my research questions, I took the key material actors – cigarettes, NRTs: the objects of nicotine regulation – as my guides. Following Latour (1987) I did my best to return to when they were facts 'in the making' and to find the people who are trying to make them more or less of a fact, to trace the closure of the black boxes and the transformations they undergo in later hands. I tried to treat entities as black boxes when this was how they were treated by the actors interacting with them, and as networks when they were problematised. My focus, the parts of the network I illuminate, was dictated in part by aims of the project: on NRTs and their relationship to tobacco rather than tobacco control more broadly, on the regulatory network in England – examining other sites only as when they influenced the situation in England. In part the decision of where to cut the network was pragmatic – dictated by the time and resources I had. I attempted to provide a good enough analysis of the network as it related to my research questions and aims. The next chapter begins this analysis by examining cigarettes and NRTs in the making.

Chapter Four: Tobacco and Nicotine in History

Introduction

Having set out the main contours of ANT approaches and made some general suggestions about how I plan to employ it here, this chapter turns to my first research question: how did different nicotine products come to be regulated in different ways? In particular, how did NRTs fall within the scope of pharmaceutical regulation? As well as exploring these issues, this chapter sets out to demonstrate more clearly and in practice the utility of ANT for this study. To do this I relate two main stories: firstly, I give a broad outline of the history of tobacco use and control; secondly, I narrow my focus and present a case study that investigates the development of nicotine gum and its emergence on the UK market as *Nicorette*. These two sections allow me to trace the translations that central actors such as tobacco, nicotine gum and nicotine have undergone and the relations they have been drawn into, and how these processes have impacted on the regulation of nicotine products.

To provide a concise account of the history of tobacco is a challenging task. Tobacco use spans a huge period of history, as well as being present across the world today. An account that attempts to trace tobacco through time and space finds itself reaching back hundreds of years into areas as diverse as Amerindian cosmology, modern day US agriculture and 16th century European medical beliefs. Nevertheless, there are certain aspects of this history that highlight important points for the following exploration of NRTs. It is through examining this history that we can begin to unpick some of the multitude of heterogeneous associations tobacco has made as it has moved through time and space, and the variety of ways it has been shaped by other actors. An ANT account that traces the movement and transformations of tobacco through time and makes visible the complex, hybrid relations in which it has become enrolled, can help to better understand the ways we think about tobacco in the present. This, in turn, helps to make us aware of the networks with which NRTs were confronted when they were introduced into the UK.

An examination of the introduction of tobacco to Europe and its use for hundreds of years shows the wide variety of practices and relationships through which tobacco has been enacted. In contrast, more recently there have been reconfigurations of the

tobacco-network through which it has been stabilised: the 'invention' of the cigarette and the 'discovery' of the connection between smoking and lung cancer. This stability is particularly important to my discussion of NRTs as it shapes the ways tobacco is mobilised today, and it is on these two moments that this history will focus. Nevertheless, it is necessary to first demonstrate the multiplicity from which these relatively durable associations emerged, as this underlines the particularity of the way we view tobacco today.

Tobacco use and control: an historical perspective

The tobacco plant is indigenous to the Americas. Breed (2002) suggests that the vast timescale, geographic area and different cultures make generalisations about Amerindian tobacco use problematic. Goodman places tobacco in the context of Amerindian hallucinogenic plant use and suggests that:

> "A very large number of New World hallucinogenic plants have been in continual use since the earliest peopling of the Americas... the use of these plants is so widespread that it is possible to speak about cultural networks of hallucinatory experiences: and... the hallucinary experience itself was paramount in Amerindian life and played a critical role in its functioning" (1993, p.20).

In light of his and other accounts (Borio 2007; Gabb 1990; Leavey 1998; Rudgley 1998; Wagner 1971), it seems safe to conclude that tobacco was being used throughout the Americas thousands of years ago and by numerous different Indian groups. In fact, Goodman (1993) suggests that tobacco was the plant most widely used by the Amerindians. It seems to have played medicinal, religious, ceremonial and social roles. Further, Amerindians consumed tobacco in a variety of ways: smoking, chewing, drinking, snuff and enemas, and utilised a range of technologies (Goodman 1993; Rudgley 1998).

Spain and Portugal were the first European countries to have been introduced to tobacco. It is generally accepted (Borio 2007; Gabb 1990; Leavey 1998) that in 1492 Christopher Columbus was given dried leaves by Indians, and later two explorers in his crew were the first Europeans to observe tobacco smoking. From Portugal, tobacco is thought to have circulated to France, Italy, Germany and other northern and central European countries in the middle of the 16th century (Gabb 1990; Leavey 1998). It is suggested that the spread and assimilation of tobacco practices to new locations was incredibly rapid; within a century the consumption or cultivation of tobacco was found in most of the world (Goodman 1993). In this movement away from the Americas,

tobacco remained intertwined with many of the practices for consuming it: chewing, oral snuff and smoking. However, it was detached from part of the setup through which it was understood, particularly the hallucinogenic experience, enrolled into new relationships and transformed. Goodman (1993) concludes that the rapid acceptance of tobacco in European culture was due to the fact that a suitable niche was already present: the belief in a universal panacea in sixteenth century medicine. This belief contributed to the enrolment of tobacco into European medicine and life more generally through being located within the humoral system of the prevailing medical philosophy. For example, Nicholas Monardes' much reproduced 1571 account established tobacco as a humoral essence (hot and dry) and listed various ailments which it cured (Goodman 1993, p.44).

Throughout much of its earlier history in England, as in the rest of Europe, tobacco was not a singular actor but was multiple and shifting: it was enrolled into diverse relationships, took multiple forms, was defined in different ways and constituted through various different practices. At this time tobacco was most often smoked using a clay pipe; however, chewing and snuffing were also taken up. In general, European use of tobacco exceeded supply and in sixteenth century England smoking tobacco was initially popular as an expensive pleasure that 'ranked with dancing, hunting and card playing among the fashionable extravagances of London's dandies' (Wagner 1971, p.11). Despite this, Goodman (1993) argues that tobacco use spread through all social classes rather than disseminating from the top downwards. As well as being transformed into a humoral essence and an expensive pleasure, he suggests that tobacco use was spread through exchange with explorers and sailors to the urban poor.

As noted above, tobacco was enrolled into existing medical practices; however, there were those who rejected this version of tobacco right from its introduction to Europe. Most famously, King James I vigorously opposed smoking tobacco and produced propaganda against it (Borio 2007; Gabb 1990; Leavey 1998). He anonymously published '*A counterblaste to Tobacco*' complaining that:

> "Smoking is 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." (James I of England, 1604 in Borio 2007, Notes: 1604)

As well as labelling tobacco smoking as loathsome and harmful, he raised import duty payable on tobacco. Later he came to realise the financial possibilities that tobacco offered, making it a Royal monopoly in 1615 and prohibiting its cultivation in England in 1620 (Borio 2007; Gabb 1990; Leavey 1998); thus beginning the economic relationship between the British rule and tobacco producers.

Tobacco was developed as a staple crop in the North America in the early seventeenth century by John Rolphe. Having seen smoking in London, he began cultivating tobacco at the British colony of Jamestown in Virginia, and exporting it to London. The success of his first commercial crop encouraged others and tobacco was established as the staple crop (Wagner 1971). With the creation of these new relations of tobacco production and importing during the seventeenth century, the demand for tobacco in England increased. Tobacco was also important in the economic development of the middle southern states of North America, so much so that it was used as currency: "Tobacco rose to become the coin of the realm throughout Virginia and the Carolinas, justifying one of the names given to it: the Golden token" (Wagner 1971, p.18). Later on, during the eighteenth century these networks were strengthened and expanded with the construction of American tobacco factories and increasing tobacco trade between America and Britain. In fact, large quantities of tobacco were exported to the continent from Britain, which become a centre for tobacco trade.

During this period snuffing grew in popularity, and with it came new sets of practices and relationships. It is suggested that it became fashionable amongst the French aristocracy, and the practice was emulated by the court in London (amongst others). In these circles snuffing was highly ritualised. There were a range of concoctions and 'jealously guarded recipes' which many prepared themselves, increasingly elaborate snuff boxes and complicated rules for its consumption (Goodman 1993). Snuffing was also common amongst other classes, although Rogozinski (1990) suggests we see the habits of ordinary people as separate from those of the upper classes. He states that snuff was less expensive than smoking tobacco and sold in a wide variety of forms (it could be flavoured, perfumed and ground differently) by many small retailers. According to Goodman (1993), snuff was the most popular form of tobacco use in Europe well into the nineteenth century and the manufacture and distribution of snuff can:

> "Clearly be viewed as 'modern'. That is to say, snuff alone, of all tobacco products, can be considered among the class of goods that historians have identified as

> belonging to the first stirrings of modern consumerism in the eighteenth century" (1993, p.90).

Until the nineteenth century tobacco was seen as having medicinal benefits, particularly in the form of snuff (Rogozinski, 1990). It is worth bearing in mind that at this time the distinction between the medical and recreational use of substances was blurred:

> "In the eighteenth century the dividing line between consumption of commodities for leisure and for health was not as clearly drawn as it is now. To keep the body in humoral balance was the objective, and tobacco was clearly perceived as playing a key role in this." (Goodman 1993, p.85).

However, Anderson suggests that by the nineteenth century:

> "Tobacco was essentially a leisure drug. Changes in society and the nature of work led to increases in leisure time and disposable income, and tobacco played an important part in social interactions" (2007, p.76).

It was also at this time that smokeless forms of tobacco were generally displaced in Europe by smoking tobacco. The briar pipe, a much better medium for smoking, was introduced to England and probably accounted for an increase in the number of pipe smokers. Packaging for cut tobacco (for smoking), which kept it moister, was improved later in the nineteenth century (Rogozinski 1990).

The modern cigarette

In England (as in Europe more generally), until the nineteenth century tobacco use took a variety of forms, both smoked and smokeless, which changed for diverse reasons including technological innovations, altering fashions and shifting networks of production and importing. In different networks (medical, aristocratic, etc) there were different tastes and tobacco was defined in conflicting ways; these changed over time and no one form of tobacco came to completely dominate. From the multiplicity that characterised tobacco for many centuries I now turn to one of the pivotal shifts in the history of tobacco use, and unpick the network that constitutes the 'invention' of the modern cigarette.

As noted above, a general growth in the popularity of smoking as a method of consuming tobacco was occurring at this time. An important innovation was that of the safety match in 1844, which made smoking much more convenient. Cigarettes in their earliest form were wrapped in vegetable matter and were not adopted by Europeans: probably because of the taste of vegetable matter and the fact that they did not burn or stay together well (Rogozinski 1990). The popular view of the introduction of the

cigarette to Europe is that the smoking of cigarettes originated in the Near East and became popularised among soldiers during the Crimean war. However, Goodman (1993) suggests that whilst the cigarette – like other technologies for consuming tobacco – has its origins in Central and South America, 'modern' cigarettes were first made in Spain. The first factories hand-rolling cigarettes in the UK opened in the 1850s. Cigarettes in this form were not yet a particularly efficient technology for the consumption of tobacco, being crudely made with a very strong type of tobacco and impractical.

In the 1860s, manufacturing of cigarettes began in the US; however, they did not become immediately popular there either. The invention of the Bonsack rolling machine, and its improvement and use by one tobacco manufacturer, Duke, in 1884 – along with the use of filtered, light, air-cured tobacco[38] – was a crucial addition to the network that contributed to popularising cigarettes as *the* technology for smoking tobacco. The Bonsack machine enabled the production of a far higher quantity of cigarettes than hand rolling and allowed Duke to undersell all his competitors. In addition, he introduced effective advertising and promotion in order to sell this vastly increased volume of product. Cigarettes had been poorly packaged in flimsy wrappers until the sliding box was introduced. This new packaging enabled the pack of cigarettes to circulate in global markets (as the containers were much sturdier) and to become an actor in advertising and brand identity networks. Developments in transport links also played an important role in mass distribution of cigarettes. Cigarettes became increasingly popular in both the US and UK. Compared to other methods of consuming tobacco, cigarettes (along with matches) were relatively clean, easy to use and affordable. They quickly became the dominant form of tobacco use and stimulated an increase in smoking.

If the cigarette is viewed as a network in itself, this brings into view the multitude of heterogeneous elements that must be associated and held together for the cigarette to exist: a certain type of tobacco; paper; but also changes in the main type of tobacco cultivated; various new practices and techniques for cultivating and preparing tobacco; a

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[38] Goodman (1993), in *Tobacco in history*, discusses this innovation. It was usually a type called 'American Bright' which produced acidic smoke and was therefore easier to inhale.

machine for rolling cigarettes; consumers who prefer a way of smoking tobacco that is clean, easy to use and affordable. The boundaries of this network can be drawn more or less narrowly to include other objects: the invention and availability of the friction then safety match and the development of the pack containing the cigarettes, and other processes such as the expansion of advertising and marketing.

The cigarette was enrolled into new networks that brought different sets of entities into relationships with each other. Duke's successful mass advertising was both the push to find a way of mass producing cigarettes and necessary to sell the amounts of cigarettes produced. This, and later changes in marketing techniques, were important in redefining the way the cigarette was produced, sold and consumed. As advertising and branding developed, they came to construct the consumer in various different ways. With mass production and mass advertising, the manufactured cigarette came to dominate a market which had, until well into the nineteenth century, been split between various smoked and smokeless tobacco types. By the end of the nineteenth century the majority of tobacco users in most European countries were smokers, but mainly of cut pipe tobacco. During the first half of the twentieth century the proportion that cigarettes formed of total tobacco products consumed in the UK rose from 33% in 1913 to 84% in 1950 (Rogozinski 1990). With the dominance of cigarettes came a move from small-scale and labour intensive production to an industry characterised by multi-national enterprise in all sectors.

In both the US and UK, the first world war is seen as playing an important part in further popularising cigarette consumption, and, more importantly, in establishing it as an integral part of everyday life. In fact, cigarettes were seen as so essential that they were included in soldiers' rations (Wagner 1971). Along with these factors, a general increase in, and more aggressive, advertising, the failure of prohibition, and the dynamics of taxation contributed to a growing public acceptance of smoking. During the nineteenth and first half of the twentieth century there were large increases in both absolute and per capita tobacco consumption. The total consumption of tobacco products in the UK rose from 97,466 US pounds in 1913 to 221,500 in 1950 (Rogozinski 1990). With more people smoking cigarettes, and smoking more of them, it increasingly became a more acceptable and normalised practice. In fact, by the 1940s

cigarettes had become more or less ubiquitous and, moreover, can be seen as defining tobacco use.

Having placed an emphasis on stabilisation in this section it must be noted that there continued to be those who characterized tobacco quite differently. Controversy over whether tobacco was harmful rose again in the nineteenth century (Goodman, 1993); moreover, the first organised anti-tobacco movement began in the US. It was an addition to the temperance movement and focussed on a broad range of health and moral concerns. By the beginning of the twentieth century, with cigarette consumption beginning to rise, there was a further upsurge in anti-tobacco campaigning. Social reformers focussed attention on the health and moral effects of smoking, with worries about moral looseness, loss of efficiency and medical harm. This movement was very successful in enrolling others: it culminated in the introduction of anti-smoking legislation in some states and by 1909, twelve states had enacted some kind of anti-tobacco restrictions (Wagner 1971). However, the growing normalisation of smoking and large increases in the amount of tobacco consumed (Rogozinski 1990) led to the repeal of all the US smoking legislation by 1927 (Wagner 1971). In the UK, whilst there was a temperance movement, there does not seem to have been the same sort of early anti-tobacco movements. The Children's Act 1908 in England banned the sale of tobacco to under-16s because of fears it stunted growth (Borio 2007). However, this legislation was tied to wider concerns about the degeneration of young people (Welshman 1996) rather than tobacco more specifically. There were similar acts for alcohol based on medical and moral issues, and particularly concern for the welfare of children in general, but there was not the same manner of organised campaigning around tobacco consumption.

Connecting tobacco and lung cancer

The second shift that I outline involves tobacco's re-enrolment in medical science networks in the middle of the twentieth century. As previously noted, suggestions that using tobacco might have negative health impacts, alongside notions of medicinal benefits, have been voiced right from its introduction to Europe. The earliest scientific study of the effects of tobacco was conducted in 1671. Francesco Redi published an account of the effects of 'oil of tobacco': he injected oil of tobacco into a number of animals, all of which died (Goodman 1993, p.115). In 1761 Dr John Hill, a London physician, suggested a link between tobacco and cancer in his investigation of the effect

of snuff on the nose. Opposing views of the medical significance of tobacco coexisted well into last century. Goodman underlines that 'the discourses in the sixteenth, seventeenth and eighteenth centuries took place without anyone really understanding what constituted tobacco' (1993: 115).

At the beginning of the twentieth century, along with rising cigarette consumption, an increase in cancer of the lungs – a striking exception to many other disease patterns (Brandt 1990) – was noticed by vital statisticians. As the RCP later noted:

> "To account for this increase it is necessary to postulate some causative agent to which human lungs have been newly and increasingly exposed during the present century. Cigarette smoke is such an agent and there is now a great deal of evidence that it is an important cause of this disease" (RCP 1962).

During the 1930s more intensive scientific investigation of the rise of lung cancer, and the relationship of the disease to cigarette smoking, began. In 1938 Dr Raymond Pearl reported to the New York Academy of Medicine on the reduced life expectancy of smokers, and in 1939 the first controlled epidemiological study, conducted in Germany[39] found a strong relationship between smoking and lung cancer. Using predominantly statistical techniques, medical researchers were tentatively linking cigarette smoking with a specific disease, 'lung cancer', and beginning to reconfigure cigarettes as risky.

Despite renewed medical interest in cigarette smoking, these new relationships, and the practices through which they were constituted, were by no means universally accepted. The initial evidence, gathered in the first half of the twentieth century, was mainly statistical. Brant observes that, at this time:

> "The field of epidemiology stood at a crossroads. The bacteriological revolution of the late nineteenth and early twentieth century had directed attention away from the traditional environmental question which had brought epidemiology to the fore. Research came to center on mechanism: identifying causative agents, universally assumed to be microorganisms. Indeed the notion that disease was actually 'caused' by hazards in the environment fell into disrepute... The whole notion of statistical inference was questioned, as research centred on the cellular level" (Brandt 1990, p.160).

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[39] Proctor (1999) notes that in Nazi Germany epidemiology was the most advanced in the world during the 1930s and 40s: "...it was in Germany in the late 1930s that we first find a broad medical recognition of both the addictive nature of tobacco and the lung cancer hazard of smoking." (1999, p.173) He suggests this recognition was linked to ideas about racial hygiene and bodily purity.

Four retrospective studies[40] of the smoking habits of lung cancer patients were published in 1950, which demonstrated an increased risk in smokers, but objections were raised about the potential for bias in the sampling methods (Brandt 1990). Later on in the decade two major prospective studies[41] conducted by Doll and Hill (1950) in the UK, and Wynder and Graham (1950) in the US came to similar conclusions. Berridge (2007) and Brandt (1990) both highlight that this research instigated debates within the scientific community about the nature of causality, proof and risk: the focus of epidemiological studies was on defining comparative risk, rather than the direct causality model of laboratory science. It was not until the end of the 1950s, with the publication of these studies, that both the relationship between cigarettes and lung cancer and the epidemiological practices through which it was constituted began to stabilise and be accepted by medical scientists more widely.

In 1962 the RCP reviewed the available scientific evidence and published a report on *Smoking and Health.* This report both gave legitimacy to the studies on the effects of smoking cigarettes and the methods through which they had come to their conclusions, and brought the evidence into the public and policy domain. It served to stabilise the fact of cigarette smoking as health risk within medical networks and translated this new definition of it into new networks. In the report's recommendations the RCP also laid out a new programme of action delineating cigarette smoking as a problem in which doctors and the Government should intervene. Nevertheless, during the 1950s and 60s, despite the growing scientific consensus (strengthened by mounting evidence and acceptance of epidemiology's medical authority) and the intervention of the RCP report, there was still unwillingness in government to take an active role in intervening in what, contrary to the RCP's programme of action, was considered to be an individual habit. This reluctance was influenced by the government's long-running relationship with the tobacco industry, the importance of tobacco taxation (Read 1996), the normalisation of smoking, and the fact that any campaign would be directed at men. It should be stressed that in 1962, as Bates commented 'smoking was almost ubiquitous in Britain – 70 per cent of men and 43 percent of women smoked' (RCP & ASH 2002). The definition of

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[40] Individuals with lung cancer were identified in hospitals and interviewed about their smoking habits. This group was then compared with a similar group who did not smoke (Brandt, 1990)

[41] In the well known study conducted by Doll and Hill, questionnaires about smoking habits were sent to all British physicians, and on their death information was obtained about the cause.

smoking as a health risk and a collective problem to be addressed by doctors and government put forward by the RCP report challenged a variety of existing networks in which smoking was defined as an everyday, individual activity and cigarettes circulated as an unproblematic consumer product. Consequently, the initial government response was muted: there was a focus on education and continuing informal discussions with the industry.

When the smoking and lung cancer link was initially raised, one of the tobacco industry's first responses was to add filter-tips. In the US the tobacco industry took a predominantly public relations stance to the emerging lung cancer and smoking connection and one of the strands was to promote filtered cigarettes as a healthier alternative (Warner 2002). As health concerns became more widely disseminated, the smoking public in both the US and UK switched to buying filter cigarettes in preference to ordinary cigarettes (Berridge 2007; D. Hoffmann et al. 2001; Warner 2002).

Berridge notes (2007) that the relationship between the British industry and government was different and there was cooperation on 'safer smoking' research. In 1953 the Tobacco Advisory Committee gave £250,000 over seven years to the government to be allocated by the Medical Research Council for research into smoking and lung cancer, particularly identifying and removing the harmful elements from tobacco. In 1956 the Tobacco Manufacturers Standing Committee was set up by UK tobacco manufacturers in order to 'assist research into smoking and health questions' (Berridge 2007, p.84). One project developed a 'smoking machine', an attempt to reproduce the features of human smoking (Berridge 2007). During the late 1960s 'safer smoking' efforts focussed on the investigation of smoking machine-measured tar and nicotine yields. The Imperial Group examined various types of cigarette filters, a filter cigar, and the development of a low tar and low nicotine cigarette in case of further smoking and health publicity (Berridge 2007). At this time safer smoking was an objective shared by industry, government and the public health community. The second RCP (1971) report also addressed reduced nicotine and tar cigarettes in a section on 'less dangerous forms of smoking' (Berridge 2007, p.101) By the end of the 1960s the tobacco industry had invested a great deal of money on R&D into tobacco toxicity and consumer acceptability.

In summary, prior to the nineteenth century tobacco use took many forms. It involved a multiplicity of practices, was used by a variety of different people, and defined in conflicting ways. In contrast to this multiplicity, there have more recently been relatively durable associations formed, through which tobacco has been translated into a more punctualised actor. These two historical processes – the 'invention' of the cigarette and the 'discovery' of the connection between smoking and lung cancer – form an important background to studying the development of nicotine regulation. As I will demonstrate more fully in the following sections, the linkages formed during these shifts (the networks around the cigarette as consumer product and the cigarette-lung cancer connection) continue to shape the character and movement of the cigarette long after their formation.

How did tobacco and NRT come to be in different regulatory spheres?

By the 1970s the cigarette-lung cancer network had grown and further stabilised. During the 1970s and 80s, new actors became associated with tobacco and important discussions took place on why people smoked and what were effective and acceptable ways to reduce the damage caused by smoking, on the role of nicotine in the 'smoking habit', and how an already established substance, tobacco, and a new and unique substance, nicotine gum, should be controlled. My account of this time examines how these questions were answered and by whom, by following the translations that occurred as two actors, the cigarette and nicotine, moved between various sites during the 1970s and 80s. Further, it underlines how the cigarette and nicotine networks became patterned as they encountered and interacted with various regulations.

Controlling cigarettes: safer smoking versus stop smoking

In 1971 the RCP published a second report called *Smoking and Health Now* (1971) and challenged the government with a proposal to take action after the report by co-ordinating the voluntary sector around smoking (Berridge 2007). In the same year the government began to address the problem of smoking and health using the soft law instrument of voluntary agreements with industry, which maintained a tradition of industry-government negotiation and cooperation (Read 1996). The first such code

focussed on advertising[42]. In response to these changes two new organisations were created to deal with the newly defined problem of smoking: the Independent Scientific Committee on Smoking and Health and Action on Smoking and Health. They had quite different remits. ASH was set up by the RCP in response to a perceived need for a 'central information point' that would inform the public about the risks of smoking. They were to act as an external pressure group to play a part in changing opinion on smoking and put pressure on government for change (Berridge 2007). Following the voluntary agreement, the Secretary of State referred the issue of cigarette packet labelling to a new expert committee comprised of scientists and industry representatives who published a report on tar and nicotine tables. In 1973, following problems with this committee, particularly industry disunity (Berridge 2007), the ISCSH was formed to provide systematic and impartial scientific advice on smoking and health.

To better understand the outlook of the ISCSH it is worth briefly exploring some of the relationships in which it was enmeshed. Regulatory networks for both licit and illicit drugs were being reshaped during this period; as a legal commodity, control for tobacco generally looked towards the regulation of licit drugs for a model. Drug safety regulation went through extensive change in the 1960s following the Thalidomide disaster. This resulted in the formation of the Committee on the Safety of Drugs in 1964 and legislation being passed in the form of the Medicines Act 1968. This legislation replaced almost all of the previous statutes relating to medicines, poisons and drugs and acted as an obligatory passage point, reshaping the process through which the substances it covers can be brought to market: it controls the manufacture and distribution of medicines – with safety, quality and efficacy criteria to be met before marketing authorisation is granted – and established the Medicines Commission and CSM (Anderson 2005). Berridge (2007) underlines the importance of personal connections between this drug safety network and the new tobacco committee: for example, the first chair of the ISCSH, Lord Hunter, had previously worked in the drug safety area.

The formation of the ISCSH in 1973 was in response to a perceived need for systematic and impartial scientific advice on smoking and health. The second RCP (1971) report

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[42] This introduced the definition of the cigarette as health risk onto cigarette packets and references to this warning on advertisements: the text read, "WARNING by HM Government. SMOKING CAN DAMAGE YOUR HEALTH."

had addressed reduced nicotine and tar cigarettes and suggested more research be undertaken on less hazardous cigarettes. The committee's membership was not from government, civil service or industry; it included prominent scientists and reported directly to health ministers. However, as was usual in the drug safety area, it retained close links with industry: the most prominent example being Lord Hunter's taking a position in the tobacco industry when he resigned from the ISCSH. The remit of the committee included receiving 'full data about the constituents of cigarettes and other smoking materials', reviewing the research into 'less dangerous smoking' and advising on 'the validity of research results and of systems of testing the health effects of tobacco and tobacco substitutes and on their predictive value to human health' (ISCSH 1975, Appendix I). From the remit, it is clear that the ISCSH's definition of the problem began with the cigarette as central. Following from this definition, along with the position of cigarettes as normal consumer products, their initial focus was on altering the cigarette by finding a less harmful material to replace much of the tobacco.

The first report of the committee (ISCSH 1975) chaired by Lord Hunter was published in 1975. It reported on the preparation of guidelines for the testing of cigarettes containing tobacco substitutes, the testing and use of additives in tobacco products, and the composition of cigarette smoke. A second report (ISCSH 1979), published in 1979, continued and extended this programme, detailing the progress made in the testing of substitutes and the decision to allow them to be marketed with specific conditions. It also discussed lower risk cigarettes, with a particular interest in the reduction of tar and nicotine yields, as well as recommending the reduction of carbon monoxide. Again the committee were focussed on making small changes to the network – this time to tobacco itself, which is un-black boxed and particular elements redefined as risky. Notably, in the second report (ISCSH 1979) one member of the committee, Donald Ball, produced a 'minority report' outlining his disagreement on 'several important details'. He emphasised the need to focus on the reduction of tobacco consumption as well as product modification; for him, a greater reconfiguration of the network is needed.

For the first couple of years the role of ASH remained fluid, with differing definitions of its function and its activities 'low key'. Its earlier aims encompassed both stopping people smoking and lowering the risk of their smoking. In 1973 Mike Daube moved

from the housing charity Shelter to take over as director of ASH. His approach was much more 'media aware' and ASH began to work at creating news rather than just reacting to it: for example, they began to attend tobacco industry AGMs and worked on anti-smoking television programmes. From its creation ASH had a close relationship with government. Initially it was funded by the Health Department, and was able to successfully put pressure on ministers for more action on smoking. Along with this growing public profile and an increasingly important role in the political process, ASH's attitude towards smoking became progressively more 'hard line' (Berridge 2007).

During this time, David Owen became involved in the smoking and health debate. Following the Labour Party victory in 1974 he was appointed Parliamentary Under-Secretary of Health and then promoted to Minister of State for Health in July of that year. Owen was interested in the area of preventative medicine and underlined the importance of the smoking and health problem. His definition of the problem was similar to that of the ISCSH. He stated in a Commons debate: "Some believe that even to talk about safer smoking is to compromise one's stand against all smoking. I do not believe that this is realistic"[43]. Owen was particularly concerned with the relationship between government and the tobacco industry and thought it necessary for the government to be able to exert more control:

> "The one proposal which I have put to them is that until you can negotiate with the industry, with them knowing that you can, that legislation is a realistic possibility, you will never have a proper negotiating machinery. The cards are stacked against the department."[44]

However, he suggests that legislation would not have been found acceptable. Instead he came up with the idea of using the Medicines Act 1968 to control the tobacco substitutes and additives being considered by the ISCSH, with the future intention of also controlling tobacco this way:

> "The order... will ensure that those tobacco products consisting of or containing a substitute for tobacco or an additive to the tobacco would need a product licence from the Government. Such a licence would be granted on advice received from a statutory committee on the safety of the product. This committee would be established under section 4 of the Medicines Act and be based on the existing independent scientific committee." (Owen, Hansard, 16th Jan 76, col. 810-11)

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[43] Owen, Hansard, Jan 20th 1976, p.4.

[44] Norman, W. Interview with David Owen, 20th January 1976. Wellcome Library for the history and understanding of medicine, ASH Archive: SA/ASH/r.24

His programme of action would, as for most other licit drugs, place the Medicines Act 1968 as an obligatory passage point in the marketing of tobacco substitutes and thereby increase the government's control in the network.

Owen managed to win backing from cabinet and the Social Security Committee for this move and was working on gaining support from the tobacco industry. On the 16th of January 1976, Member of Parliament Kilroy-Silk put a motion to the House proposing the order. A draft bill was produced, the regulation passed all the legislative scrutiny (UK-POL-05) and was to be included in the Queen's speech; however, there were concerns about the order procedure – that it would be found to be '*ultra vires*', an exceptional use of powers – and politicisation of the Medicines Act. Owen also cited lack of legislative time as an issue, suggesting that it had to be delayed due to legal complexities and pressure on the timetable[45]. In September 1976 David Owen moved to the post of Foreign Secretary. Whilst it does appear that Owen's desired move ran into some trouble with doubts about the procedure and continuing negotiations with the tobacco industry, it seems that without Owen, the key actor working to connect the Medicines Act and tobacco substitutes, the initiative lost momentum. Owen later suggested that: "The legislation was never brought forward because the Labour government feared too much the effect on the voters and the capacity of the tobacco industry to generate criticism" (Owen 1988, pp.147-8).

The ISCSH did not gain the power to grant a product licence. This, along with another failure of their influence, shifted their approach to the smoking and health issue during the 1970s. To understand this change it is necessary to consider the story of 'New Smoking Material' (Berridge 2007). New Smoking Material was a tobacco substitute developed by Imperial Tobacco and referred to the ISCSH for testing. Imperial invested heavily in the product, and worked closely with the committee on its evaluation. New Smoking Material cigarettes were marketed in July 1977. Despite the support of the ISCSH, by this time the position of other important actors in the network had shifted: there were increasing tensions between the government and industry about price controls, health issues and cigarette advertising, which the New Smoking Material

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[45]Norman, W. Interview with David Owen, 20th January 1976. Wellcome Library for the history and understanding of medicine, ASH Archive: SA/ASH/r.24

launch brought to a head; the anti-smoking lobby was stronger; and the financial position of substitutes had changed (Berridge 2007). Imperial and the ISCSH failed to enrol others into their programme of action: the New Smoking Material cigarettes did not take hold in the marketplace and Imperial made major losses. Government and industry relations also deteriorated from this time. Moreover, feeling that the launch of New Smoking Material had eclipsed the third RCP (1977) report and that the focus on tobacco substitutes had held up progress, ASH became more opposed to the idea of 'safer smoking'.

After this unsuccessful episode, the committee adopted a less radical approach. Their focus shifted towards making existing products safer, mainly through the reduction of nicotine and tar; but they maintained their cigarette-focussed definition of the problem. They published a report (ISCSH 1983) in 1983, this time headed by Dr Peter Froggatt, that investigated issues in the development of less harmful cigarettes including: the role played by tar in lung cancer and the reduction of tar yields; the role played by nicotine in smoking related diseases and the smoking habit, and levels of nicotine in cigarettes; the role of CO; investigations of other components of tobacco smoke; and monitoring of the health effects of modified products. A report published in 1988 (ISCSH 1988) represented a continuance of this more cautious programme and examined the yields of tar, CO and nicotine in cigarettes. Notably, it is the first of the ISCSH's reports to begin by emphasising that people should be encouraged to stop smoking, before going on to say that, if they are not able to, they should be encouraged to smoke less harmful products. Through the 1970s and 80s the ISCSH maintained a close relationship with the tobacco industry. Although there was a shift in the late 1970s, there was a focus on how tobacco – particularly cigarette – smoking might be altered to make it safer.

Meanwhile, during the late 1970s ASH developed a close relationship with the Health Education Council (HEC), chaired by former Chief Medical Officer Sir George Godber. The position of both organisations on the 'safer smoking' programme pursued by the ISCSH with the tobacco industry became increasingly critical. Berridge (2007) suggests that – with this support from the HEC as well as Sir Robert Platt president of the RCP and Dr Keith Ball, one of ASH's founders – ASH's position in the late 1970s and 80s became directed towards the elimination of smoking. In addition, as it became more opposed to the risk reduction approach, ASH's relationship with the tobacco industry

became increasingly hostile. The stance of ASH and the HEC characterised the approach of the public health policy community more generally. During this time the public health understanding of smoking was moving away from the medical model and becoming more influenced by the social sciences, and particularly social psychology. This led to a focus on changing attitudes and behaviours, and an emphasis on self-control in stopping smoking.

Consequently, the efforts of this emergent public health network, as it detached itself from the alliance around safer smoking, were directed towards health education media campaigns, establishing control of tobacco advertising, higher taxation and a growing human rights discourse on the rights of the non-smoker. Berridge points out that this new direction was part of a wider programme for public health: "The 'new public health' concentrated on relationships and the responsibility of the individual. Self-discipline, central publicity, and habit-changing campaigns were central to its ethos" (2007, p.179). Much of the push for control was directed towards the issue of advertising, the main focus of a succession of voluntary agreements between government and industry, whilst control of the product was managed through committee-led collaboration with industry. In the case of cigarettes, no set of regulations was able to insert itself as an obligatory passage point on their way to market. The cigarette-as-consumer-product network was already too strongly established and regulations that encountered it were undermined and translated into industry self-regulation. The process for nicotine was rather different, as we shall see next.

Regulating nicotine: tobacco substitute, poison, food, drug

The active principle of tobacco was discovered in 1809 by a French chemist, Louis Vauquin, and named nicotine. It was isolated in 1828 and the first pharmacological studies were undertaken in 1843, although it was not synthesized until the end of the century (Anderson 2007). During the 1970s and 80s, much of the work in the UK on the role of nicotine in smoking was done by Michael Russell and his team at the Addiction Research Unit (ARU). Similar work was being done at this time in the US by Murray Jarvik, a psychopharmacologist. Russell trained as a doctor and started in Psychiatry at the Maudsley hospital in 1965. He joined the ARU as a researcher in 1969. The institutional location of the ARU, part of a unit exploring alcohol and drug addiction within the Institute of Psychiatry, set it apart from the networks we have seen

forming around the smoking and health problem. As Russell states in an account of the unit's work:

> "The early incorporation of a smoking section within an addiction unit... underline the ARU's awareness of tobacco use as a form of drug dependence at a time when this was not widely accepted." (1989, p.853)

In the early 1970s both Russell (1971) and Jarvik (1970) reviewed the evidence on the role of nicotine in smoking. A number of studies in the first half of the twentieth century had examined the actions of nicotine or smoking on the body, showing effects on the peripheral and central nervous system. Other studies took a different approach and investigated the relationship between smoking patterns and personality. Both Russell (1971) and Jarvik (1970) were interested in linking the 'many and various' (Russell 1971) actions of nicotine to the 'smoking habit', rather than the attributes of smokers. They shared the view that nicotine is the key reason people smoke, as Russell underlined: "If it were not for the nicotine in tobacco smoke people would be little more inclined to smoke cigarettes that they are to blow bubbles or light sparklers! (Russell 1971, p.7) Two previous studies in particular are highlighted. In 1942 L. M. Johnston (1942) undertook the first study of the possible rewarding effects of nicotine by observing the effects of nicotine injections on smokers and non-smokers. He found smokers were disinclined to smoke for some time after the injections. Later Lucchesi et al (1967) studied the effects of intravenous infusions of nicotine on smoking behaviour, finding that intravenous nicotine significantly reduced cigarette consumption. Russell's work was concerned with strengthening and expanding on this link. He was concerned with why people start, continue and stop smoking, and what it is about nicotine that motivates people to smoke.

Nicotine is also a central actor in the story of nicotine gum. This started, according to Ove Fernö, with a letter:

> "On the 12th December 1967, I got a personal letter from a friend of mine, Dr Claes Lundgren... [he] suggested a tobacco substitute for oral use in such a way that suitable doses of nicotine could be administered, which would prevent the user from being exposed to the many harmful constituents of tobacco smoke... he had noticed that submariners, because they were not allowed to smoke, could switch to chewing tobacco in the boat without too much difficulty." (Addiction 1994)

In contrast to the peripheral role nicotine is designated by the ISCSH, Fernö starts out by defining nicotine as central in developing a substitute for smoking. For Fernö it was an unambiguous object: he states that he did not have any doubt that 'nicotine was the

main element in the smoking habit' (Addiction 1994). He describes nicotine as very active: it causes addiction and plays a major part in making people smoke. As Fernö was Research Director at Leo Pharmaceutical Company in Sweden, he had the resources and freedom to act on his definition. The story Fernö narrates tells of the transformation of nicotine in a Swedish pharmaceutical company into various new objects.

Fernö begins with the recognition that administering pure nicotine orally is a possible substitute for tobacco. He describes the process of moving from this recognition to nicotine gum as one where nicotine has an active role in determining its form as a substitute: it needed to be absorbed in the buccal cavity like chewing tobacco and oral snuff; it was dangerous if swallowed in large quantities and it had to be protected from being released too quickly. He notes simply that: "The idea of using chewing gum as a vehicle for nicotine presented itself. From chewing tobacco to chewing gum is not a large step" (Addiction 1994). To enrol nicotine into his gum Fernö had to meet these conditions by testing, then enrolling, a suitable insoluble 'ion exchange resin' so that the nicotine is only released when the gum is chewed. He also had to enrol a chewing gum manufacturer to produce the gum.

Nicotine also played a role on the work of the ISCSH. In their second report (1979), where they first turn their attention to the constituents of tobacco smoke, they come to the conclusion that:

> "Since it is nicotine that the majority of dependent smokers seem to require, it may be necessary for manufacturers to modify the nicotine delivery of cigarettes... Some companies have suggested the addition of natural nicotine or nicotine salts to ultra low tar and nicotine products would produce a more acceptable smoke for dependent smokers. If this practice resulted in an increased dependence among smokers, then it would be difficult to approve it." (ISCSH 1979, p.7)

Later their position seems to solidify further when they state that: "There are many reasons why people start to smoke but dependence on nicotine is probably the most important single reason for their continuing to smoke" (ISCSH 1983, p.5), and therefore that they: "'Wish to encourage a lower nicotine intake on the ground that this will reduce dependence on tobacco and thus help smokers to give up" (ISCSH 1983, p.6).

Starting with nicotine, also leads to recognition of the importance of being able to follow nicotine when it enters the body. During the 1970s the ARU team publish several papers examining smoking behaviour by measuring plasma, urine or blood nicotine

levels (e.g. Russell et al. 1975; Russell et al. 1976; Russell et al. 1980). In several papers Russell stresses the importance of being able to measure nicotine in the blood (e.g. Russell et al. 1975). The measurement of nicotine in smokers' blood is important in understanding how people smoke, how this is affected by the levels of nicotine in cigarettes, as well as making comparisons to smoking machine measurement of tar and nicotine. Russell argues that 'people are not smoking machines' and that 'smokers tend to respond to changes in the tar and nicotine yields of cigarettes by altering their smoking pattern to regulate the nicotine intake' (Russell et al. 1975).

As well as an interest in the role of nicotine in smoking, Russell's work demonstrates a desire to tie his insights about nicotine to smoking policy. The focus of the team at the ARU on nicotine led them to consider the ratio of tar to nicotine in cigarettes. For Russell, unlike the various 'toxic components of cigarette smoke there is 'no evidence that nicotine is harmful in smoking doses' and no doubt that nicotine is the 'primary addictive component of tobacco' (1976, p.1432). He was clear that the problem is the harm smoking causes, not that it is addictive. This led him to advocate a 'safer smoking' approach (Russell 1977). Of the reduction of tar and nicotine yields in British cigarettes and the increased use of filter-tipped cigarettes he stated that 'this is a major achievement and will probably save more lives than much fruitless effort to persuade people not to smoke' (1976, p.1432). However, Russell was critical of the low-tar low-nicotine approach advocated by the ISCSH (Jarvis & Russell 1980), suggesting instead a low-tar, medium-nicotine approach (Russell 1976) In a comment on the second report, Jarvis and Russell (1980) assert that the committee ignore smokers' tendency to regulate their nicotine intake, which undermines the health advantages of switching to low-tar low-nicotine cigarettes, and are too dependent on machine-smoked yields.

The ability to follow nicotine when it enters the body also becomes important to Fernö once nicotine has been, at least partially, successfully enrolled into gum: 'We also realised that we must have a method of analysing nicotine in the blood of smokers, so we started in 1969 to develop such a method" (Addiction 1994). Fernö needed to quantify the amount of nicotine in the body to compare the absorption of nicotine from cigarettes, snuff and the gum. He explains that measuring and understanding nicotine in the blood is crucial for further understanding of nicotine and also for stabilising the gum. By around 1972 Fernö had enrolled nicotine into his gum and had successfully

devised a way to measure nicotine in the blood. The ability to measure blood nicotine demonstrated that nicotine was not being absorbed well from the gum: nicotine was not absorbed well in the neutral pH of saliva and was still not playing its part properly in the nicotine gum network. An alkaline 'buffering agent', sodium carbonate, was necessary to improve the absorption of nicotine and further stabilise this network. Fernö suggests that, 'nicotine has a very strong taste and it has to be masked in some way' (Addiction 1994), so a flavour was also added to the gum. At this point the gum was a in a stable form, the method existed to validate its effects, and Fernö, Russell and their teams were working on improving and testing it. As with Russell and his team, it is recognition of the importance of the role of nicotine in smoking that led the first researchers in Sweden to work with nicotine gum, as one recounted:

> *'I had a very open and positive expectation* [of the gum]... *At that time I was fairly convinced that this is not just a habit; there is an element of drug addiction here and nicotine is probably the culprit."* (SW-RES-02)

For its creator and the small groups of people working with it, nicotine gum is clearly an advance in the treatment of a disease: nicotine dependence.

However, both Fernö and Russell suggest that at this point more work needed to be done enrolling Fernö's company, Leo Pharmaceuticals. Russell states that 'the company president and the scientific advisory committee had resisted supporting the gum for some 4-5 years' (Addiction 2004). A researcher suggested this was because:

> *"The pharmaceutical company was mainly involved with anti-cancer drugs and antibiotics, painkillers ... they said... what is the indication? Smoking cessation. That's not a disease. So, what's the substance? Nicotine. That's a poison. What's the administration form? A chewing gum. Oh, that's candy... nothing about it really fitted into being a scientific, sophisticated product for a research-orientated pharmaceutical company."* (SW-RES-02)

Fernö also surmised that, "The problem was that chewing gum is not a typical product for a pharmaceutical company. Most people in the company did not realise the potential in this idea at all" (Addiction 1994). This resistance provides an insight into how nicotine gum was seen by other actors. For Leo it is not a traditional pharmaceutical product and potentially unethical, as one Swedish researcher commented *'nicotine was a first class poison and doctors killed their rats with it after they had done their experiments, and it had other sorts of baggage around it'* (SW-RES-02). In other pharmaceutical companies: 'no-one was interested' and 'smoking was just a question of willpower', whilst 'the establishment were mostly dubious about the effect of nicotine and over-emphasised the psychological part of the smoking habit' (Addiction 1994, p.1219). In fact, in Sweden it took some

time for the gum to be licensed as neither the food or drug regulatory agency would accept responsibility:

> *"The new head* [of the Swedish food regulatory body] *said of course that it is absolutely impossible: you can't add nicotine to food, it's a poison'. So that road was blocked. And the drugs people still said, 'no it's not a disease; you can't apply for a registration'. So that was in 75."* (SW-PHA-04)

As a researcher commented, *'it turned out to be a hot potato that nobody wanted to hold'* (SW-RES-02). When nicotine gum initially encountered regulations, first food and then drug regulations, it fitted into neither framework: a substance containing nicotine could not be food; however, a treatment without a disease could not be a medicine. The regulations acted as an obligatory passage point through which the gum could not pass, being neither able to associate itself with the category of food nor of medicine, and it was prevented from entering the Swedish market until it was successfully able to act as a medicine within the drug regulatory network.

Both Russell and Fernö (Addiction 1994, 2004) underline the importance of the work of Russell's team in enrolling Leo and further legitimating the gum. Russell attended a Leo board meeting with Fernö, and he and his team had access to blood nicotine determinations and started extensive studies of the absorption of nicotine from the gum (Addiction 2004). Fernö commented (Addiction 1994) that these studies and others demonstrated the safety and efficacy of the gum and played a large part in getting the gum registered as a drug in other countries (in the UK in 1980). A 'full-scale randomised double-blind trial' was conducted by the team at the ARU in 1982. The trial further legitimated the gum and was crucial in it being licensed in the US Here again we see the importance of the ability to measure nicotine in the blood, as well as the role nicotine gum played in the understanding of nicotine. As Fernö stated, nicotine gum 'has been helpful in establishing that nicotine is an addictive drug' (Addiction 1994).

In the UK *Nicorette* was launched by manufacturers Lundbeck on the 16th June 1980, against a background of increasing scrutiny of prescribing practices[46]. Prior to the

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[46] Traditionally doctors had a great deal of freedom in prescribing whatever product they deemed necessary; however, from the 1970s governments attempted to reduce the increasing drug budget in more formal ways, starting with placing controls on what can truly be defined as a medicine. A committee was set up due to concerns that doctors ought to be discouraged from prescribing preparations of a 'doubtful or unethical' nature, unnecessarily expensive brands, and that they should justify prescribing products it could be argued were not drugs or medicines. With the introduction of licensing controls over medicines

launch, the UK CSM considered whether *Nicorette* ought to be given regulatory approval. Unlike in Sweden, nicotine gum was seen in the UK as *'...A medicine right from the start, that was quite clear...* [It] *went to the Medicines Regulation'* (03). It seems that the gum's positioning within a pharmaceutical company was important:

> *'I think it was seen as a drug from the beginning by the inventor of the product... he was head of the R&D of the pharmaceutical company so it was a natural thing for him to see."* (SW-PHA-04)

Although in the UK nicotine gum was accepted as a drug to be considered by the CSM, the license for nicotine gum took some time. There was initial concern about the safety of a nicotine medicine and questions were asked about its cardiovascular effects: nicotine's categorisation as a medicine was still unstable. The CSM eventually found nicotine gum to be a medicinal product that was satisfactory in quality, safety and efficacy, and licensed it as a prescription only medicine to be used as a 'tobacco substitute in smoking cessation'.

The translation of nicotine gum into a 'prescribable drug to help people give up smoking' called *Nicorette* was not, however, the end of the story. Another actor, the Advisory Committee for Borderline Substances (ACBS), intervened in the process of *Nicorette* getting to the marketplace. Lundbeck submitted *Nicorette* to the ACBS to consider whether the product could be prescribed at NHS expense. From the beginning of the correspondence between representatives of the ACBS and Lundbeck the way *Nicorette* is defined differs. Lundbeck, in their letter requesting their product be considered referred to it as, 'our new pharmaceutical product' and suggested that it is: "Intended for patients with smoking associated diseases such as bronchitis, emphysema, etc. And in which the General Practitioner considers continued smoking a serious risk to their physical (and) mental health." Like Fernö they stressed that 'the active ingredient nicotine is a most pharmacologically active drug'. Again, in a later letter[47] they referred to *Nicorette* as 'our new medicinal product', as well as referring to it as a drug

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in 1971 the terms of reference of this committee were further restricted to the consideration of 'borderline substances' and it was renamed as the Advisory Committee on Borderline Substances. Its main criterion was then whether a substance had a therapeutic purpose in the treatment of disease. The recommendations of the ACBS were initially taken to be guidance; however, doctors' prescribing freedom was further limited in 1985 when the Government made it a breach of contract between the doctor and the relevant NHS authority to prescribe a product against the ACBS's recommendations.

[47] National Archives, Ministry of Health papers, MH149/2021, D.E. Middleton to B.A.J Bennett, 10/7/80

and underlining its utility to GPs. However, the ACBS challenged Lundbeck's definition of *Nicorette*, or rather Lundbeck's right to apply this definition, throughout the process. This is demonstrated quite markedly in their response to a letter Lundbeck sent to GPs:

> "I hope you will not mind if I take the opportunity to mention the concern felt here about a particular piece of phraseology which has been employed namely:- '...until the ACBS has completed consideration of the drug.' We feel that the use of the word 'drug' in this context to be unhelpful, indeed, it may unintentionally mislead doctors."[48]

For Lundbeck, *Nicorette* is clearly a pharmacologically active drug and a medicine to treat a defined medical condition: smoking associated diseases. For the ACBS it is an uncertain object, which it is their job to define.

The ACBS first considered *Nicorette* at a meeting on the 26th March 1980. For them, *Nicorette* fell into the category of an 'anti-smoking preparation'. Anderson (2007) notes that in 1965 16 anti-smoking preparations were available over the counter from pharmacies and little was known about their success. The ACBS had previously considered other anti-smoking preparations and found them to be 'not drugs'. Between 1973 and 74 the ACBS considered four products to 'assist patients to give up smoking': *Respaton*, *Lobidan*, *Bantron* and *Nicobrevin*. The first of these was intended to create a 'foul taste' in the mouth when it interacted with tobacco smoke and the other three to reduce cravings – the latter two specifically for nicotine. *Nicobrevin* was granted a product licence in 1973. A summary of the ACBS's position reports that there was no evidence from controlled trials, and the products had 'no therapeutic effect on patient's condition'; therefore they were considered 'not a drug'. In the meeting on *Nicorette* the committee were reminded of this stance. The minutes also record that they were 'mindful of the importance of having the views of specialists in respiratory medicine and of epidemiologists in coming to a decision' and advised 'to consider the likely consequences of a positive affirmation by the committee that *Nicorette* was a drug – "something that cured smoking"'. Here the committee mapped *Nicorette* onto the category 'anti-smoking preparation' and identified other actors who will be allowed to provide their definitions of *Nicorette*.

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[48]National Archives, Ministry of Health papers, MH149/2021, D.R. Chamberlain to W.P. Evans, 21/7/80: 1

The ACBS initially wrote to these chosen specialists in May 1980 and the input of additional specialists was sought during this summer. The experts invited to consider *Nicorette* were specifically asked:

> "Whether Nicorette were [sic] likely to provide a significant benefit to the health of smokers when compared to other tobacco substitutes – none of which are available on the NHS – and other preventative measures, such as anti-smoking educational campaigns."[49]

The way that the various experts defined the problem and the resultant recommendations varied. Many suggested that the evidence they had been provided with was not very impressive and raised doubts about *Nicorette*'s effectiveness; only one of these reported personal experience in testing it. The minority whose recommendations on *Nicorette* were positive challenged the ACBS's definition of the problem in one way or another, and focused on what *Nicorette* can do.

Having collected various opinions, the committee made their decision on *Nicorette* in a meeting on the 22nd October 1980. The minutes from this meeting record the chairman's suggestion that they consider whether smoking can properly be seen as a disease and the committee's suggestion that 'smoking should be regarded more as a habit than an addiction'. They deliberated on what sort of thing *Nicorette* should best be viewed as for their discussion:

> "It was clearly not a 'toiletry' and they queried how it could be regarded as a 'food' item, since it contained a poison (nicotine). The Secretary observed that the indications implied 'Nicorette' might be regarded in the round as an 'anti-smoking preparation'. However, it was notably different from other anti-smoking preparations which the Committee had considered and so it was proper for the product to be examined as critically as any other new product coming before the Committee for the first time."[50]

It was noted that the trials the experts reviewed were found by them to be 'defective in their methodology' and the feeling of the committee was that

> '*Nicorette* was a nicotine substitute which did not appear to have a truly curative effect on those who used it in the hope that it would eradicate their smoking; that there was demonstrably a need for more testing of the product over a longer term with more people."[51]

For these reasons, the ACBS finalised their definition of *Nicorette* as 'not a drug', but suggested that the decision would be reviewed when further evidence became available.

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[49] National Archives, Ministry of Health papers, MH149/2022 , Draft letter, May 1980
[50] National Archives, Ministry of Health papers, MH149/2018, Minutes, 22/10/80, p3
[51] National Archives, Ministry of Health papers, MH149/2018, Minutes, 22/10/80, p3

This decision placed *Nicorette* in the strange position of being a licensed medicine available on prescription that doctors cannot prescribe on the NHS. Whilst medicines regulation acted to enrol *Nicorette* into the network as an object that is a safe, effective medicine, a treatment for a specific disease, to be prescribed by doctors; the ACBS was able to impede its circulation within the network by limiting the ability of doctors to prescribe and patients to access it.

Discussion

Through following two non-human actors – cigarettes and nicotine – I have brought into (partial) view a variety of different networks and the ways that they intersect and by-pass one another. Examining these networks – the connections and associations that they, and the actors that make them, are constituted through – has allowed me to describe how these two central actors are translated as they move from one site to another. Moreover, I have explored the interactions between these two actors and the regulations they encounter; interactions which I suggest shape their action in important ways.

It is clear that for both Russell and Fernö nicotine is central. It is with nicotine that both begin in their interpretation of the smoking and health issue. They view nicotine as active; in their work it is the actor that causes dependence in cigarette smoking. They both also work on detaching nicotine from tobacco in various ways. They underline the importance of following nicotine as it enters the body and of finding ways to quantify it when it appears in blood. These methods for making nicotine speak tell of the different ways that smokers smoke their cigarettes and of how different ways of putting nicotine into the body affect the amount of nicotine in the blood. This measuring also reveals more about nicotine itself and underlines the argument that nicotine is addictive. It follows that for both Russell and Fernö the utility of nicotine gum is clear, as Russell states, 'people smoke for nicotine but they die from the tar' (Russell 1976, p.1431). Separating nicotine from the tobacco and from the tar is an obvious step. For them the gum is a great success, the first effective treatment for nicotine addiction and great progress.

Yet, as *Nicorette* moved into other sites and interacted with other actors – some that had agendas similar in many ways – it was largely ignored. The ISCSH, who were never brought into contact with *Nicorette*, began their work from a distinctly different starting

point from Fernö and Russell; they were also positioned in quite different networks. From the beginning the ISCSH's focus was on tobacco and the idea of safer cigarettes, with nicotine of only peripheral interest. They investigated nicotine with other tobacco constituents, particularly tar and CO, as potentially harmful and therefore in need of reduction in tobacco: the ISCSH's reasoning on nicotine took them the other way from Russell and Fernö. Moreover, the experience with the failure of New Smoking Material turned their attention away from the idea of substitutes. It is also likely that the ISCSH's relationship with the tobacco industry shaped the way that they approached the problem. Further, the influence of ASH and the shifting of the public health agenda made abstinence, as a way of dealing with the smoking problem, much more central in policy circles. The concept of smoking as nicotine addiction did not enter these networks, as a colleague of Russell's commented:

> *"As the tobacco control field grew, most people in the field, apart from us lot, the scientists at the unit, were very, very uncomfortable with the idea of nicotine treatment because it medicalises things...They didn't really like the idea of emphasising that it's an addiction. In their minds it went against the idea that you can change it, or that you can easily change it..."* (UK-RES-03)

As *Nicorette* moved into networks which were not shaped by ideas about the role of nicotine in smoking, but by ideas of abstinence and will power, it was detached from the disease it was to treat – nicotine addiction – and became an uncertain actor that did not fit easily anywhere.

During the 1970s and 80s the government enrolled various soft law mechanisms and actors in ordering the cigarette network; public education, product modification and collaboration with other stakeholders, particularly the industry were emphasised. A regulatory regime for the tobacco products in circulation was gradually put together and solidified as the health impacts of tobacco use became more widely accepted and the tobacco control community became more influential. Nicotine gum, on the other hand, as a new actor in these networks, was translated as it became part of them. The success of nicotine gum, developed within a pharmaceutical company, depended on its categorisation as a medicine, and since there was a pre-existing regime in which medicines were regulated, it was enrolled into this regime. In Sweden, this was by no means straightforward and the gum had to be made to act like a medicine, with a specific disease to treat. In the UK, nicotine gum was able to act as a medicine more easily and pass through the obligatory passage point of the CSM; however, another actor

was able to set itself up as a further obligatory passage point and disrupt the flow of *Nicorette* within the network.

For the ACBS, *Nicorette* came to its attention at a time when there was an emphasis on greater control of what doctors could prescribe and therefore a greater need to control what would be seen by the NHS as a drug. Moreover, for the ACBS *Nicorette* could be mapped on to a group of products, 'anti-smoking preparations', already categorised by them as 'not drug'. Their consultation with experts in the smoking and health field showed that both the definition of what sort of problem smoking was, and what sort of thing *Nicorette* was, were not stable. The ACBS defined the problem with *Nicorette* as whether it was proved to be effective, 'truly curative' as they say, in treating smoking, whilst others draw the boundaries of the problem much more widely discussing the harm caused by smoking. The ACBS, whilst not a legal body, was able to intervene with *Nicorette* as it was translated into a prescription only medical product to treat smoking associated diseases and position it as a potentially ineffective anti-smoking preparation that doctors could not prescribe on the NHS.

Medicalisation

To develop our understanding of the translations tobacco and nicotine have undergone in this chapter, as well as those I will describe in the next chapters, I now turn to the concept of "medicalisation". The term medicalisation is used to describe the process whereby areas outside the remit of medicine have come to be treated as medical problems and defined in medical terms (Conrad 1992). Early explorations of medicalisation in the 1960s and 70s (i.e. Freidson 1970; Szasz 1963; Zola 1972), took a social constructionist approach to examining the medical profession's expanding jurisdiction over determining what illness is and how it is to be recognised, and were often critical of medicine, particularly the field of psychiatry. Conrad and Schneider's *Deviance and Medicalisation* (1980) drew on this earlier work to examine the transformation of particular moral problems such as madness, drunkenness and opiate use from the legal realm of 'badness' to the medical one of 'sickness'. Strong (1979), however, has argued that sociologists' analysis of medical imperialism may be distorted by their own professional ambitions, leading them to overstate the problem and overlook the limits to medical imperialism. He observes that critiques of medical imperialism tend to lack a historical awareness, to mistake the activities of small groups of 'missionaries' for the strategy of the profession as a whole, to underestimate the technical successes of

modern medicine, and to overestimate the importance of medicine in patients' lives. He goes on to argue that there are several factors which constrain medicalisation including, importantly, doctors' own view of the "essential" work of their profession which 'revolves around those fundamentally biological matters which are one and the same time both technologically complex and susceptible to practical intervention' (Strong 1979, p.209). Strong (1979) makes the point that doctors are, in fact, unwilling to intervene in problems, such as alcoholism, that are seen as predominantly psychiatric, and where there are doubts about the efficacy of interventions.

Conrad (1992) has later proposed that, in order to move away from assuming that medicalisation involves a movement into the domain of the medical profession, the 'definitional issue' ought to be regarded as key. He states that:

> "Medicalisation consists of defining a problem in medical terms, using medical language to describe a problem, adopting a medical framework to understand a problem, or using a medical intervention to 'treat' it." (Conrad 1992, p.211)

The ideas of Michel Foucault have also been influential in shifting focus from the medical profession to the relationship between 'medical discourses' (medical systems of thought and knowledge) and the exercise of power in society. Lupton (1997), echoing Strong (1979), notes that the 'medicalisation critique' has, in a rather 'black-and-white' manner, seen medicine in a negative light, with doctors as concerned with increasing their power, and patients as powerless. She argues that Foucault's ideas help to highlight the positive, productive and distributed nature of power, and, further, underline the participation of medical knowledge and practices in the constitution of bodies and subjectivities, in the way we understand and experience our bodies. Rose (2004) also highlights the centrality of medicine to the notion of a normal person. Furthermore, the rise of epidemiology and preventative medicine, with their focus on risk factors and health promotion, are seen as having moved medical and health concerns into every corner of everyday life (Armstrong 1995; Lupton 1995; Nettleton 1997).

Recent work has underlined that processes of medicalisation are 'complex, multisited and multidirectional' (A. E. Clarke et al. 2003), that they may not directly involve the medical profession and that other actors such as consumers and the pharmaceutical industry are playing an increasingly important role (Conrad 2005). Clarke et al (2003) see this as the transformation of medicalisation into 'biomedicalisation': the transformations of both the human and nonhuman made possible by technoscientific innovations.

Whilst Conrad (2005) argues for seeing these changes as shifts in processes of medicalisation. Much has been written on the role of pharmaceuticals and the pharmaceutical industry in processes of medicalisation. The pharmaceutical industry is increasingly seen as driving processes of medicalisation (e.g. Conrad 2005; Williams et al. 2008) or even 'disease mongering': the promotion of a new disease concept to sell a drug (e.g. Healy 2004, 2006; Lexchin 2006; Moynihan 2003; Tiefer 2006). Williams et al argue for use of the separate term 'pharmaceuticalisation' to examine concerns to do with the: 'potentially widespread use and uptake of pharmaceuticals for diverse purposes which extend far beyond the realms of medicine' (2008, p.3).

Tracing the shifting English tobacco control network as it was constructed during the 1960s and 70s, suggests that tobacco use, like the use of other recreational drugs, has gradually enrolled networks of medical definitions, objects, professionals and practices. This process began with the redefining of smoking from leisure activity to risk factor for, and later leading cause of, lung cancer. The concept of nicotine addiction, developed when various scientists, particularly Michael Russell, studied the action of nicotine in the body, shifted smoking from risk factor to disease, understood in physiological-pharmacological terms. This new understanding enrolled medical explanations and ways of thinking. However, as Strong notes for alcoholism:

> "Although doctors may have been persuaded that there is a lot of alcoholism about, and they may also have come to see it at least partly in disease terms, very few of them think that it is a disease about which they themselves could or should do very much" (Strong 1979, p.206)

Although a 'small group of missionaries', as Strong (1979) puts it, had expanded medical definitions into a new area, the creation of the disease nicotine addiction and the enrolment of the medical profession and the wider public health community around this new idea proved to be a far harder and longer struggle than is often described in the medicalisation literature. Whilst the development within a pharmaceutical company of a treatment to deal with nicotine cravings both enrolled and strengthened this new definition, there followed a long period in which actors such as Michael Russell and Ove Fernö worked to enrol others into their programme of action. The tobacco control network, constructed around ideas of habit and abstinence, resisted this new definition and their progress was slow.

Chapter Five: Contesting and Translating 'Harm Reduction'

Introduction

In the previous chapter I considered the history of the cigarette: the way it came to dominate tobacco products, its later positioning as a public health risk, and the main strategies used to control this new problem. New organisations such as the ISCSH and ASH were created to deal with the problem of smoking, and an anti-tobacco coalition began to be formed to advocate action on smoking. The action required was increasingly defined as abstinence from smoking as opposed to 'safer smoking'; especially as the tobacco industry became increasingly seen as the enemy by the anti-tobacco coalition. The parallel story of the emergence of the concept of nicotine addiction and the development of nicotine gum was outlined, and the coproduction of these two actors highlighted. I concluded Chapter four at the point where nicotine gum was licensed as a prescription only medication, *Nicorette,* but ambiguously positioned as a borderline substance. In this chapter I continue this story by tracing the growth of, and shifts in, the anti-tobacco coalition from the 1980s, the extension of control over cigarettes, the stabilisation of the concept of nicotine addiction and how this reshaped the tobacco control network. I then turn my attention to the strategy that is currently being deployed in an attempt to further reshape the tobacco control network. This coordinating strategy, 'harm reduction', draws together and translates various discussions within tobacco control, dividing the community. Furthermore, it has implications for how various nicotine products, particularly NRTs, are understood and circulate.

During the 1980s and 90s there were some significant changes within the public health network. The anti-tobacco coalition grew and began to broaden, enrolling influential actors: for instance, the British Medical Association became more involved in public health issues and started working with ASH and the HEC on tobacco issues in the mid-1980s. The interests of the coalition also evolved. During the 1970s ASH had underlined the need to take into account the rights of non-smokers, as had previous anti-smoking groups; however, during the 1980s this was translated from an issue of rights to medical harm. A paper by Hirayama et al (1981), published in 1981, investigated the health of the non-smoking wives of smokers, and, using epidemiological methods, linked the inhaling of their husbands' smoke, or 'passive smoking', to an

increased risk of lung cancer. The new concept of passive smoking reshaped the public health network in a number of ways: it translated the inconvenienced non-smoker into a new category – the innocent victim of smoking; brought in the legal and occupational health fields; created links with biomedical research (through the need to measure smoke intake of non-smokers) and contributed to the increasingly adversarial relationship with the tobacco industry (Berridge 2007). However, Berridge (2007) suggests that the two key actors in the anti-tobacco coalition, ASH and the HEC, had problems during the 1980s and 90s: ASH was in difficulties for much of the 1980s with inconsistent leadership and a loss of influence with ministers; the HEC also had a poor relationship with ministers, who formed the Health Education Authority in 1986 partly as a way of limiting the power of the HEC (Berridge 2007).

At the end of the period described in Chapter four, in 1979, a Conservative government came to power. This almost 20 year period, until they left office in 1997, can be seen as one of gradual shifts in the tobacco control network. An interviewee commented that: *"...the whole of these years, through the 1980s, we had a very unsympathetic government"* (UK-RES-06). The early 80s saw the departure of various ministers who were sympathetic to public health interests (Berridge 2007). Maintenance of the close relationship between government and the tobacco industry is illustrated by the continued negotiation of voluntary agreements on tobacco; this also reflected the tendency of British political culture to 'seek pragmatic solutions, avoid conflict and proceed by consensus' (Raw et al. 1990). As previously noted, the agreements began in 1971 and negotiations continued into the 1990s. These agreements very much focussed on the ways tobacco products could be presented and promoted (i.e. TV advertising, health warnings, sports sponsorship): an issue that was high on the public health agenda during this time. Another series of agreements was negotiated during the 1980s on product modification and research that measured and publicised the levels of tar, CO and nicotine in cigarettes. As highlighted in Chapter four, tobacco products continued to be shaped by soft law.

Along with voluntary agreements, various other strategies were used to control cigarette smoking. Smoking had been increasingly restricted on public transport and in cinemas during the 1970s and 80s. In 1987, following a fire in Kings Cross underground, smoking was banned throughout the underground network. As the tobacco control

community worked to stabilise the concept of passive smoking during the 1980s and 90s, private companies increasingly implemented restrictions on smoking in the workplace. Rather than use existing (i.e. the Health and Safety at Work Act 1974) or newly negotiated (i.e. the Environmental Protection Bill 1990) legal mechanisms, the government produced recommendations, guidelines and targets – for example the Department of Environment produced guidelines on the introduction of restrictions on smoking in public places in 1991 and targets for the reduction of smoking in public places were included in the *Health of the Nation* (DH 1992) White Paper – and restrictions were enacted through voluntary action by employers (although the law was present in the fear of legal action for health damages) (Berridge 2007). Control of tobacco through increasing taxation was also high on the anti-smoking agenda: in 1993 health care organisations led by the Health Education Authority and ASH made a joint submission to the Chancellor of the Exchequer, Ken Clarke, urging the Government to raise the tax on tobacco and later that year Clarke announced his intention to increase excise duty on tobacco products by at least 3% on average each year in future Budgets.

In the late 1980s there was the first shift away from voluntary agreements in UK tobacco control. This was driven by an ASH campaign against Skoal Bandits, a brand of oral tobacco. An account is given in *Clearing the Smoke*, a book which sets out a guide for 'action on tobacco':

> "Alison Hillhouse at ASH Scotland heard about US Tobacco's plan to manufacture Skoal Bandits in Scotland from a journalist in January 1985. Publicity about the factory provoked outrage because it was to be built with the help of money from the government." (Raw et al. 1990, p.103)

ASH Scotland began a campaign asking the government to ban smokeless tobacco and withdraw support from the factory. The campaign built support from the local community, health professionals, the media and other campaigning bodies, and particularly underlined the need to protect children. It developed enough support to force the government to act: in July 1986 the Protection of Children (Tobacco) Act was passed, which made it an offence to sell any tobacco product to persons under the age of sixteen. In February 1988 the government announced that it would ban oral snuff under the Consumer Protection Act 1987, and after a period of consultation and notification of the European Community, the announcement was made that oral snuff would be banned from March 1988. This legislation formed the basis for a 1991 EC Directive.

In fact, the tobacco control network was connected to European and international sites to a greater degree during the 1990s. Most directly, Directives passed in Europe intervened in the UK to replace soft law in the form of voluntary agreements with various binding legal controls over how tobacco could be promoted and sold. It is therefore worth taking a brief diversion here and giving an account of tobacco control in some other connected sites, particularly the EU. The first European conference on tobacco control was held in Madrid in November 1988 and jointly organised by the WHO, the EC and the Spanish Ministry of Health. This was a clear indication that the EC wanted to take a more active role in tobacco control policy. Previously, the EC had launched the European Programme against Cancer (EPAC), which recognised the importance of tobacco control in their first action plan. The earlier Single European Act gave a greater weight to health in the community: Article 95 (ex100a) states that when the community takes harmonising measures to create a single market, a high level of health should be taken as a basis for proposals. Further, in 1993 the Treaty of Maastricht formalised the Community's role in public health in article 129 which provides the direct legal basis for EU health policy.

In the late 1980s the EC announced its intention to legislate on health warnings and restrict tobacco advertising and promotion as a market harmonisation measure based on Article 95. In 1989, despite Britain's opposition, the European Council of Health Ministers voted to legislate for stricter, larger health warnings on tobacco packs and advertising throughout Europe. The Ministers also adopted Directive 90/239/EEC setting maximum permissible tar levels in cigarettes. In 1991 the UK government announced a series of new, larger health warnings for tobacco packaging, in line with the EC requirements. Coming into force in 1992, the Children and Young Persons (Protection from Tobacco) Act 1991 tightened up existing legislation on the sale of cigarettes to children under 16. In 1992 a Directive banned certain oral tobacco products. In 1993 the EU Workplace Directive required employers to provide smoke-free rest areas in new or improved workplaces and gave existing workplaces until 1996 to comply. Directive 98/43/EC banning tobacco advertising throughout the EU was adopted by member states in 1998. This Directive had been blocked in the Health Council of Ministers since 1992. It was the object of a great deal of lobbying within the EU by both public health organisations and the tobacco industry, who argued that it

was driven by public health concerns but presented as an internal market measure. The tobacco industry challenged the Directive and it was annulled by the European Court of Justice in 2001, which ruled that a total ban went beyond the EU's powers. However, the Court stated that the EU could legitimately introduce a more limited ban on tobacco advertising and sponsorship. Finally, the tobacco products Directive 2001/37/EC introduced a range of measures relating to the formulation of cigarettes and their packaging. It required new, large, written warnings to appear on the front and back of tobacco packaging, maximum yields for tar, nicotine and CO, the banning of misleading descriptors such as "light" or "mild", the disclosure of ingredients, and a regular review of the Directive. Various pieces of legislation were passed in the UK to comply with these Directives.

The mid-1990s saw another shift in the scale of tobacco control network: the intervention of international law in the form of a WHO Framework Convention. It is suggested that this was a response to the globalisation of the 'tobacco epidemic' bringing issues such as smuggling and the US use of trade liberalisation arguments and threats of sanctions to open closed tobacco markets, mainly in Asia[52]. As previously noted, the WHO had been involved in tobacco control since 1970, urging individual countries to take tobacco control measures; moreover during the 1980s and 90s international networks of tobacco control advocates had been formed. An article by actors prominent in the development of the treaty recounts how the FCTC began with an article by Allyn Taylor outlining the idea of utilising the WHO's constitutional authority to develop international conventions to advance global health (Roemer et al. 2005). US academic Ruth Roemer promoted the application of this idea to tobacco control at various tobacco control conferences (Roemer et al. 2005) and it was formally initiated in May 1995 at the 48th World Health Assembly. Resolution WHA49.17 requested that the Director General "report to the 49th World Health Assembly on the feasibility of developing an international instrument, such as guidelines, a declaration or an international convention on tobacco control to be adopted by the United Nations", and was adopted by the WHO executive board a year later. A new Director General, Gro Harlem Brundtland, was elected in 1998 and made global tobacco control and

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[52] See Brandt (2007) for a discussion of tobacco industry's expansion into markets in developing countries.

combating malaria her priorities for the WHO (Roemer et al. 2005), and negotiations on the WHO FCTC began in 1999. On the 21st May 2003 the 56th World Health Assembly unanimously adopted the FCTC. It opened for signature in June (168 States signed during the one year period) and entered into force on the 27th February 2005.

The core provisions in the FCTC are price and tax measures; protection from exposure to tobacco smoke; contents regulation, packaging and labelling, and advertising, promotion and sponsorship of tobacco products; education, communication, training and public awareness; cessation; illicit trade; sales to and by minors; provision of support for economically viable alternative activities. The FCTC codifies the tobacco control interventions established in developed countries. Some commitments are obligatory, some hortatory and there are no punitive sanctions. The WHO Conference of the Parties, compromising all Parties to the Convention, is its governing body. It promotes and reviews the implementation of the Convention. The FCTC is the first international public health treaty (the majority of previous framework conventions had addressed environmental issues) and WHO's first treaty making enterprise. Mackay (2003) suggests that even before its adoption, the FCTC 'mobilised technical and financial resources for tobacco control, encouraged governments to take action ahead of the finalisation of the Convention and raised awareness among other government ministries' (2003, p.551). A World Bank report (1999) on the economics of tobacco control, which concluded that tobacco control can bring unprecedented health benefits without harming economies, was important in providing an economic justification for the FCTC. It is suggested (e.g. Mamudu et al. 2008; Roemer et al. 2005; Mackay 2003) that the tobacco industry worked to influence the drafting of the treaty – trying to convince governments, particularly in developing countries, of its potential for economic harm – and undermine the World Bank's analysis, although the WHO was able to counter these efforts (Mamudu et al. 2008).

Tracing nicotine addiction

"Outside the tent"

Chapter four recounted the translation of nicotine gum into *Nicorette*: a licensed prescription-only medical product to be used as a tobacco substitute in smoking cessation, and a borderline anti-smoking preparation that doctors were not allowed to prescribe on the NHS. Although the first two RCP reports (1962, 1971) recognised that

smokers might be addicted to nicotine, both the concept of nicotine addiction and that of nicotine replacement were marginal to the public health network, as an American psychologist remembered:

> '[Nicotine research] *...wasn't considered a particularly fit subject for study. I just distinctly remember colleagues in graduate school saying well why would you study that?*
> Int: And why wasn't it?
> *In part it was seen as a sort of just uninteresting little quirky habit people have I think."* (NA-RES-11)

During the 1980s and 90s the conceptualisation of smoking as nicotine addiction gradually began to become more accepted in, and central to, public health. A colleague of Russell's remembered the earlier resistance to their ideas:

> *"So all this time during the 1980s... it was a very fruitless kind of battle. Officialdom was against us. But not just officialdom: there was very little support from groups that you might think would give support...* [The then chair of ASH], *he was very, very unwilling to support the key issues. One, to acknowledge that smoking was nicotine addiction. He wouldn't do it. He had this argument that it would give smokers a kind of let out because, you know, then they wouldn't take responsibility for their behaviour."* (UK-RES-06)

He suggested that the tobacco group at the ARU and their ideas on the role of nicotine in smoking were very much on the outside of the anti-smoking coalition in the 1980s:

> *"The kind of self image of our group was that we were outsiders who were not inside the tent pissing out, we were inside the tent pissing in and telling these people that you've got it all wrong, and you've got to change your model of what tobacco use it all about..."* (UK-RES-06)

The disciplinary location of the tobacco group in addiction research and psychiatry and perhaps the fact that '*most of the people in tobacco control don't read the scientific literature, because they're not, themselves, tobacco scientists*' (UK-RES-06) may have contributed to this outsider status. The status of treatment for smoking may also have had an impact.

Historically in the UK there had been no medically organised treatment sector for tobacco, unlike alcohol and some illicit drugs (Berridge 2007). The National Society of Non-Smokers had run clinics, which focussed on exercising self control in becoming abstinent. In 1964 there were 30 NHS clinics in operation, each using different methods. The smoking cessation sector expanded in 1970s, as did commercial anti-smoking aids. Smoking cessation techniques were influenced by theories of behaviour change, particularly the stages of change model, which emphasised the importance of education. Berridge (2007) notes that from the end of the 1970s, there was a greater emphasis on the role of the GP in giving advice, influenced by papers written by Michael Russell and Griffith Edwards (e.g. Russell et al. 1979) and a reshaping of the

role of general practice, which was cemented by inclusion of anti-smoking activities in the renegotiated 1990 GP contract.

The concept of nicotine addiction was stabilised during the 1980s, first internationally – again highlighting the way the tobacco control network in the UK was connected to sites beyond the UK. In 1965 the WHO replaced the previous categories of 'drug addiction' and 'drug habituation' as components of 'drug abuse' with the term 'drug dependence' in the ICD 8. An important point in this stabilisation was the inclusion of 'tobacco dependence' in the revised ICD 9 published in 1975, although under the separate code of "Non-dependent abuse of drugs". 'Tobacco dependence' and 'tobacco withdrawal' were added as psychiatric diagnoses in the third edition of the American Psychiatric Association's DSM in 1980: a *'distinct milestone'* (NA-RES-11). As Timmermans and Berg note, these kinds of terminological standards 'ensure stability of meaning over different sites and times' (2003, p.25); moreover, standards, do structuring work, bringing into being new ideas, entities and subjects. The US Surgeon General published a report on nicotine addiction in 1988 which took into account the work done at the ARU, along with work by Murray Jarvik and his group. As Martin Jarvis suggests in a paper considering the implications of the report:

> "What is important about the Surgeon General's report is that **it symbolises the emergence and acceptance of a new paradigm of tobacco use**. It has moved the conceptual goalposts. Tobacco smoking is firmly labelled as a form of drug addiction, rather than simply a socially learned habit." (Jarvis 1991, p.644, emphasis mine)

A few years later in 1994 the Society for Research on Nicotine and Tobacco was founded in the US.

In the same year the U.S Food and Drugs Administration (FDA), after many years of petitioning by public health organizations (NA-POL-12; NA-POL-14), announced that it would begin an investigation into whether the cigarette should be seen as a drug delivery device and regulated by them. During this time internal tobacco industry documents began to circulate: produced during the discovery process in various legal cases, for example the 1994 civil case *Mangini v. R.J. Reynolds Tobacco Company, as* well as thousands of pages of Brown & Williamson Tobacco Corporation documents that were donated unsolicited to the University of California San Francisco Tobacco Control

Archives in 1994[53]. In 1995 the FDA found nicotine to be a drug and declared tobacco to be under their jurisdiction[54]. Further internal documents from the major US tobacco industry companies and organizations were made available through the Master Settlement Agreement (1998)[55]. An employee who was involved in the investigation underlined the shifting understandings of the tobacco industry and the cigarette:

> *"I think that the work in the US profoundly changed globally public perception of what the cigarette is and what the tobacco industry and the business that the tobacco industry is in... And that's the story that we tried to piece together at FDA and when the evidence started coming out... I think that historically government, the public health community, the tobacco control community, research community, never really understood how highly engineered the cigarette was: the degree of sophistication that went into perfecting its drug delivery qualities."* (NA-POL-14)

During the 1980s and 90s understandings of why people smoke, what sort of problem smoking is and what kind of actor the cigarette is, shifted significantly.

"The sea change"

In the UK change was slower. An interviewee suggested one reason for this might be a lack of engagement with 'the science of tobacco dependence':

> *"The sort of vehicle for this sort of thing would have been Royal College of Physician reports but they were in a sort of hiatus at that time... I think the people who were the movers and the shakers... Keith Ball and people were, partly, a different generation and they weren't into the science of tobacco dependence. They were also, I think, running out of steam a bit."* (UK-RES-06)

Both Russell and a colleague suggest he was not 'very good on the policy side' (Addiction 2004, p.18; UK-RES-06): in translating the ideas produced by the ARU meaningfully for influential policy actors. The election of a Labour government in 1997 and the subsequent publication of their White paper '*Smoking Kills*' (DH 1998) are seen by many interviewees as marking the beginning of a new period in tobacco control, a '*sea change*' (UK-RES-06). A change in the leadership of ASH was also seen as important:

> *"I think there was absolutely no doubt that the change in government brought about a change in thinking. And Clive Bates coming into ASH in the1990s was very helpful because he*

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[53] See http://legacy.library.ucsf.edu/about/about_collections.jsp for information

[54] This decision was invalidated by the supreme court in 1999. Ten years later the Family Smoking Prevention and Tobacco Control Act (2009) has given authority to the FDA for the regulation of tobacco products.

[55] In the early to mid-1990s, more than 40 states commenced litigation against the tobacco industry, seeking monetary, equitable, and injunctive relief under various consumer-protection and antitrust laws. The lawsuits sought recovery for Medicaid and other public health expenses incurred in the treatment of smoking-induced illnesses. The Master Settlement Agreement settled these lawsuits.

was a force of nature, and was a very strong advocate for the Mike Russell type approach." (UK-RES-06)

A colleague of Russell's recalls presenting at the summit that led to the White Paper, which he saw as '*the key shift in government policy*' (UK-RES-06), as well as working with the new Medical Officer at the DH, as a shift in relationship: "... *that was a big improvement because you felt that you weren't working against... you were actually starting to work with...*" (UK-RES-06) He also suggested that having a '*tobacco behaviour person*' on the Scientific Committee on Tobacco or Health (the successor to the ISCSH) also helped the acceptance of the ARU's ideas and was part of their movement '*onto the inside*' (UK-RES-06). The labour party had committed to banning tobacco advertising in its 1992 manifesto and reiterated this in 1997: "Smoking is the greatest single cause of preventable illness and premature death in the UK. We will therefore ban tobacco advertising", as well as committing to creating a new minister for public health. This commitment was reiterated in *Smoking Kills*, along with increases in tobacco taxation (the first budget had announced that, in future, tobacco duties would be increased on average by at least 5 per cent in real terms a year), developing Smoking Cessation Services and increasing access to NRT, and development of further codes of practice on smoking in public places. A bill on Tobacco Advertising and Promotion was passed in 2002.

Harm Reduction

Having outlined how the public health network around tobacco, the 'tobacco control network', had expanded and been reshaped during the 1980s and 90s, I now want to focus on a strategy that is in the process of reshaping the tobacco control network again – *harm reduction*. Harm reduction is the cause of much controversy within the tobacco control community, and is currently playing a role in the re-positioning of NRTs, and other actors, within the UK. The term 'harm reduction' seems to have come into the area of tobacco research from the illicit drugs field (Warner 2002; SW-RES-02) fairly recently; however, links can be traced back to ideas circulating several decades ago. It is crucial to examine the history of harm reduction – where it came from and how it has developed – as well as how it is currently deployed and for what purposes, because harm reduction ideas are intertwined with notions about what sort of a thing NRTs are and how they ought to be used.

The term 'harm reduction' is most commonly associated with approaches to the control of heroin use, particularly in response to the risk of HIV transmission that became an issue in the 1980s. However, both Berridge (1999a, 1999b) and Mold (2008) point out that harm reduction type ideas have a long history in this area. Berridge (1999b) notes that the reduction of harm from drug use has been a consistent in UK drugs policy since the nineteenth century. The Rolleston Report in 1926 on heroin addiction laid the foundation for what became known as the 'British system' which treated addicts as patients as opposed to criminals (Berridge 1999b; Mold 2008). There has remained a complex tension between medical and legal approaches to drug control and the emphasis has shifted between the two approaches over time. In the 1960s heroin addiction came to be seen in public health terms as an epidemic and a danger to society, and the focus shifted to social control and involvement of a wider range of actors. In the 1970s oral methadone was introduced as a way of stabilising addiction, which enabled a shift back to a more medicalised model of treatment (Mold 2008), but also a clash between maintenance and withdrawal orientations. The concept of harm reduction became central in response to the threat of HIV infection in the 1980s. The 1988 report of the Advisory Committee on the Misuse of Drugs signalled a change in thinking. It accepted that ceasing drug use was not a realistic short term aim for many and stated that 'the threat of HIV is a greater threat to public and individual health than drug misuse' (Berridge 1999b; Mold 2008). Harm reduction, including needle exchange programmes to reduce risks of HIV transmission and daily oral methadone introduced to reduce risks associated with injecting (overdose, infection and crime), became government policy.

Whilst the term 'harm reduction' is a relatively recent addition to the smoking and health debate, many of the ideas and practices it refers to have a longer history, some of which I have addressed in the previous chapter. Here I will elaborate on how this history fits with the more recent debates on harm reduction before going on to trace the main themes of these discussions. Rodu and Godshall (2006) in their recent review of harm reduction suggest that the: "History of tobacco harm reduction may be traced back to 1974, with the publication of a special article in the Lancet by British tobacco addiction research expert Michael A.H. Russell" (2006, p.2). Others trace some of the ideas further back. One interviewee suggested that harm reduction ideas have a long history in the US:

"...the harm reduction debate has been with us as long as health concerns about tobacco have been with us... We now know from the tobacco industry's documents it's the way the tobacco industry wanted the debate to go. And our National Cancer Institute, the American Medical Association, all spent a lot of time talking about harm reduction in the 1960s and if one were to go back and take a look at that history, that debate turned into frankly a marketing tool for the tobacco industry. It doesn't mean that the concept is a right or a wrong one, it just means it's not a new issue." (NA-POL-12)

Other tobacco control experts such as Ken Warner (2002), as well as the historian Virginia Berridge (2007) trace the idea back to ideas about 'safer smoking' or the 'less harmful cigarette' in the 1950s. In Chapter four, I outlined some of these developments, including the addition of filter-tips to cigarettes and the removal of harmful elements, particularly focussing on low-tar, low-nicotine cigarettes, both of which were promoted as healthier alternatives with physician and public health authority endorsement. Chapter four also recounted the change in relationships between government, the anti-tobacco lobby and the tobacco industry during the 1970s and 80s, with greater hostility to industry from the anti-tobacco lobby and a move away from safer smoking to an approach focussing on abstinence.

I described some of the work done by the ISCSH and the ARU in the UK which continued the work on 'safer smoking', although translating it in different ways. The National Cancer Institute in the US was also working in this area during the 1970s and 80s. The ISCSH did work on tobacco substitutes and additives and, when these did not yield positive results, on the harmfulness of various constituents of tobacco smoke and on low-tar low-nicotine cigarettes. The tobacco section of the ARU was responsible for much of the formative work on the role of nicotine in smoking and made various arguments about reducing harm to smokers:

'[Russell] was the guy that was saying: it's nicotine that people are after but it is the tar and carbon monoxide that is killing them so why not give them the nicotine, and not the tar and carbon monoxide. So he was looking at other alternatives such as snuff, which is also a tobacco product but less dangerous, and the idea of a high-nicotine, low-tar cigarette so you'd manufacture the cigarette in such a way that smokers were getting much more nicotine for the amount of tar". (UK-RES-18)

A colleague of Russell's described the key ideas of the ARU group about reducing harm to smokers:

'We published in 1980 a brief paper in the Lancet, called 'A new age for snuff'. *It was based on showing that dependent nasal snuff takers had blood nicotines which were very similar to cigarette smokers and we said that suggested it would be a viable alternative. A couple of years later in the BMJ we published a more extended paper on snuff users and we followed that up, later on, with a study we got a collaborator in Sweden to work on. It was on nicotine intakes in users of snus, and showed again how they were very similar. And then*

> *there were these papers on* Skoal Bandits, *and this and that, as well as of course all the work on* NRT. *So that was all stuff pointing in this direction. And Mike, you know, as early as the mid-70s had argued the case for safer cigarettes, so in papers for the BMJ. I think probably a key publication was a Lancet editorial he did, which was unsigned as Lancet editorials are, which was I think published in 1991. And it was given the title* 'Nicotine use in the year 2000' *and that was making the case for the feasibility of switching from cigarettes to non-combustible tobacco use...*" (UK-RES-06)

The work that was done at the ARU translated the concept of 'safer smoking' through the ideas they produced on the role of nicotine in smoking. The concept now centred on the nicotine intake of users and the use of 'safer' types of tobacco.

The third RCP report (1977), however, signalled the beginnings of a move away from 'safer smoking' as a central public health policy, with a more limited section on safer smoking, and controversy over what public health objectives ought to be 'it was clear that there was disagreement in the committee as to whether the primary aim should be to urge people to stop smoking or whether the emphasis should be on safer methods of smoking' (minutes of meeting 7 Apr 1975 quoted in Berridge, 2007: 151). According to research on tobacco industry documents, many tobacco companies abandoned their efforts to develop a safer cigarette during the 1980s having discovered that the task was far more technologically difficult than first anticipated and in response to industry lawyers' concerns that such research undermined the stance that existing cigarettes were not unsafe (Glantz et al. 1998). Despite the shift away from safer smoking, these sorts of ideas never completely disappeared; they continue to circulate around the tobacco control network, mainly as an interest in the utility of various forms of smokeless tobacco as less harmful alternatives to cigarettes. Russell's team at the ARU published follow-up studies on nasal snuff in 1981 and on an oral smokeless tobacco product in 1985 (Rodu & Godshall 2006). In the US, Lynn Kozlowski, a prominent smoking and nicotine addiction expert, was writing on similar sorts of ideas: in 1984 and 1989 he noted that smokeless tobacco products conferred fewer risks to users and therefore might serve as effective substitutes for cigarettes (Rodu & Godshall 2006). In 1994 oral pathologist Brad Rodu began writing about the reduced risks of oral smokeless tobacco products (Rodu & Godshall 2006).

People come to the table for different reasons

As noted at the beginning of this section, during the 1990s the concept of 'harm reduction' started to gather interest in the tobacco control network. Discussions about

'harm reduction' began to appear in the journal *Tobacco Control* at the end of the 1990s. In 2003, Simon Chapman highlighted in an editorial both the growing attention to harm reduction and the divisive effect it has on the tobacco control community:

> "In recent years, the tobacco control community has experienced impassioned and at times acrimonious debate about harm reduction. For years, tobacco control has stood fast on a doctrinaire devotion to an absolutist precept: that tobacco use of any sort was unacceptable." (Chapman 2003, p.341)

During my interviews, a variety of reasons were put forward for the (re)appearance of harm reduction into, and growing importance in, the tobacco control network. An influential article on the subject published in 2002 noted that 'starting in 1995, several conference and advisory committees have addressed this topic' (Shiffman et al. 2002). In the UK a meeting at the Health Education Authority on harm reduction was highlighted by one interviewee. Held in London in 1996, this meeting gathered together 'a group of addiction experts and other interested parties from the public health field... to discuss the future of nicotine delivery systems in England' (Raw 1997, p.2). A report from the seminar states the aims were to stimulate discussion on the role of nicotine delivery devices in tobacco control and reach a common understanding about nicotine products and their part in an English tobacco control strategy (Raw 1997).

As the tobacco control community has observed a deceleration in the trend of falling smoking rates in recent years, and even a rise in some groups, there has been increasing attention paid to the characteristics of the remaining smokers. A common explanation is that there is significant group of smokers who either cannot or will not quit – with some arguing that 'hardcore smokers', who are more dependent and have greater difficulty quitting, are coming to dominate the population of remaining smokers (Warner & Burns 2003) – as well as a deepening of inequality related to smoking. There is felt to be a need to explain why this was happening and to generate ways to address it. The notion of cigarette smoking as nicotine addiction provides a framework for explaining these questions. For some, an interest in harm reduction came from 'disappointment' in the progress that tobacco control efforts have made:

> *"I do think that the interest in harm reduction grows in part out of disappointment at how poorly we've done getting more people not to smoke at all. ...in a way it's an acknowledgement of our failure to succeed at that, that you need to say, well, look, we're not succeeding at eliminating the harm: are there things we can do to reduce the harm?"* (NA-RES-11)

Another interviewee describes looking for new approaches and coming to the conclusion that, whilst tobacco control does things to get people to never engage in the

dangerous activity; to get people to quit and to protect third parties; they are not doing things to reduce the risk to people who are using nicotine:

> *"So doing all of these things and then by the early 90s recognising that I was running into the whole law of diminishing returns. So once you have most places going smoke-free, and once you ban most forms of tobacco advertising and marketing, and once you've got your taxes amongst the highest in the world, what do you do next when you still have five million smokers? ...What else have you got?"* (NA-POL-10)

Echoing Michael Russell, he suggested that the area of tobacco control is:

> *"...probably the clearest case for harm reduction that I could think of because virtually all the harm was from getting the nicotine through smoking as opposed to the drug itself... Here's an area where we could essentially eliminate the problem by essentially changing the delivery system. And very few people were willing to talk about it."* (NA-POL-10)

The need to change strategy and look for new approaches is not, however, accepted by all. Some question whether remaining smokers are more dependent. For example Chapman and MacKenzie argue against the 'persistent, seductive and erroneous appeal of the "hardening hypothesis" (2010, p.3). An interviewee felt this interpretation of the role of tobacco control is problematic:

> *'I am against the concept that some people find it so hard to quit that they can't, and, therefore, they need to be sustained in their nicotine addiction: I don't think the health lobby should have anything to do with that."* (UK-POL-20)

In an article this interviewee sent me, he suggested harm reduction itself was 'an admission of failure' and that a change in tobacco control 'tools and techniques' is unnecessary:

> "Many of us believe that there is no such thing as safe tobacco use. Our ambition is to help people give up. So-called 'harm reduction', for those who cannot break their addiction, is an admission of failure. It implies that we have not got the right tools or techniques to do the job properly. It is a policy of despair: it risks diverting our proper interests and efforts. Instead, we should continue our tobacco control advocacy, which does most to reduce prevalence; and improve our skills in helping smokers to quit, which does most to benefit individual health and well-being." (UK-POL-20, personal communication)

On the other hand, for others in the tobacco control community it has been the awareness of 'alternative products' that has stimulated this interest in harm reduction.

Snus and the Swedish experience

One of these alternative products, and one of the most controversial strands of the harm reduction assemblage, is *snus*. One Swedish interviewee traced the renewed interest in harm reduction to the situation in Sweden:

> *"Harm reduction has been always the case with illicit drugs, and methadone and needle exchange etc, at least for thirty, forty years. It started to became an issue here* [in the tobacco field] *when the Swedish experience started to be recognised; when some, including myself, started to preach about it. So smokeless, I think, and the experience in Sweden, started it all; has been the instigation here into harm reduction discussion."* (SW-RES-02)

Another explains why 'the Swedish experience' is seen by him and others as important in terms of the evidence it provides:

> *"There is this live experiment in Sweden where there's been a very large uptake over a few decades in the amount of tobacco that's consumed smokelessly... an accelerated trend of smoking cessation in Sweden partly because of the switch to snus as well as quitting. Snus functions as a gateway out of smoking and onto quitting. The snus story isn't just a pure hypothesis. Sweden has the lowest rates of cancer and heart disease in the OECD* [Organisation for International Cooperation and Development] *and the highest levels of snus use, and throat cancer. You've got this evidence of a different pattern of tobacco use that is possible."* (UK-POL-01)

The long-running use of *snus* in Sweden, accompanied by reductions in smoking rates, is put forward by some as evidence or 'proof of concept' that a different pattern of tobacco use is possible; however this 'evidence' is hotly contested and interpreted very differently by others in tobacco control who question whether *snus* has played a role in reducing smoking in Sweden (Tomar et al. 2003). In an article outlining 'the strongest arguments for and against promoting Swedish *snus* as a form of harm reduction', Garner and Hall (2007) argue that decades of use in Sweden have allowed the effects of *snus* on smoking prevalence and health to be studied, and that the health risks 'are comparable to those of regular alcohol use rather than cigarette smoking' (2007, p.1138); that *snus* use would provide a net benefit 'as it appears to have done in Sweden'; and that smokers have an 'ethical right' to be informed about harm reduction products. Arguing against them, Chapman and Freeman are concerned that the experience with *snus* in Sweden may not transfer to other nations; that the tobacco industry would use *snus* to undermine advertising bans and promote 'dual use' (smoking and *snus* use); and that there are better uses of the limited resources of tobacco control. Others are concerned that *snus* may be a 'gateway' to smoking initiation (Tomar et al. 2009) and that moving away from the simple message 'smoking is bad' is problematic (UK-POL-20, personal communication).

A new generation of harm reduction products

The tobacco industry's entry into the 'harm reduction market' with new modifications to traditional cigarettes and 'cigarette-like' products has provided another, less sought after, reason for considering harm reduction. As Warner notes, the tobacco industry in

the US again began working on safer cigarettes: "[Russell's idea] has been resurrected in the late 1980s and 1990s, however, in the form of new industry-produced pseudo-cigarettes that greatly reduced tar deliveries"' (2001, p.111). This has given the public health community another reason to become engaged with the issue. These new types of cigarette are designed to, 'generate an aerosol with nicotine in the range present in the smoke of conventional filter cigarettes, but low to very low emissions of tar and of toxic and carcinogenic agents' during smoking (D. Hoffmann et al. 2001, p.779). R.J. Reynolds developed the first of this new type of cigarette which they test marketed in 1988 under the name *Premier*. *Premier* met with opposition from the public health community, who argued that it should be regulated by the FDA as a drug; failed its market tests, with many smokers complaining about the taste; and was withdrawn. *Next*, a virtually nicotine free cigarette, was launched by Philip Morris the next year and also withdrawn. *Eclipse*, a later design by R.J. Reynolds, that works by heating tobacco and is claimed to reduce second hand smoke by 85-90%, has been test marketed in several countries and in 1997 Philip Morris also began consumer testing *Accord*, which burns tobacco at a much lower temperature than traditional cigarettes. More recently a small company called Star Scientific developed a process for removing nitrosamines (cancer causing compounds) from tobacco. In 1999 Brown and Williamson purchased tobacco cured with this process intending to introduce a cigarette with little or no nitrosamines. In 2000, under a contractual agreement with Brown & Williamson, Star Scientific began test marketing this cigarette, containing the modified tobacco and activated charcoal filters, under the name *Advance*. It claims to have substantially lowered levels of nitrosamines, CO and tar.

The public health community in the US has, for the most part, maintained that there is no such thing as a safe cigarette and that all tobacco industry attempts to create one are disingenuous. A US interviewee noted that it is difficult to evaluate these products because of a lack of 'science', which led the FDA to commission the Institute of Medicine to study the scientific basis for the regulation of novel nicotine delivery devices. He went on to outline why he was suspicious of these tobacco industry developments:

> *"...My concern was we were in the process of repeating history for all the wrong reasons. It was a new generation of products that in my mind were just a reincarnation of light cigarettes: just fancier, cooler sounding, with more fantastic claims about reducing harm."* (NA-POL-14)

This suspicion links to another influential actor within the tobacco control network: the 'low-tar lie'.

The low-tar lie

As I have already outlined, an important development in relations between the tobacco industry and the tobacco control community was the circulation of 'tobacco industry documents' through litigation and whistle blower actions. Much work has been done within the tobacco control community on examining these documents, particularly to establish 'what the tobacco industry knew' about the harms of smoking, the role of nicotine and other developments in the general understanding of smoking. A narrative has been constructed about what the industry has covered up and what it has deceived the public about (Warner 2002) that is highly influential on the actions of those within the tobacco control community. One instance in particular shapes the network, especially in the US Its significance can be seen in the ways that it is often referred to: 'The Low Tar Lie' or 'The Light Cigarette Fiasco'. Various articles can be found in *Tobacco Control* reflecting on the issue. Nigel Gray (2000) considers it in an article entitled *Reflections on the saga of tar content: why did we measure the wrong thing?*, as does Shopland (2001) in *Historical perspective: the low tar lie.* A report by the U.S Institute of Medicine describes low yield cigarettes as follows:

> "*[They]* ...emit lower tar, carbon monoxide and nicotine than other products as measured by the Federal Trade Commission (FTC) assay (the "smoking machine") ...Consumers believed, and still do, that these products pose less risk to health that other cigarettes... most current assessments of the epidemiological and toxicological data suggest, however, that low-yield products are associated with far less health benefit than predicted based on FTC assay-generated tar, CO, and nicotine levels." (Institute of Medicine 2001, p.26).

They go on to say that the reason for this lower than predicted health benefit is 'compensatory smoking', a topic Michael Russell and his team highlighted in the 1980s: smokers inhale more deeply in order to maintain adequate exposure to nicotine. The Federal Trade Commission machine generated yields do not account for the wide range of smoking behaviour and this compensatory smoking. It is now thought that smokers inhale as much tar from 'low tar' or 'light' brands of cigarettes; however, initially they were marketed as less harmful with endorsement from the public health community.

The origin of some strands of 'safer smoking' ideas in the early reaction of the tobacco industry to the link between smoking and lung cancer and the connections linking the newer actor, 'harm reduction', back to these ideas, help explain why it is rejected by

many in the tobacco control field. In an article examining the 'promises and perils' of harm reduction, Ken Warner outlines this line of thought:

> "Coupled with the experience with the earlier generations of new products, lawsuit-generated revelations of the depths of industry deception have fostered a deep-seated scepticism in many knowledgeable industry observers. Under no circumstances will they trust the industry's motivation, much less its behaviors... In this regard, discovery that consumers of a new product, Eclipse, are at risk of inhaling fiberglass particles (Pauly et al., 1998) harkens back to the revelation that Kent's 'exclusive Micronite Filter' of the 1950s was made of asbestos." (Warner 2002, p.S54)

This suspicion is something that was emphasised in my interviews, particularly by those in the US tobacco control community. One highlighted the impact he felt the 'light cigarettes fiasco' has had on the tobacco control community:

> *'I think there's a way in which the light cigarettes fiasco in, I guess that would have been the '70s, has really influenced people's thinking, to thinking that it's inevitably going to be a sham and somehow be exploited by the tobacco industry to their benefit and not in public health benefit."* (NA-RES-11)

Another links his reservations about harm reduction approaches to this history:

> *'Well historically it has been a new way of talking about the same old thing and historically it is almost always turned into a mechanism for the tobacco industry convincing users and potential users, that there is a choice other than quitting or not smoking. So we just need to be very careful in talking about harm reduction that we don't fall into that same pitfall."* (NA-POL-12)

In its translation from the drugs field into the tobacco control network, the term harm reduction assembles both new ideas and important links to the past. Those in public health cite different reasons for enrolling or rejecting this ambivalent actor and deploy it in different ways.

Divides the field

One thing that there is general agreement on over harm reduction is that it is a contested and controversial actor – *'a loaded concept'* (SW-RES-02) and a *'divisive issue'* that elicits an *'emotional reaction'* (NA-POL-10). As one person put it: *"There has been a massive, massive row over this that has gone on for a few years... The entire public health community got its knickers in a massive twist over this: 'you're encouraging people to use tobacco'"* (UK-POL-01). Another underlines the divisive of effect harm reduction on the tobacco control community:

> *"...splits the field in an incredibly antagonistic way. ...some people just go mad if you just mention the word. I mean it's just like, it's extraordinary to me, it's amazing the effect it has on the field, it just rips it to pieces: rips it apart."* (UK-RES-03)

In an article discussing the debate over *snus*, one member of the health lobby suggested that the tobacco control community used to be united in its belief that the 'solution to the tobacco problem, at a personal level, is total abstinence', and came back to this in our interview, saying it was a shame that, although the community is still united on most things, this issue is taking up 'an awful lot of energy, and time, and debating space' (UK-POL-20).

Pragmatists vs. Moralists

The conflict over harm reduction, and the different sides involved, was described in some rather striking ways during my interviews. An opponent of harm reduction approaches linked the increasing focus on harm reduction to people in the tobacco control movement receiving grants from the pharmaceutical industry. He suggested that the area is 'big business', and that this has diverted attention from getting people to quit (UK-POL-20 Chapman & MacKenzie 2010 also raise these concerns). Alternatively, a common thread that was introduced by advocates of harm reduction was that those who opposed harm reduction had taken a moral stance:

> *"There are tobacco control activists who take a very simplistic view of the problem that we face. And the view that they take is that: tobacco bad; nicotine bad; no one should be doing it and the only acceptable goal is to have everyone off tobacco and nicotine. And that to me looks like a moral judgement."* (UK-RES-18)

Asked why harm reduction has been such a controversial issue, an interviewee from the US also discussed this 'strain of moralism':

> *"I think there is a strain of moralism in there: that particularly as tobacco control's gotten political, it's attracted people who really are zealous – now they're very valuable, but who at some level think smoking is just bad, and wrong, and dirty, and we shouldn't let people do it, we shouldn't accept doing it at all. ...Because the controversy's been so emotional, I don't think science has frankly played much of a role in it, but I think in fact the science is very difficult. It's very difficult to know how much harm reduction, if any, one can expect out of various policies or changes in behaviour..."* (NA-RES-11)

The disagreement over harm reduction was described by some as between two opposing schools of thought with different goals.

> *"I think there's always been at least two strands to the tobacco control movement. One is the sort of pragmatic, trying to reduce the burden of death and disease and you do what will work to do that: so a kind of empirical, pragmatic approach. And then there is a school who take a sort of moral position who are sort of agin tobacco root and branch, and that's reflected in quite a lot of the goals and missions like 'tobacco free world' and... addiction being the enemy and all this sort of stuff."* (UK-RES-06)

Harm reduction is seen as having, "*...brought to the fore these divisions between the pragmatic school and the absolutist school*" (UK-RES-06).

Alderman et al suggest that 'opposing positions in a health policy dispute are each grounded in moral principles' (2010, p.2). Drawing on moral psychology, they argue that different 'moral foundations' underlie harm reduction debates. 'Harm reductionists' give greater weight to the primary moral concept of 'autonomy' and the related values of fairness and harm; whilst harm reduction opponents 'often seek to balance these factors with concerns about in-group, authority, and purity' (Alderman et al. 2010, p.4), values that are linked with the moral concepts of "community" and "divinity" ('meaning not religious ideas but concepts like sacredness and purity'). They suggest that social justice values such as fairness and harm are the primary organising principles behind public health, and other ethical norms are often excluded. Alderman et al's (2010) analysis is useful in highlighting the conflict in values that underlie harm reduction discussions. A parallel to these two sets of positions can be found in Hasson's (2003, 2006) description of the range of opinions held by policy makers – from pragmatist to idealist – on the role of divorce law in modern society. Hasson points to the differences in underlying views of the role of law: as existing to set a moral standard ('moral regulation') or a narrower conception with morality 'reconstituted in terms of reflexively exercising choice with responsibility' (2006, pp.278-9). This reflects the diverging views on the role of public health presented here, as setting an ideal standard of no tobacco or nicotine use, or enabling people to make more responsible choices.

This more recent division within the community was felt to be problematic for a number of reasons. One was the perception that the issues had become very 'politicised':

> *"Actually there is one thing that I think is very important. Tobacco issues have gotten very politicised. That's been a good thing to some extent in that, as I say, you kind of need muck-rakers, and hell-raisers, and political zealots, to move things along, but it's had some pretty serious side-effects in that there is a kind of politicisation and polarisation of the debates that really doesn't serve anyone well. So people are mostly calling each other names and lobbing grenades over the barricades about harm reduction and I think that does have the effect of drowning out what are real... I think there's some real controversies and real policy dilemmas and scientific gaps and needs that tend to get drowned out because people are so polarised around it and that's a relatively recent trend, a very troubled one, and I think is contaminating the scientific and policy debate."* (NA-RES-11)

In particular, he felt that this politicisation has a negative effect on the scientific debate. In fact, many of these accounts highlight importance of 'the science' and 'the data'; the need for more science to aid policy decisions and the need for science to be kept

separate from the contaminations of moral positions and politicisation. This is a common view of the relationship between science and policy as 'speaking truth to power', which many STS accounts have critiqued. As Irwin underlines, STS studies:

> "...problematize the conventional assumption that what is 'scientific' or 'political' (or 'factual' or 'objective') can be straightforwardly identified and ring-fenced. Instead, the very demarcation of certain entities and discussion points as 'scientific' or 'political' represents a key element in scientific governance and an essential component in STS analysis." (2008, p.583)

Framing the problem as one of needing more data or better science, rather than moral or political debate, is an effective way of removing it from the purview of ethical discussion (Irwin 2008). Moreover, STS work has underlined that more, or clearer, scientific advice does not necessarily help in making a policy decision (e.g. Jasanoff & Wynne 1998).

The particularly divisive nature of bringing *snus* into tobacco control was highlighted by a UK participant:

> *"Snus is, of course, the issue around which we have fallen out big time, and around which we continue to fall out big time; but harm reduction is the more acceptable face of that particular argument."* (UK-POL-20)

It is clear that the intertwining of harm reduction with ideas about smokeless tobacco as a safer way of consuming tobacco, along with tobacco industry strategies, has shaped the ability of the concept to mobilise other actors within the tobacco control network. Having outlined key aspects of the harm reduction assemblage and the conflicts over it, I now move on to examine the work that this strategy, harm reduction, does within the tobacco control network, before considering the ways that these divisions have been negotiated.

Harm reduction and organising, including and excluding actors

Harm reduction does various sorts of work including organising other actors, and including and excluding various actors. Different actors deploy different harm reductions which organise, include and exclude differently. In general, these can be split into two types of harm reduction: 'harm reduction writ small' or 'methods of reducing harm due to continuing tobacco use' (Shiffman et al. 2002); and harm reduction as any intervention that leads to a reduction in harm to a population. The former positions harm reduction as a tobacco control tool, amongst others. It includes methods for reducing harm that involve continued use of tobacco/nicotine, so: *"taking the strategy of*

saying that if you can't eliminate the harm by getting people not to smoke, you're trying to do things that reduce the harmful impact" (NA-RES-11). The latter, larger harm reduction network stretches to encompass the more 'traditional' tobacco control strategies of prevention of uptake and cessation by individuals. Harm reduction writ large, then, is strategically presented as having many continuities; as something that tobacco control is already engaged in. For example Warner argues 'in its broadest context, although not the way the term is used in common parlance, *tobacco harm reduction* logically refers to the overall goal of the field of tobacco control, namely minimization of tobacco-related disease and death' (2002, pp.S54-5) and Shiffman et al state 'tobacco harm reduction has always been at the core of tobacco control' (2002, p.S113). One supporter of harm reduction said of his perception of harm reduction:

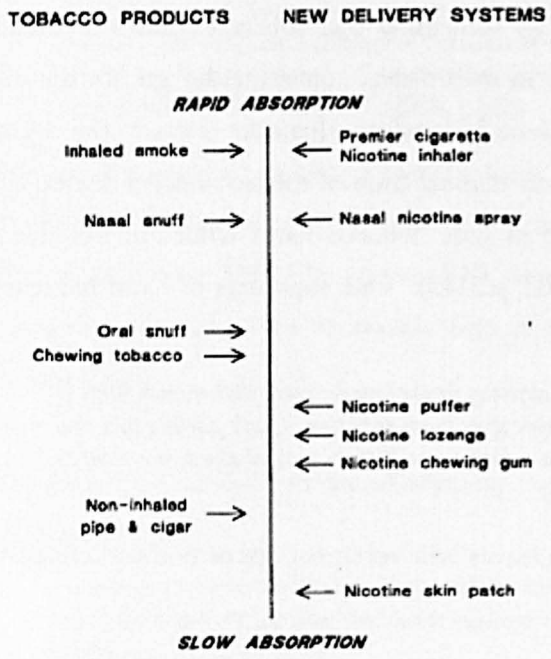
> *'I would define it* [harm reduction] *as anything in the broader sense that reduces harm to a person. So almost anything could be thought of as harm reduction. That's partly why I find the opposition to harm reduction as such a ridiculous position because of course you want to reduce harm to somebody."* (UK-RES-03)

The broader harm reduction formulation leaves little room for opposition and criticism: how can you be against reducing harm?!

The more commonly deployed actor, harm reduction writ small, deploys various tools in its categorising of other actors. One of these tools is the *'continuum of risk'* and regularly appears in diagram format. It organises actors by two key attributes: nicotine delivery characteristics – primarily speed; and harm, risk or whether a product is tobacco or pure. Again this is an aspect of harm reduction that can be traced back to Michael Russell's work. In a paper published in the *British Journal Addiction* in 1991 with the title 'The future of nicotine replacement' (Russell 1991) he suggests that: "It may be helpful to consider the range of nicotine replacement products in terms of the relative rates of nicotine absorption obtained from their use, and to compare these with traditional tobacco products" and provides the diagram below (see Figure 1). Russell's 'rate of absorption spectrum' works to place tobacco products and new delivery systems into the same conceptual space, as actors that are used to provide nicotine, and arranges them according to how much nicotine they provide.

Figure 1: Russell's rate of absorption spectrum

"Tobacco products and new nicotine delivery systems can be positioned roughly on a spectrum based on the rate of nicotine absorption obtained from their use."



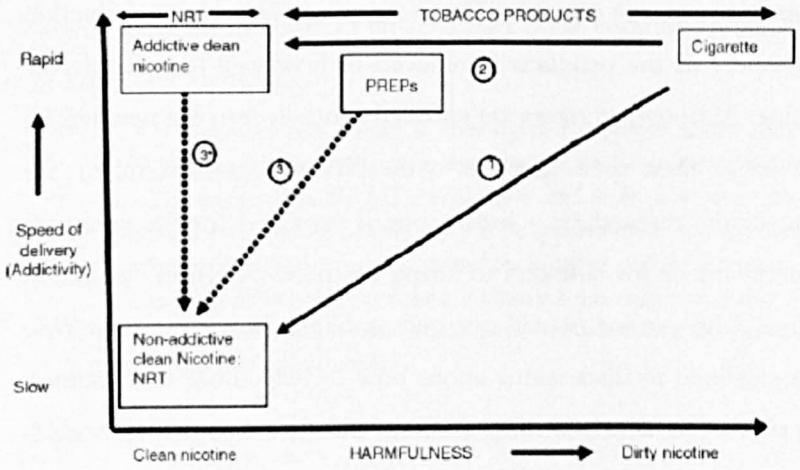
Source: Russell (1991, p.657)

This connecting of different types of actors using nicotine is also at work in the 'continuum of risk':

> *"I think part of that is that you have to really push the concept of: it's a continuum of risk of products within a broader category. There is nothing that clearly differentiates between cigarettes and pharmaceuticals, or tobacco products and pharmaceuticals; you can put them all on the continuum... Why would some require huge expenditure to get approved as a medicine and others are either totally banned from the market when they are far safer than cigarettes? Or allowed on the market when the pharmaceutical products aren't? It doesn't make any sense. Why would we not be looking at differentiating them when there is such a huge difference in risk?"* (NA-POL-10)

The continuum blurs the boundaries between tobacco and pharmaceutical, instead delineating actors that are all drug delivery devices for delivering nicotine to the body. This rearranging of conceptual space is again shown in a more recent diagram (see Figure 2 below) by Yves Martinet et al (2006)

Figure 2: 'Characterisation of different nicotine delivery systems'



"Any nicotine delivery system can be defined by its: (i) nature (non-tobacco products versus tobacco products); (ii) harmfulness (clean versus dirty nicotine); and (iii) addictivity power (largely determined by a slow versus rapid delivery)"

Source: Martinet et al (2006, p.2)

This diagram arranges actors in terms of their relative speed of delivery (or addictiveness) and harmfulness (or how 'clean'/'dirty'). Underlying this conceptual work are ideas about the nature of nicotine and the nature of harm. Nicotine is seen as not itself one of the harmful components of tobacco; as not in itself dangerous:

> *"...if it turns out to be a relatively benign drug like nicotine, there are some exceptions where nicotine poses genuine safety problems, but in the main nicotine is a pretty benign drug."* (NA-POL-14)

Or as dependence forming as tobacco:

> *"Because NRT is not in any way as dependence forming as the cigarette and the tobacco and there are more things in the tobacco, particularly, tobacco smoke, that contribute to dependence than nicotine. And this is why... I mean no one breaks into pharmacy to steal nicotine, no one makes pure nicotine. I mean it's much simpler to make nicotine than this methamphetamine."* (SW-RES-02)

Whilst harm is seen more as the physical harm caused by tobacco:

> *"And when I view harm here I first of all think of the physical harm, the lung cancer, the cardiovascular disease etc, there is also the dependence of course. But I don't think we can deal with both the dependence and the other disease at the same time..."* (SW-RES-02)

A key issue is whether addiction constitutes harm.

As we have seen through the example of the continuum of risk and the other related diagrams, harm reduction emphasises particular qualities of the actors it organises: speed of nicotine delivery or addictiveness and physical harmfulness. However, one interviewee noted that smokers would have difficulty moving 'down' this continuum as there is a, 'residual in pleasure' in moving from cigarettes to smokeless tobacco, and then from smokeless tobacco to NRT (SW-RES-02). This points to an aspect that rarely appears in tobacco control discourses: pleasure. Or, more correctly, in harm reduction discourses the pleasure aspect of the products is reduced to how well they satisfy the users' cravings for nicotine. Although smokers are enrolled centrally into the network by the various actors who act as their spokespersons – the pharmaceutical industry, the tobacco industry, and academic researchers – little scope is provided for the voices of individual smokers to be heard or for smokers to shape the network. Harm reduction discourses talk of smokers who cannot or will not quit smoking; however, those who will not quit tend to be sidelined in discussions about how to help those who cannot. Thinking back to Star's (1991) comments about those who are marginal to actor-networks, the question of the ways that smokers confront or resist this network is raised. A recent article by Chapman and MacKenzie (2010) highlights another experience that is excluded from tobacco control networks. He points out that unassisted cessation or stopping smoking 'cold turkey' – the approach he argues that is most commonly used by people who have successfully stopped smoking – is neglected within the tobacco control community due to smoking cessation becoming increasingly medicalised and the increasing influence of the pharmaceutical industry.

Having examined some of the work that harm reduction does in the tobacco control network and its difficulties in enrolling other actors, I want to turn to two examples of the way that harm reduction has been translated in order to enable it to enrol crucial actors and begin to stabilise in the tobacco control network.

Harm reduction in the US: a Strategic Dialogue

The first of these examples is the process of *The Strategic Dialogue on Harm Reduction* which was an attempt in the US to bring together key actors in tobacco control to 'create some common ground' over harm reduction. I was able to talk to Mitch Zeller, who was key in instigating the process and chaired the meetings. He suggested that the impetus for the process was the 'new generation of products':

"We're all being exposed to this new generation of tobacco based products that are making various promises either in regulated environments or unregulated environments to reduce exposure and risk. ...And the concern is that they're aimed at the health concerned smoker who has some interest in quitting, and addicted smokers who haven't been able to quit. ...any tobacco offering that would keep them in the tobacco franchise and make them less motivated and interested in quitting, is a public health concern."[56]

Adding that consideration of these new products was 'framed by the public health disaster of light cigarettes'. He also highlighted the difficulties the emotional debate over smokeless tobacco had caused in bringing people together. Zeller wanted to bring people together to consider what impact these products might have on cessation efforts and uptake of smoking:

"There never had been a place to come together to sort of discuss these issues... But we saw the opportunity with timing being everything – with legitimate prospects for regulation (this has now happened in the US), with work still to be done under the role of articles of the Framework Convention – there really is an opportunity to sort this stuff out and apply it to a regulated marketplace. So we convened the dialogue and the idea was... Could we create some common ground to debate and discuss tobacco harm reduction issues? Would it be possible to envision a shared future that would guide the work that we do when we're back at our institutions and organisations?"

The main principles agreed on during the dialogue appear in an article in the British Medical Journal:

- The primary goal of tobacco control is to reduce mortality and morbidity associated with tobacco use.
- "Tobacco free" should be the norm. Policy interventions such as clean indoor air laws, sustained media campaigns and excise tax hikes, coupled with expanded prevention and treatment efforts, should continue to be at the forefront of tobacco control efforts to denormalise tobacco use.
- Achieving the primary goal might entail continued use of selected nicotine-containing products if doing so would deter the use of more toxic tobacco products and would result in a significant reduction in tobacco-related morbidity and mortality.
- Any company marketing nicotine-containing products needs to be accountable for the toxicity of its products and must bear the burden of proof for any product claims... (Zeller & Hatsukami 2009)

The main short term objectives set were regulatory control over tobacco products and 'shifting people down the continuum of risk' towards the least harmful products, defined as medicinal nicotine. One of the key areas of consensus was the embracing of the continuum of risk, whilst the place of smokeless tobacco remained an unresolved issue. Here harm reduction reinforces and is set firmly in the context of traditional

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[56] The quotes in this section, unless directed otherwise, are taken from a presentation by Mitch Zellar in October 2009 on the process of the strategic dialogue.

tobacco control goals and methods: achieving 'tobacco free' through restrictions on where people can smoke, media campaigns, taxation and treatment:

> *"Here it was let's not forget the policy interventions that we know work and that should stay at the forefront of tobacco control even as we try to navigate the tobacco harm reduction waters; let's not forget that it's still ultimately about becoming tobacco-free".*

Divisions over *snus* were negotiated through a focus on the continuum of risk, and the focus on medicinal nicotine, as well as the displacement of *snus* as an initiative 'worthy of further exploration and research'.

Harm reduction in the UK: strategic network-building

In the UK, a new strategy on tobacco control *A Smoke-free future* (DH 2010a) was recently published. The inclusion of harm reduction ideas in this document – new routes to quitting that include 'managing nicotine addiction' and using 'a safer alternative' to smoking are part of a strand that aims 'to motivate and assist every smoker to quit' – is the result of strategic network building that has worked to translate the concept of harm reduction so it is able to enrol a wider range of actors. Key in this consensus building has been ASH and particularly director Deborah Arnott. As one interviewee said *'she seems to have found the ways to get people on board – where the middle ground is'* and later:

> *"I think the sort of cautious incremental strategy that Deborah is pursuing is probably, politically, the wise one. But that is likely to start off with more the effective, if they become available, the more effective nicotine things being prescribed. My personal view is, in the long term it probably wants to be a market led thing rather than a medically driven."* (UK-RES-06)

The key to this network-building, clearly stated in the DH strategy, is the exclusion of tobacco products, including smokeless tobacco, and the tobacco industry from the network: "Given the ongoing concerns about the health impacts of using *snus* (an oral smokeless tobacco which is illegal to sell in the UK), the UK continues to support the current European prohibition on the sale of this type of tobacco" (DH 2010a). As a representative of the DH explained:

> *"What the government is clear about is that substituting one tobacco product with another tobacco product is not a solution here. And that's why the government is very clear and has restated the position within the strategy that the UK currently supports the EU prohibition on Snus and doesn't have any plans to revisit that. I think it's important that that point is made ...I think that it doesn't make a lot of sense to replace one harmful tobacco product with another, albeit less harmful, but still harmful, tobacco product when there is medicinal NRT available which is safer again still. I think that the most responsible way forward is to think about what we can do about medicinal NRT first".* (UK-POL-17)

Here the focus is firmly on 'medicinal nicotine' and the pharmaceutical industry.

A key actor in enrolling harm reduction into the UK tobacco control network has been the RCP. In a presentation at a round table to inform the new strategy[57], Arnott traced the recent discussion on harm reduction to a RCP report (2002) published in 2002. *Protecting Smokers, Saving Lives* takes as its starting point the final recommendations of the previous report on Nicotine Addiction, as well as of the Commons Health Select Committee (2000), on the need to reconsider nicotine regulation. After a detailed consideration of regulatory issues and options, it argues for the creation of a 'tobacco and nicotine regulatory authority' in the UK. It also, in a section on forthcoming issues in tobacco policy, raised the subject of smokeless tobacco as a harm reduction option and asked whether the ban on oral tobacco should be lifted? Arnott, who took over from Clive Bates as director of ASH in 2003, suggested that it was 'clear that people ignored the rest of the report and became obsessed by *snus*'. She felt that a long term approach was needed to achieve anything and that, whilst *snus* had been useful to move people to the centre ground and reframe the debate, with *snus* on the agenda it was going to be difficult to make progress.

The DH's 2004 white paper *Choosing Health* highlighted helping people give up smoking and aimed to 'widen the use and availability of NRT', along with continued engagement with the pharmaceutical industry and MHRA. With a shift in attitude from the MHRA and widening access to NRTs from 2005 (which I will lay out in greater detail in the next chapter), both the MHRA and the pharmaceutical industry became more engaged in this area. The RCP published *Harm reduction in nicotine addiction* (RCP 2007) in 2007, which explored the issues put forward in 2002 in greater detail. The RCP considered the evidence on nicotine addiction, and the risks of smoking, medicinal nicotine and smokeless tobacco. They argue that conventional preventative measures and cessation approaches will be ineffective for many smokers; and that tobacco control policy needs to be 'radically extended with the implementation of effective harm reduction strategies' that provide smokers with safer sources of nicotine including 'more effective, more acceptable and user-friendly medicinal nicotine' and possibly low nitrosamine smokeless

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[57] 'What would a harm reduction strategy look like? A round table discussion.' Convened by ASH on the 5th June 2009 at Chartered Institute of Environmental Health, London.

tobacco products. They again emphasise the need for the creation of a nicotine regulatory authority.

The RCP is a central actor in the tobacco control network. Their report is key in stabilising harm reduction. It lays out the main arguments, assesses the 'evidence base', and puts the weight of the RCP and its long experience in the tobacco control field behind them, giving harm reduction greater legitimacy, particularly in policy circles. Representatives of both the MHRA and the DH pointed to the importance of the report in the acceptance of the idea of harm reduction: "*Of course the government does consider reports like that seriously – I mean RCP reports are always very thoroughly researched and of an excellent standard*" (UK-POL-17). Various groups signed up to a harm reduction agenda after its publication: The British Heart Foundation and Cancer Research UK were supportive:

> "We welcome this report which highlights the stark fact that cigarettes - which are the most dangerous way of obtaining nicotine - are freely available and accessible, while medicinal nicotine products - which by comparison carry minimal risk - are heavily regulated and therefore much less readily available." (Cancer Research UK 2007)

The 2007 UK National Smoking Cessation annual Conference voted to support the statement:

> "The UK National Smoking Cessation Conference supports the RCP's call for an overhaul of nicotine regulation to give smokers long-term access to less harmful forms of nicotine as a real alternative to smoking. We call on the government to take steps to implement such a strategy now."

In 2008 ASH produced the report *Beyond Smoking Kills* (2008), with funding from the British Heart Foundation and Cancer Research, to mark the 10th anniversary since *Smoking Kills.* This included a section on 'Alternatives to Smoking' that explicitly focused on medicinal nicotine only: 'current efforts to improve choices for smokers must focus on the even safer option of using pure nicotine products', and included the recommendation to:

> "Develop a strategy and appropriate regulatory structure to improve the acceptability, attractiveness and accessibility of nicotine products as an alternative to smoking for those who are currently unable or unwilling to quit." (ASH 2008)

Over 100 health and social welfare organisations signed up to these recommendations. The DH launched a consultation on the 'future of tobacco control', also in 2008, that included 'considering the potential of a harm reduction approach in tobacco control to help people whose addiction to nicotine makes it extremely difficult to quit altogether'

(DH 2008a, p.5). The consultation report published at the end of the year concluded that:

> "Around 80 per cent of respondents are in favour of a harm reduction approach based on medicinal nicotine replacement therapy (NRT). However, around half of these suggest that this should be as part of a structured approach leading to permanent smoking cessation." (DH 2008b, p.33)

The British Medical Association followed with a policy position in 2009 that supported harm reduction, although framing it within the following statement: "It is important to note, however, that for all smokers cessation should be considered the ultimate goal" (The British Medical Association 2009).

Although *Harm reduction in nicotine addiction* (RCP 2007) considered the role of both medicinal nicotine and smokeless tobacco, the evolving harm reduction network in the UK explicitly excludes smokeless tobacco and is stabilising around what we might call a 'medicalised harm reduction': harm reduction based on medicinal nicotine and with smoking cessation as 'the ultimate goal'. As we have seen, this reshaped harm reduction is far more effective at enrolling other actors, as one harm reduction sceptic said:

> *"Harm reduction, if it means helping people to quit over a longer period of time – that's what's in the new strategy – I can go along with that. It's fine. If it* [harm reduction] *means just substituting chewing NRT for smoking and giving NRT out to everyone, I don't think the health lobby should have anything to do with that." (UK-POL-20)*

Almost everyone in the tobacco control community can support the elements 'medicalised harm reduction' includes whilst the most divisive actor, smokeless tobacco, has been excluded from the network.

Discussion

Nicotine addiction was stabilised in the tobacco control network with first the broader enrolment of the medical profession through central actor-networks such as the ICD, DSM, US Surgeon General and RCP and then a new and more sympathetic government in the UK. With the support of a DH keen to take action on health the tobacco control network was reshaped around the disease-treatment set of ideas, which enrolled medical professionals, treatment settings and practices, and pharmaceutical companies far more centrally into the network. Tobacco use as a disease, a medical problem, has become the dominant framing for in the tobacco control network, and treatment with counselling or drugs an important solution.

In parallel to these later shifts, the idea of harm reduction has also begun to reshape the network. Harm reduction mobilises and translates a range of different actors – i.e. safer smoking, tobacco and pharmaceutical companies, smokeless tobacco and NRT. The recent contestations within tobacco control over it allow me to trace many of the associations it makes and the ways different actors in the network are trying to deploy it. Harm reduction delineates a set of actors as drug delivery devices and arranges them according to particular attributes: speed of nicotine delivery and risk. However, whether an actor is tobacco or not remains a crucial distinction that problematises the role of *snus* within the network by linking it with the tobacco industry, a powerful network that tobacco control is constantly working to exclude. The harm reduction actor-network that is being assembled in the UK places NRT or 'medicinal nicotine' as a central actor. Medicalised harm reduction, by restricting what nicotine delivery devices are included in the tobacco control network is able to mobilise many other actors. Harm reduction, which with the enrolment of *snus* has the potential to push the tobacco control network in quite different directions, has in England further stabilised medical networks in tobacco control. It also shapes NRT and has enrolled the pharmaceutical industry as an increasingly important actor in the tobacco control network, changing how the industry conceives of its products, customers and role in tobacco control.

Harm reduction and NRT

As highlighted, the harm reduction network that is being assembled in the UK has NRT or 'medicinal nicotine' as a central actor. This shapes both what actors are included in the harm reduction network (not smoked or smokeless tobacco products, not the tobacco industry, NRT, the pharmaceutical industry) and also shapes NRT:

> *"... looking at the present portfolio and things that are changing, as you know, with the kind of ongoing debates in the UK around harm reduction and... I think that's kind of driving a lot of discussion these days, in terms of what would be an optimum product from an NRT perspective."* (UK-PHA-07)

The changing views discussed here – about why people smoke and the importance of nicotine, the characteristics of the remaining smokers, and the strategies that tobacco control should pursue – are reshaping conceptions of what NRT is, what it is to be used for and how it ought to be made available. The shift from a treatment approach focussed exclusively on abrupt smoking cessation to 'medicalised harm reduction' has enrolled the pharmaceutical industry as an increasingly important actor in the tobacco control network – a countervailing power to the tobacco industry – and has also shaped

how the industry conceives of its products and is reshaping how it views its role in tobacco control. This move from the treatment-cessation assemblage to the idea of considering 'the nicotine market as a whole' opens up new pathways for NRT, as well as for other nicotine products. It also begins to blur the boundaries between tobacco, pharmaceutical, recreational and medicinal products in interesting ways.

Chapter Six: Product Innovation

> *'The whole history was a struggle. First prescription, short duration, low dose; and you had to fight to liberalise and over the counter: 'oh no! Over the counter – that would be dangerous!' And then again the opposition to general sale, actually, that there is in many countries. It had to be abrupt stopping. Temporary use of this for smoking reduction: absolutely not, controversial. So there has been a fight for sort of every step here and now we are fighting with harm reduction"* (SW-RES-02)

Introduction

In Chapter four I described the development of nicotine gum and its problematic and partial transformation into a medical product. This chapter picks up from the 1980s to examine the various ways the nicotine replacement therapy assemblage has been translated and extended during the last three decades. It looks at the development of different types of NRT products, the changing ways NRTs have been controlled, their shifting enrolment in the treatment sector and their changing position within the tobacco control community. This brings us to the main focus of this chapter, which is to examine the ways both the current regulatory situation and the recent alignment of actors around the *medicalised harm reduction* assemblage, described in the previous chapter, impact on the development and distribution of new NRT products.

Reshaping the NRT assemblage: 1980 – Present

As underlined in Chapter four, an important part of positioning a product as a medicine is having an accepted disease to treat. The gradual stabilisation of nicotine addiction as a disease in need of treatment, described in Chapter five, helped to steadily reinforce the position of NRT as a medicine. The development of nicotine gum also played a role in stabilising ideas about nicotine, as a tobacco researcher commented:

> *"I think that* [nicotine gum being tested] *was very influential because people argued for example that it was fiddling with the cigarette and so on, but once you could show that you could give people nicotine in a gum and it would make a difference in whether they could abstain* [from smoking] *or not, I think it was clear that nicotine had a role, even if not the sole role."* (NA-RES-11)

In this way, nicotine gum and the concept of nicotine addiction can be seen as having been co-constructed, each reinforcing the other. However, as Chapter four made clear, not all actors initially saw *Nicorette* as useful. In fact, ASH and other anti-smoking

organisations were hostile to NRT when it was first introduced (UK-POL-01, UK-RES-03 & UK-RES-06) in the UK:

> *'The National Society for Non-smokers, which is now called Quit, campaigned vigorously against NRT on the grounds that you shouldn't fight fire with fire and that nicotine was an addictive drug. I'm paraphrasing, but yes that it was a bad thing."* (UK-RES-03)

It is suggested that *Nicorette* did not fit the model of smoking or the way that treatment was organised:

> *'This was nothing that was welcomed. We have to keep in mind that at that time it wasn't seen as a drug dependence. It certainly was seen as difficult to give up and a habit, a very strong habit. Therefore psychologists were interested here and the treatments that were given were based on psychologist methods theory and we are still in some ways suffering from that baggage that is following us: setting a quit date and few other things."* (SW-RES-02)

In the UK *Nicorette* continued to be considered 'not a drug' by the ACBS and was placed on the 'blacklist' when it was introduced.

However, the ACBS's decision on *Nicorette* did not go uncontested. The ACBS received letters, many from GPs, questioning their decision. In a somewhat irritated letter to the ACBS secretariat, Michael Russell pointed out:

> "I have been working in the smoking cessation field for more than ten years. This has been a very difficult and frustrating area of work. When for the first time we come up with a really effective treatment, it is very frustrating to find it relegated to the status of borderline substance."[58]

The issue is addressed in a meeting in 1981 on the 'respective responsibilities' of the ACBS and CSM:

> "'Nicorette' was a licensed medicinal product for 'a tobacco substitute for use in smoking cessation'; it was also an 'anti-smoking preparation': one of a group regarded as 'not drugs' by the ACBS." [59]

This brings to light a problematic disjunction between the two committees' definition of *Nicorette.* The Secretary of State for Social Services was asked several parliamentary questions on the ACBS's position on *Nicorette* (Hansard, Written Answers, 8th Aug 1980 Col.529w; 13 Nov 1981 Col.188w; 1st Dec 1982 Col.224w; 14 Feb 1983, Col.30w)

During the 1980s some GPs resisted this decision by continuing to prescribe *Nicorette.* One GP in Manchester, Dr Chris Steele, recounts the result of his resistance:

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[58]National Archives, Ministry of health papers, MH149/2443, letter from M. Russell, 26th Jan 1981 p2
[59] National Archives, Ministry of Health papers, MH149/2018, Minutes, 24th March 1981

> "As a result of 'breaking the rules' the author faced various disciplinary hearings eventually having to present his case to a Tribunal of Independent Referees. At that tribunal a statement for the Secretary of State for Health read as follows: 'Smoking is a habit – it is not a disease or condition – even though it may be a contributory cause of, or may aggravate, a disease or condition such as bronchitis, carcinoma of the lung, arteriosclerosis and so on.'" (Steele 2006)

The referees at the tribunal in 1984 came to the conclusions that: 1) tobacco dependency ought to be considered a disease; 2) nicotine prescribed for this purpose has both a pharmacological and a therapeutic effect, and 3) this method of treatment is the most effective that has so far been evolved. Despite these conclusions, *Nicorette* remained blacklisted. In what a colleague of Russell's described as a *'completely contradictory position'* (UK-RES-06), a 1989 BMJ news article reported that 'the Department of Health has launched a criminal prosecution against the manufacturers of an antismoking mouth spray for selling a medicinal product without a licence' (Dyer 1989a; Steele 2006). Here the DH argued that smoking is a disease and the '*Mustop*' spray, which was 'largely water, with a small amount of silver acetate', is supplied for a medicinal purpose. The company was convicted of breaching the Medicines Act 1968 (Dyer 1989b). It is clear that during the 1980s *Nicorette*'s positioning as a medicine, and as we saw in Chapter five, the concept of nicotine addiction, remained unstable and contested.

Fernö and his team at Leo Pharmaceuticals and Russell and his team at the ARU continued to work collaboratively on the development of nicotine replacement. Progressing this work continued to be a struggle. Fernö (Addiction 1994) noted that he had discussed the patenting of a nicotine patch in 1981 but that Leo was not interested. Leo was also given the opportunity to apply to have *Nicorette* transferred from prescription only medicine status to pharmacy sale three years after it was licensed; however, as one of Fernö's colleagues remembers, they:

> *"Chickened out of that, because our top management was strictly RX* [prescription only medicines] *people and they couldn't see this product as an OTC* [over the counter] *product because they didn't perceive potential benefit from that and they were not used to working with them."* (SW-PHA-04, see also Fagerström et al. 2008)

He goes on to describe how this position changed:

> *"So then it took another, until the end of the 80s for people to see that the positions were helpful in some instances, but were a barrier to larger sales. So a switch application was put together stating the case for a P* [pharmacy medicine] *status and as far as I remember that was to reach more smokers and get more benefit from the product and that worked without any particular hitches."* (SW-PHA-04)

The 2mg nicotine gum was given pharmacy medicine status in the UK in 1991 allowing it to be purchased from pharmacies. A representative of the MHRA remembered the main reservations about this change being doubts about its efficacy without support and concerns about the cardiovascular effects of nicotine (UK-POL-19). The shift to pharmacy sales[60] introduced new circuits for the movement of *Nicorette* outside of medical control.

In the US there was also work being done on nicotine replacement. Murray Jarvik began to turn his attention to the role of nicotine in smoking in the late 1960s (Addiction 2001; also NA-RES-11), and his team at the University of California, Los Angeles had carried out clinical studies with nicotine gum in the 1970s. During the 1980s, Jarvik and his colleague Jed Rose started investigating the possibility of delivering nicotine through the skin. They began work developing a nicotine patch in 1984. The patch was finally patented in 1990 (Addiction 2001) and first launched in the UK under the name *Nicotinell TTS* by Novartis in 1992, quickly followed by other brands (Anderson 2007).

Russell and his team became interested in nasal snuff during the 1980s. Russell noted that the rapidity of nicotine absorption from snuff suggested the potential of the nasal mucosa as another site for nicotine absorption (Addiction 2004). He suggested this to Fernö, who began development of a nicotine nasal spray 'on the premise that some smokers might find it more helpful to receive nicotine that is absorbed more rapidly' (Addiction 1994). He notes that Pharmacia were still not keen on investing in nicotine replacement: "They were really not interested in the NNS *[nicotine nasal spray]* either at that time. I had to fight to make sure it was patented." (Fernö in Addiction 1994, p.1224) *Nicorette* nasal spray was introduced in the UK in 1995 as a prescription only medicine product. In the US the FDA had concerns about the abuse liability and long term use of the nasal spray and considered licensing it as a controlled substance; however, they also licensed it as a prescription medicine in 1995 (Fagerström et al. 2008). Three other main types of NRT products were developed after the nasal spray: a nicotine inhalator was licensed in 1998 and Microtabs in 1999, both by Pharmacia;

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[60] Itself embedded in broader changes making it easier to reclassify certain medicines due to pressure on the drugs bill.

whilst Novartis introduced a 1mg nicotine lozenge in 2000. In the late 90s Boots and GSK entered the UK NRT market. During the 1980s and 90s, scientists working on nicotine addiction and replacement strengthened their relationship with the pharmaceutical companies, and gradually extended the NRT network.

Some interviewees, however, felt that little progress had been made:

> *"We were continuing throughout the early 1990s to feel just as frustrated. There were no positive developments. Of course different* NRT *products had come along: we had the nasal spray and obviously had the patch, but they were all covered by the refusal to reimburse. The Thatcher government was a big block."* (UK-RES-06)

As with tobacco control more generally, the election of a Labour government in 1997 and the white paper that followed in 1998 – *Smoking Kills* – are considered to be significant turning points for the status of NRT. In *Smoking Kills* the DH stated their intention to build NHS services to help smokers give up smoking, provide NRT on the NHS, along with a consultation by the Medicines Control Agency on widening access to NRT. The NHS Plan reiterated that: '...the NHS will provide a comprehensive smoking cessation service. Nicotine replacement therapy (NRT) will be available on prescription from GPs...' and the CSM '...will also be asked to consider whether nicotine replacement therapy can be made available for general sale' (DH 2000, p.109). In 1999 the first smoking cessation treatment services were established in the English NHS. This included a voucher scheme for 1 week's (extended to 4-6 weeks the next year) free NRT for smokers eligible for prescriptions. The 2mg strength of nicotine chewing gum[61] was reclassified as a GSL product, and in 2001, over 20 years after it was first licensed, NRT became available on NHS prescription. With the greater acceptance of the idea of nicotine addiction in the public health community and the DH working with the tobacco control experts, the nicotine addiction/treatment networks were extended and strengthened in England. This series of changes, regarded as an enormous step forward by the UK tobacco control community, brought NRT and smoking more firmly within medical networks but also broadened access outside of medicine. Now the NHS provided both services and medications to help smokers stop smoking. The move to pharmacy medicine and then GSL status allowed NRTs to circulate with less and less medical intervention. The pharmaceutical industry was able to communicate about

[61] The 4mg nicotine gum, nicotine lozenges and patches were later added to the General Sales List.

NRTs and smoking cessation directly with 'consumers' via packaging, patient information leaflets and later advertising.

As recounted in Chapter four, when nicotine gum was introduced the indication it was approved for was as an 'aid to smoking cessation'. Smoking cessation was envisaged as a fairly swift process involving setting a 'quit date' to stop smoking completely and then discontinuing use of NRT after a short period (four weeks). NRT was also 'contraindicated' – in other words not advised – for particular groups including those with cardiovascular disease, pregnant women and adolescents due to concerns about the effects of nicotine. Some of those working within the tobacco control field began to criticise the Medicines Control Agency's approach to NRTs as too strict. One interviewee recounted his views at this time on 'the flaws in the regulation of NRT':

> *"...I think we dubbed it 'reckless caution' at the time. The sense that you put on all these scary messages about pregnant women and blah, blah, and you take no responsibility for the consequences of them continuing to smoke. The asymmetry with the regulation of smoking and the regulation of NRTs, I think created these perverse consequences: you were much too cautious with the alternative nicotine products without factoring in the fact that if you didn't use them more broadly and take more risks with them then the person would harm themselves by continuing to smoke."* (UK-POL-01)

The issue of taking into account, or taking responsibility for, the harm caused by tobacco was highlighted, with the main criticism being that the Medicines Control Agency's approach created an asymmetry in the way nicotine products were regulated. Representatives of the Medicines Control Agency began meeting with representatives of the tobacco control community in 2000 but at first these meetings were not felt to be productive, with the MHRA's attitude remaining traditional. Those responsible for the regulation of NRT had doubts about these arguments. I talked with someone who had worked in the licensing division of the, then, Medicines Control Agency on variations and over the counter medicines during the late 1990s and early 2000s. He was quick to emphasise that NRT *'was no different than any other product'* from the point of view of assessing a medicine 'so *it was... we regarded it as a medicine and it had to be assessed as such and you couldn't treat it any differently*' (NA-POL-15). Also that the MHRA worked within a particular set of rules: *"So there was a lot of sympathy to make NRT widely available and to as wide a population as possible. But to make the classification system any different was quite beyond at that stage the powers of the MHRA"* (NA-POL-15). Similarly, he emphasised that the agency had a set role:

> *'It doesn't fit with what they do or their role. I mean it's the type of product which is presented to them on which to give their opinion based on what the regulations are. You can't*

> *blame the agency. That's the agency responding to its responsibilities, meeting the public need, protecting the public, and trying to serve its customers which are after all are partly the ministers, partly the public and partly the pharmaceutical companies and who forever are running sometimes quite difficult lines."* (NA-POL-15)

He also highlighted the importance of judging medicines on their 'scientific merit' and the 'scientific approach to the switching of medicines'.

Smoking Kills demonstrated the Government's interest in widening access to NRT and enrolled the pharmaceutical industry, the NHS and the MHRA into their programme of action. In 2002 NICE was enrolled into the network and published its first guidance on NRT. This reflected the dominant model of use at the time with NRT to be prescribed as part of an 'abstinent-contingent treatment', where the smoker must commit to stopping smoking on a set date and NRT is used for two weeks after the stop date (NICE, 2002). In 2003 the Medicines Control Agency was merged with the Medical Devices Agency to form the MHRA, whose remit now included, 'making an effective contribution to public health', whilst the *Choosing Health* white paper (2004) underlined a greater focus on the prevention of illness and promotion of health in the NHS. In 2005 a working group was set up by the CSM to 'look at the current evidence' (MHRA 2005) on the safety and efficacy of NRT, particularly in contraindicated groups. A representative of the MHRA suggested this was the culmination of a gradual shift in regulatory thinking, during which people had become increasingly uncomfortable about these vulnerable populations; a shift from nicotine being seen as dangerous and needing to be kept away from these groups to the realisation that these groups needed NRT most (UK-POL-19).

The central conclusion of the report the CSM produced was that: "...overall, the benefits of quitting smoking clearly outweighed any risk there may be with NRT and that the product information for both users and healthcare professionals should clearly state this" (MHRA 2005, p.9). Consequently, at the end of 2005 the MHRA widened access to NRT, making it available to those over 12 years, pregnant or breast feeding women, smokers with underlying diseases and those taking concurrent medication. The warning not to use more than one product at a time was also removed and duration of recommended use was increased to nine months (MHRA 2005). The gum and inhalator

products were licensed[62] for cutting down smoking 'as a "stepping stone" to stopping completely[63], for smokers who are currently unable to stop abruptly'. This was based on several studies examining the effectiveness of NRT in reducing the number of cigarettes smoked. They found that, on follow up, a higher proportion of the group using NRT had stopped smoking than those on placebo. A representative of the MHRA underlined the importance of the shift from seeing NRT in isolation as a medical product – with concern about nicotine toxicity – to the recognition that the comparator should be smoking not placebo. A pharmaceutical company representative also highlighted the importance of this recognition of cigarettes as 'the comparator':

> *"...That was probably the first time that it was written down... that at the end of the day we need to be thinking, when we look at safety and things with these products, that we have one eye on the fact that the comparator should be cigarettes. We're not really talking about the risk of nicotine to someone who's never been using nicotine; we're talking about the risk of medicinal nicotine to someone who otherwise is likely to continue smoking."* (UK-PHA-07)

Further, value added tax on NRTs was reduced from 17.5% to 5% in 2007; 'temporary abstinence' was added as an indication in 2008, approving the use of NRT by smokers in situations where they cannot smoke[64]; and NICE guidance on Smoking Cessation Services replaced the previous guidance on NRT (bringing it in line with the change in contraindications, although maintaining the abstinent-contingent set-up).

Improving the NRT assemblage

As outlined above, there has been substantial reshaping of the NRT assemblage over the last decade: with a greater variety of products, wider availability and more integration into medical networks. As noted in the previous chapter, the harm reduction network that is being assembled in the UK is playing an important role in reshaping conceptions of what NRT is, what it is to be used for and how it is made available. These developments are leading many actors in the network to reconsider various aspects of the NRT assemblage. In discussions about how NRT products might be improved, various aspects of the current NRT assemblage were brought up as problematic including the attitudes of the pharmaceutical industry towards NRT, how consumers

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[62] This is inconsistent with the European Medicines Agency guidelines which maintain that: "Smoking reduction is not considered an indication target. The benefit of smoking reduction on health outcome is debatable" (European Medicines Agency 2008).

[63] The process was defined as reducing smoking within 6 weeks, with an attempt at smoking cessation within 6 months and a review of treatment if abstinence not achieved within 9 months.

[64] This also included a review if unable to undertake permanent quit attempt within six months.

perceive NRT and how the products are actually used, networks of distribution and the treatment set-up within which NRTs are sometimes enmeshed.

Pharmaceutical companies: from cessation and inertia to engaging with harm reduction

Some interviewees suggested that in the past companies have not *'really tried to push the envelope'*, and that there had been no major innovations in NRT products since the main delivery sites (first through the buccal mucosa with the gum, then the skin with patches, and finally through the nasal mucosa using the nasal spray):

> *"...since these first NRT products were developed no real advancement had taken place. Patches had became transparent, gums in more flavours and taste, larger and smaller package sizes and... Really nothing that helped the smoker go through the withdrawal more easily."* (SW-RES-02)

This participant discussed his experience of trying to stimulate product development, having consulted for various companies:

> *"I have tried to encourage them to develop faster acting, better products. Ya, they listen, the product manager they have for these products can see the dollar signs and yes that would be interesting. But there are two problems: one, when you go up in the company... smoking cessation products are a small part of these big companies' profits and importance is not that big. They don't want to risk that there will be abuse: I mean faster absorption that could be abused; we don't want to see on the papers that a seventeen year old girl is taking this for slimming purposes or something. And also the companies have said all the time that the regulatory authority would not allow it. So the regulatory authority and the companies' sort of reluctance to get into a grey area where they might lose their ethics of a highly sophisticated, research orientated, serious company has been hurdles for developing the products."* (SW-RES-02)

Here NRTs are not a priority and, more than that, are potentially problematic for the company's image. Another interviewee suggested that it was for this reason that companies were reluctant, at first, to pursue new indications such as getting people to *'cut down or ready themselves'*:

> *The companies themselves were very reticent about going down that line because they didn't want to be seen to be creating a new line of addictive products. Plenty of activists who would say it was 'big pharma' muscling in on big tobacco's turf to make more profits."* (UK-POL-01)

Another person I spoke to, who has worked within the industry, felt that the in large companies *'people are very careful, in going out on a limb and supporting new products'* (SW-PHA-04). However, when considering NRT products currently on the market, a representative of the pharmaceutical industry suggested that it is important to bear in mind the context in which these products were being developed:

> *'I guess the products that are available on the market now... the companies doing the development work weren't looking at anything other than cessation... So I think it is fair to*

say that people were very conscious at that time that you want something that is an alternative to cigarettes, but part of a cessation approach. And I guess when they were developed cessation was very much: it's the abrupt cessation, stop smoking, straight onto NRT *for (depending on what product) eight, ten, twelve weeks, then you stop that, and you're nicotine as well as smoke-free ...it was very cigarettes over there and we're moving away from it."* (UK-PHA-07)

With the focus in the tobacco control community on an abrupt smoking cessation approach, the pharmaceutical industry was not motivated to, *'push the envelope'.*

However, harm reduction has been changing the ways the pharmaceutical industry is thinking about NRT. As we saw in the previous section, with growing interest around these ideas within the English tobacco control community, a more supportive government, and a changing regulatory environment, the position of the pharmaceutical industry in the network is shifting. In a meeting between representatives of a pharmaceutical company and members of the UK tobacco control community on developing new NRT products, representatives of the company noted that the 2008 RCP report had changed the 'licensing environment'. They outlined how the report had stimulated a conversation within the company thinking more broadly about smokers (rather than just those who are trying to quit) and smoking cessation. Another interviewee pointed out the importance for the pharmaceutical companies in seeing the production of NRT as a profitable enterprise:

"I think what pharmaceutical companies need to see is that there is some profit to be made in making NRT *available because at the end of the day pharmaceutical companies are profit making entities. And they would say as well that they have an interest in improving public health, and that sort of magnanimous approach to life, but at the end of the day I think, like any profit-making organisation, money talks and there is profit to be made and that is important."* (UK-POL-17)

Harm reduction has great potential to increase the market for NRT; however, the pharmaceutical companies' concern with image also shapes how they enter the discussion on harm reduction:

"...one of the things that we recognised was until the public health and tobacco control communities had come to some degree of consensus that this [harm reduction] *was an appropriate public health strategy to engage in, until that happened, then if we had started to become involved those who wanted to undermine it, or those who didn't understand it, or were concerned about it, would potentially say: well that's just about private sector organisations wanting to see an addictive compound being used in an ongoing addictive style to further their sales."* (UK-PHA-07)

There remain concerns about the way their product, containing nicotine as it does, might be seen.

Circulation from company to consumer

Distribution networks

Another part of the NRT assemblage that is highlighted as problematic, especially by those within the pharmaceutical industry, are the circuits along which NRTs are distributed and sold, through which they move from company to consumer. The need to increase the access of consumers to products is highlighted:

> *"So while they are widely available in pharmacy and many of the grocery outlets (so they are available in Tesco etc) there are additional outlets that it might be useful to have more access to: railway stations and airports."* (UK-PHA-16)

These networks are seen as particularly important in relation to the cigarette:

> *"I think that increasingly everyone is thinking more in terms of the fact that these products are up against cigarettes and they are available anytime, anyplace, anywhere."* (UK-PHA-07)

In fact, the problem is seen less as access to NRT, than the ubiquity of cigarettes and their 'hold on small retailers':

> *"The access to products in this country is extremely good... Almost all NRT products are GSL, which means you can buy them at any secure retail outlet... The trouble is you can't make newsagents stock NRT, whereas all newsagents' stock cigarettes and... The tobacco companies still have a major hold on the small retailers and the point of sale material is almost advertising in its own right."* (UK-PHA-08)

Some question whether there is much more that can be done in this area. A representative of the MHRA wondered what there was left for regulation to do in terms of availability and what requirements could be lifted.

Treatment

The effectiveness of over the counter NRT is also raised as a problem:

> *"So, it looks as though people who just go out and buy nicotine replacement therapy over the counter, for example, are not getting a great deal of benefit from it: they don't use enough, they use it with the wrong expectation, they don't use it for long enough, they are not using it specifically as part of a structured quit plan. So what the stop smoking specialist can do is to address all these issues..."* (UK-RES-18)

As well as being sold over the counter, NRTs are embedded in medical settings where they are prescribed by various healthcare professionals, interaction is shaped by various rules, guidelines and targets, and they are combined with advice and other forms of support such as therapy. It was suggested by several of those I interviewed that NRTs

are more effective within treatment settings. The combination of NRT with counselling is seen as particularly important:

> *'I think also another thing that would help the overall efficacy is to work more on: how do you marry the products with the behavioural support programmes that are out there? ...how do you help people, more than just giving them nicotine? So how do you kind of put them* [NRTs] *in a situation where they can be most helpful or effective? Because we do know that if you couple NRT use with heavy counselling, the effect is much, much better than if you just take NRT and vice versa. So the problem is how do you do that outside of smoking clinics? How do you give that advice to the man on the street basically? Who doesn't go to those clinics?"* (SW-PHA-09)

NRT provided in a treatment setting was not, however, always seen as best:

> *'We need to think about whether people are put off by the medicalisation of quitting and whether there is some way to make the NHS stop smoking services less medical in their approach..."* (UK-POL-17)

Moreover, the way NRT is enacted within the treatment set-up is another aspect of the current network that is problematised. A DH representative suggested that the quitting process within the NHS is too 'rigid':

> *'Well the challenge that we have at the moment is that through the way that NRT has been licensed, the way that we support people to quit through the NHS is quite rigid and there is quite a strict process and only one way to go about it. The different forms of NRT, for example, that the NHS offers is quite rigid and what we need to do it find more flexible ways of being able to support smokers' to quit and recognise that different smokers have different needs and some people... might need to use NRT for longer in order to quit."* (UK-POL-17)

The length of NRT treatment prescribed was also mentioned by a pharmaceutical company representative:

> *"A large majority of Primary Care Trusts only fund a six to eight week course. If the smoker wants to complete the full treatment course, which is often ten/twelve weeks depending on what product they are using, then they are referred back to the GP... they are not getting a full treatment course in terms of the licensing. And not accessing any ongoing behavioural support..."* (UK-PHA-16)

This respondent also highlighted two other aspects concerning NRT prescribed on the NHS: there could be greater use made of 'combination products' (i.e. an NRT patch used with an oral product such as the gum) and more flexibility in allowing a 'gradual' process rather than 'the abrupt NHS quit'. The set-up within which NRT is embedded is again highlighted as important. In a presentation at a harm reduction round table[65], Nicky Willis (then a member of the DH Tobacco Policy Team focussing on supporting

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[65] 'What would a harm reduction strategy look like? A round table discussion.' Convened by ASH on the 5th June 2009 at Chartered Institute of Environmental Health, London.

smokers to stop) considered current issues within the NHS treatment network and potential problems with incorporating harm reduction ideas in the treatment network. Problems she identified were: low use of services; that current incentives are not driving action; and that current treatment is very much focussed on the goal of total abstinence. She noted that alternative 'harm reduction' uses of NRT (e.g. partial or long-term substitution of tobacco with NRT) do not align well with current treatment protocols, duration of treatment episodes, funding or data reporting requirements. She also suggested that, given the negative attitudes of some healthcare professionals to short-term use of medications, long-term use and/or partial substitution may be a 'tough sell'. She suggested that these approaches would need to be framed on a continuum with the clear long-term goal of abstinence.

Imagining users

As noted in the previous chapter, within the tobacco control community there is a growing interest in defining who the remaining smokers are and whether/how this population is changing. As the pharmaceutical industry is becoming more engaged in this area, they are becoming increasingly concerned with the users of their products. This group of people – smokers; users; consumers – and their needs, thoughts and expectations are being imagined and constructed in various ways. They are often seen as unable to stop using nicotine:

> *"And you have to be aware that at any given time most people are not really willing and able to totally quit all forms of nicotine."* (NA-POL-10)

One interviewee suggested that this is because, in some cases, the nicotine helps with a medical condition such as Schizophrenia or Attention Deficit Disorder (NA-POL-10). There is also particular emphasis on defining the 'remaining' smoker:

> *"And the only thing that's changed is: who is the remaining smoker today? ...it's still the same number of smokers. So I would argue that we've gotten the most highly educated and the most highly informed people, with the greatest access to services, to quit... and what we're left with is lower SES* [socio-economic status], *more downtrodden people with a much higher incidence of mental core morbidities, and they are so much harder to reach. And that's why we're stuck at about 20%* [smoking prevalence in the US]." (NA-POL-14)

The remaining smokers are frequently seen as people who will find it harder to quit. There is also an interest in dividing smokers into different segments. In one meeting I attended a pharmaceutical company outlined their work on identifying different segments of smokers defined by their desire to quit smoking, whilst another interviewee underlined the need to consider the requirements of what he saw as a large group of

smokers who 'have health concerns and varying degrees of interest in quitting' (NA-POL-14). It is clear that this imagining of the attributes of smokers and different groups of smokers has consequences for the ways that are put forward for tackling smoking.

Another aspect of this discussion is the way that smokers are thought to see themselves *'you've got people who generally don't view themselves as sick or ill; are therefore not going to walk into the doctors and say help me!'* (UK-PHA-07) This is seen as impacting on their behaviour and views of NRT:

> *"The smokers don't want to see themselves as sick and they don't want to see this as medicine. They speak about it as an aid, a help, and they don't want to need a prescription, they don't even want to go the pharmacy; much better if they can find it other places and also they can find it all times of the day virtually: there is better service."* (SW-RES-02)

Here the enrolment of NRTs in medical settings is problematised. It is suggested that the products are, in fact, too medicinal, especially in comparison to how cigarettes are perceived:

> *"They're very medicinal looking. The tobacco companies are in the same business: delivering nicotine. And even now that we have regulation, it's still going to be a cool and fun product to use.* ...[with NRT] *it's go to the drug store, get a box, like you're getting a box of allergy medication or high blood pressure medication, and it's medicinal, medicinal, medicinal, medicinal!"* (NA-POL-14)

A related problem, that was frequently mentioned, is people's perceptions of nicotine:

> *"There is the issue, of course, that the general public don't understand where the health risk from smoking comes from. And there's clear opinion, not only amongst the general public but even among people who should know better for example healthcare professions, a misguided belief that nicotine in tobacco causes smoking related illness when actually it is not the case."* (UK-POL-17)

There are also suggestions made for how smokers' ought to think:

> *"People have to understand that it is not the nicotine in cigarettes that is dangerous. It is not dangerous to take the recommended daily dose of NRT" (SW-PHA-09).*

Ideas are put forward for how their thinking might be changed and who should be responsible.

User compliance

An issue with the current NRT assemblage that was highlighted by all the pharmaceutical industry representatives I interviewed and many academics relates to the way nicotine, and therefore NRT, is perceived:

"Still large numbers of GPs and healthcare professionals have concerns about nicotine being one of the cancer causing agents in cigarettes. Then you are up to sort of 70-odd percent of consumers. So I guess in that context there is also the issue around perceptions of the safety of the products." (UK-PHA-07)

It is suggested that because of these 'incorrect' perceptions of nicotine consumer acceptance of NRT is problematic:

"We've done some work, and I know [another company] *have done some work, in this area, looking at consumers' understanding and beliefs, and they are really confused around nicotine. They recognise they are addicted to cigarettes and then they look at the cigarette packet and nicotine and tar are on these. So there is a strong association between nicotine and tar and the harm of cigarettes. That association with harm is also translated to* NRT *so there is a natural resistance, because of a misunderstanding with the consumers, to actually utilise these products [NRTs]..."* (UK-PHA-16)

Therefore, the way that consumers actually use NRTs – 'user compliance' – is a problem:

"If you look at where we are already, there is a big problem around compliance and usage. And... most consumers don't use much more than 3 weeks, many don't get anything like that far through a course. And we kind of know that if they took the 12 week course the chances of quit and relapse improve." (UK-PHA-07)

We are introduced to a variety of ways in which consumers do not comply with recommend use of NRT or use NRT incorrectly. These include not using products for the recommended length of time, 'under-dosing' or not using enough NRT and therefore not absorbing enough nicotine, or even avoiding using NRT products altogether. Users of NRT are constructed as lacking in knowledge about the relative harmfulness of smoking, nicotine and NRT, and the correct way of using NRT.

Reconceptualising the assemblage: constructing a 'better' NRT product

Along with issues raised with the existing NRT network and the ways it is interacting with harm reduction, there is concern within the tobacco control community that existing NRT products themselves are not as effective as they could be, especially as a harm reduction product. In considering whether barriers to the innovation of new, more effective NRT products exist it is first necessary to unpick what constitutes a better, more effective product. On first glance this might appear to be a relatively straightforward question; however, in practice it becomes more complex.

Stronger and faster acting

As discussed earlier, there is the feeling that, with the focus on abrupt cessation, the pharmaceutical companies had not put a great deal of effort into developing NRTs.

With the shift to a harm reduction orientation, some in tobacco control are beginning to rethink what a more effective NRT product might do. At a meeting on harm reduction[66], Martin Jarvis envisaged the better product as having an adequately rapid nicotine absorption profile and sensory properties to permit secondary conditioning and consumer acceptability, and giving users the capacity to regulate blood nicotine concentrations (he included smokeless tobacco in his thinking). He set this in the context of nicotine as the underlying motive for smoking and the cigarette as a highly efficient nicotine delivery device. He conceptualised products on a 'rate of absorption spectrum' (see Chapter five, Figure 1) according to their nicotine delivery characteristics, with NRT products at the slow absorption end. Further, drawing on Michael Russell's typology of smokers as either 'peak seekers' or 'trough maintainers' – motivated by 'positive rewards from sharp increments in blood nicotine' or mitigation of withdrawal respectively – he suggested that NRT products are largely geared towards the 'trough maintainer' and lacking in positive rewards. He argued that NRTs not only have to help the smoker get through withdrawal more easily but must produce some kind of 'positive reward'.

The importance of 'positive rewards', particularly in the form of faster and greater nicotine delivery, was a view shared by most of the interviewees working on these issues, both within and outside the pharmaceutical industry. For example, a pharmaceutical industry scientist highlighted the need for products to deliver nicotine more rapidly and deliver more nicotine:

> *"I think we as an R&D organisation, and also backed by many of the sort of leaders and experts, generally we are pretty convinced that there are at least two primary things that we need to work on and that is: the speed of onset – we need to develop products that would deliver nicotine more rapidly to the system... that would be a big win I think. Okay. The other area that I think is important is... delivering more nicotine to the system – a stronger product."* (SW-PHA-09)

Like Jarvis, many compared the delivery characteristics of NRT to cigarettes:

> *"Cigarettes deliver nicotine to the lung and into the brain in about seven seconds. So the metric is seconds. The metric for NRT is minutes and we're lucky if we can get an NRT product that can get the nicotine in the brain in seven minutes."* (NA-POL-14)

One method suggested for achieving this speed was pulmonary delivery:

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[66] 'What would a harm reduction strategy look like? A round table discussion.' Convened by ASH on the 5th June 2009 at Chartered Institute of Environmental Health, London.

> *"...I think we need essentially more aggressive forms. It may be higher doses. I actually think that faster dosing is likely to have more impact than more dose, because we've tried very high dose patches and they're unimpressive in terms of the improvement. So there have got to be a couple of dozen groups working on inhalers of various sorts to achieve pulmonary delivery."* (NA-RES-11)

This involves delivering nicotine to the body via the same route as cigarettes – through inhaling nicotine into the lungs.

The ultimate product?

Pulmonary delivery of nicotine was often put forward as the aim for NRT products:

> *'The ultimate product would be of course a lung delivery system to deliver nicotine to the lungs. Then you would have the same profile as you have in a cigarette."* (SW-PHA-09)

This would involve NRT being more cigarette-like in terms of delivery characteristics. However, several interviewees also raised problems with this delivery method such as causing irritation in the throat, safety concerns from absorbing nicotine into the lungs, the need for a medical device and the fact that it would be on prescription to begin with. There are also implications about the cost of an inhalation device, and therefore its attractiveness and availability:

> *'If you look at the inhaled insulin product that was on the market in the UK, that device was... a very high tech device. It also then becomes a very costly device, and that's not necessarily just costly to develop ...it inevitably gets passed on in terms of the cost of the products... and I guess if the only way that you came up with an innovative product was through an expensive device, that's not necessarily attractive to people when you compare it to cigarettes and things".* (UK-PHA-07)

One tobacco scientist particularly highlighted the safety concerns in delivering pure nicotine into the lungs:

> *"...there may be an issue with pulmonary delivery, which is that nicotine itself is an astringent, nicotine is quite harsh, and the lining of the lungs are quite sensitive... But to my mind it is not impossible, and it actually seems quite likely, that putting nicotine into the lungs would damage the lungs. If that is the case, then we need to think of an alternative route and given that nasal snuff gives quite rapid nicotine delivery and given that you can get quite rapid nicotine delivery from snus, I think that there may be more merit in products that are not pulmonary but that are more efficient in delivering nicotine through the nasal and oral mucosa."* (UK-RES-18)

Although a lung inhalation device was often positioned, sometimes implicitly, as the ultimate NRT product, problems and questions appear around it. In the same way, faster and stronger NRT products were revealed to be simultaneously better and problematic.

More than stronger/faster

Although much of the discussion of the better NRT product focuses on nicotine delivery characteristics, some experts highlight other aspects of the product that they see as important, as Jarvis did in his specifications. Some of these come back to the ways products are perceived by users, whilst others tap into changing ideas about addiction. One interviewee suggested a related problem to NRT products being too medicinal:

> *"...and maybe products should be more, should I say, dressed. The cigarette you have a package, you get the cigarette out, you need a lighter, you light the cigarette, you suck on it, you fiddle around a bit with things; the patch you take out and put it on and you do nothing for whole day... So, the current products are too naked in a sense and too medical."* (SW-RES-02)

Here, the way in which nicotine products are presented, and the way that consumers interact with them, is important. Another aspect of this 'consumer friendliness', price in comparison to cigarettes, is highlighted in the below quote:

> *"...we also need to ensure that NRT is priced in a way that can make it competitive with cigarettes, and at the moment I am not sure that NRT is priced in a way that makes it comparable to cigarettes."* (UK-POL-17)

Many ideas about the ways NRTs ought to be developed stem from changing understandings of dependence. One expert noted that cigarette dependence is not just about nicotine:

> *"Because NRT is not in any way as dependence forming as the cigarette and tobacco, and there are more things in the tobacco, particularly tobacco smoke, that contribute to dependence than nicotine."* (SW-RES-02)

Whilst another, asked about the most important changes in the way smoking has been understood over the years, highlighted the growing understanding of the complexity of dependence:

> *"...the fact that it is not a simple phenomenon of a chemical that you have in your system and when you don't have it in your system you feel bad so you seek to get it back in your system."* (UK-RES-18)

He went on to suggest that this changing understanding meant that *'we need to think in a more sophisticated way about the kinds of nicotine delivery system that could substitute for smoking'* (UK-RES-18). One particular aspect that he highlighted as important was 'finger tip control':

> *"...the thing about a cigarette is you puff on it at intervals that you decide – you don't get the whole dose of a cigarette in one go – so when people are smoking a cigarette they are deciding how often they want to puff, how deeply they want to inhale, and so on. And because nicotine is operating in a rather narrow window of addressing these issues to do with dependence and pleasure and toxicity – feeling sick and palpitations and so on – the smoker needs to be able to adjust that. So the kinds of nicotine delivery system that we are going to be looking for to*

substitute for cigarettes are going to be ones that give you that finger tip control." (UK-RES-18)

He also explained that recent research has suggested that nicotine is a 'pleasure amplifier', which means if nicotine is associated to a stimulus that is slightly pleasurable it becomes much more pleasurable:

> *"So for smokers the feeling in the lungs, the smell of the tobacco, the cellophane wrapping, all of those things that have an aesthetic appeal, that appeal is being amplified by the nicotine. If that is the case then an acceptable alternative nicotine delivery product is going to have to have other aesthetic features to it, to which nicotine can attach itself to make it attractive."* (UK-RES-18)

It is not just stronger and faster acting nicotine products that are important; nicotine dependence experts also highlight the need to examine the ways smokers interact with cigarettes – the way they control the dose of nicotine; the importance of look, packaging, ritual, ease of use, 'pleasant sensations' – and how this can be translated into better alternative nicotine delivery products.

Stronger/faster is not always better

In many of my interviews, faster and stronger NRT products were seen clearly as better; however in one interview, having discussed consumers perceptions of nicotine, I asked: 'So products that might in some ways be seen as being potentially more effective, there would be worries about how they would be accepted by consumers?' – assuming, from previous discussions, that more effective meant faster and stronger. This assumption was challenged:

> *"I think it depends on what you mean by effective. It is this idea of: what does a consumer want? If they want to quit, they want to be able to stop smoking and they don't want to be taking any treatment after they have gone through their programme. They don't ask specifically for a product that gives a rapid hit. I think there has been a lot of discussion amongst experts about developing a rapid delivery system... that is more like a cigarette. That is not necessarily what a smoker is asking for. They are asking for something that will stop the smoking. It is an academic belief that by giving them something that replaces the nicotine hit; you will be able to get more people to replace cigarettes."* (UK-PHA-16)

Here concerns are raised about whether smokers want faster acting, stronger NRTs. Like issues with 'user compliance', these concerns are linked to discussions about perceptions about nicotine. One pharmaceutical company representative, after discussing consumers' understandings of nicotine, raised some concerns:

> *"If we brought out something that is quite fast acting and gave* [consumers] *the sense of getting a bit of a hit like a cigarette – they might even turn round and say this is not a treatment, this must be highly dangerous because it feels like a cigarette."* (UK-PHA-16)

Indeed, it is difficult to communicate with smokers about stronger products because of these 'misunderstandings':

> *"When you do consumer research it is also very difficult to talk about this in a meaningful way to the consumer. I mean, how do they respond to better efficacy? You can't say that this is a stronger product because if they are already afraid of nicotine, stronger doesn't actually translate into something good, even if we know that if they just take it they would feel the difference. And then it is difficult to have this conversation with the commercial people because they can more easily measure that a cherry flavour is what the consumer wants – they know what a cherry flavour is..."* (SW-PHA-09)

NRT products that are more cigarette-like in their nicotine delivery characteristics also become problematic precisely because of this likeness to cigarettes.

> *"You hear some opinion leaders saying, 'well, arguably the right product' – and they are not in the position of being in a company and looking at having to license things – who would say that arguably, particularly in harm reduction terms, if there is no potential of that kind of misuse from some people, then perhaps it isn't going to be an attractive enough product for the smokers who believe they cannot or will not quit that you want to draw in."* (UK-PHA-07)

Here tension is revealed between academic views on the value of the 'better' product that has been constructed and the pharmaceutical companies' views on this product, which take in issues of the image of the company and licensing a potentially more addictive product.

Despite a growth in interest in the NRT market and harm reduction providing a new way for pharmaceutical companies to look at NRT products, as 'healthcare companies' it is important that the work that they do and the products they produce are seen in a particular way:

> *"I think people like* [Names of pharmaceutical companies] *are healthcare companies and we want to work within a healthcare environment and a healthcare orientation. For us these products are designed to help people stop smoking and that is a medical claim."* (UK-PHA-16)

Whilst greater acceptance of nicotine as an addictive substance has been important in stabilising NRTs, the issue of addiction in relation to company image becomes problematic, as an academic observer notes:

> *"...they* [pure nicotine delivery systems] *are being manufactured by pharmaceutical companies whose ethos is not to produce leisure products but to produce medicines that treat illnesses and they are not necessarily particularly keen to get into the leisure product industry because of course that affects the whole image and the way that people view them."* (UK-RES-18)

A DH representative also raised concerns regarding addiction:

> *"There is an issue I think with NRT products about making available what is potentially an addictive substance... I think compared to other recreational drugs nicotine is not that*

> *exciting is it? But still the potential is there. If you make* NRT *products that... deliver nicotine quickly... you could potentially end up in a situation where people could be addicted to these products and there is a moral dilemma there about whether or not people should be encouraged to use* NRT *if it just means that they will get hooked on these products instead of smoked tobacco. But the argument is probably clear that the majority of the harm from the use of smoked tobacco comes through heart disease, COPD* [chronic obstructive pulmonary disease] *and lung cancer and each of those diseases is caused by consumption of smoke essentially and all the gunk that comes through breathing in smoke of lit tobacco. So you could argue... even if people were addicted to medicinal* NRT, *it is a lot cleaner, there is a lot less risk in being addicted to that compared to using lit tobacco.* (UK-POL-17)

Again, nicotine, an addictive substance, is revealed to be a problematic and unstable actor.

Not just NRTs?

A final shift in the frame of reference that came up when discussing the 'better' product was a widening to include products that are not NRTs. The emphasis on speed of delivery here works to sometimes, for some, include tobacco products as the 'better product':

> *'I think that would be a step forward, basically faster nicotine delivery from the medicines...* [For] *the advocates of snus, that's one key advantage. Not only is it cheaper and its tobacco – lives in a tobacco space – it's that its delivery characteristics are superior in terms of speed and total delivery than the medicines."* (NA-POL-13)

One interviewee felt that smokeless tobacco (particularly *snus*) constituted a 'better' product:

> *'The most important issue for me is not pharmaceutical regulation because I don't think medicalised products will ever eat that far into the market for cigarettes as alternative products. The issue of smokeless tobacco just has to be faced."* (UK-POL-01)

Here smokeless tobacco is 'better' because it is more like cigarettes and therefore a stronger competitor to cigarettes; however, as we saw in the harm reduction debate around *snus* this is also what makes it unacceptable to others.

NRTs and Regulations

Having unpicked problems in the current NRT assemblage and ideas surrounding the 'better' NRT product, I now want to move on to consider what barriers are seen as holding back innovation of these 'new generation' NRT products, and particularly how NRTs interact with regulations.

Asymmetry and regulatory hurdles

Whilst the position of the MHRA is acknowledged to have shifted and they are now considered to be leaders in this area, it is suggested that to some extent an asymmetry still remains. For many interviewees, however, the problem is that tobacco is not controlled strictly enough and far less than 'the least harmful' product:

> *"It is now upside-down when cigarettes are almost – not unregulated, they are regulated also more and more – but they are less regulated at least than the least harmful which are most regulated. So that should turn the world upside-down."* (SW-RES-02)

A pharmaceutical company representative emphasised the standards NRTs must meet:

> *"...we've got to prove that with every puff you would deliver the same amount* [of nicotine] *...cigarettes don't have to prove that because they are not a medicine. And we have to prove purity..."* (UK-PHA-08)

There are various ways that the regulatory hurdles that NRTs have to cross are seen as barriers. The biggest one is the cost of satisfying the requirements for safety and efficacy data:

> *"I think the difficulty with the new products is that the products we develop essentially have medical claims around them: 'this will help you to stop smoking'. They, quite rightly, need to go through a clinical development programme for them to develop the efficacy and safety data in order for them to be licensed and that just costs money. It is a significant investment to develop a new product and to promote these products. The added complexity of launching to a healthcare professional audience and to a consumer audience and to getting widespread retail distribution is actually quite large and costly to the company in terms of not just cash but also resource."* (UK-PHA-16)

This is particularly the case in developing a product that is stronger or faster than existing products:

> *"...if you go outside the current boundaries in terms of more nicotine or faster nicotine delivery, there is an increased burden of documentation that you have to provide. ...if you develop a product that is truly more efficacious, you have to prove that in pretty costly clinical studies. Even if it is very questionable whether you really need to do that – at least show safety from a systemic perspective. But you need to remember that people are coming from the cigarette and they have typically much higher levels of nicotine already."* (SW-PHA-09)

The cost of clinical trials was put into the perspective of nicotine being a generic substance:

> *"Nicotine is not a new chemical entity, it is a generic. Multiple companies have nicotine products on the market. But if you were to go down a completely new treatment route... the products would have to be significantly better to penetrate the NRT market significantly, very, very quickly before someone else would get that it's a good format: let's bring out something of our own. We all have patches and gums etc. There is nothing there that is truly novel and unique that one company has. To make that money back in that market is difficult, and you are making the money back on what is effectively a non-patented or non-protected product.* (UK-PHA-16)

A couple of interviewees suggested that it is difficult for companies to make back the money they invest on NRT products because they are not protected by patents. NRTs, and nicotine as the active ingredient, do not fit well into the network in terms of patent regulations.

The issues with the regulation of NRT products that those within the pharmaceutical industry raise are seen as less problematic by some others. One expert suggested that he thought the MHRA's approach was 'pretty much right':

> *"...nicotine is a potentially toxic drug, if you've got any kind of product... where a person is going to ingest chemicals you've got to do basic safety checks and quality checks to make sure that that product is not dangerous. And at the same time, if you've got a product that claims that it is delivering nicotine as a positive attribute, you've got to make sure that it does deliver nicotine... So I think that it is absolutely right that the MHRA should say to anyone coming up with a new product: I want to see your pharmacokinetic data, I want to see the amount of nicotine that's absorbed and I want to see the rate at which it is absorbed so that we know what we are dealing with, and I want to see you do some basic toxicology to make sure there is nothing else horrible in there. And that's all that they are doing. If you want to make a claim that this is better than some other product then you have to show it – I think that's fair."* (UK-RES-18)

Whilst, when I asked representatives of the MHRA, 'in terms of licensing new products, are there any potential innovations or products that would cause concerns?', they underlined that they are not really thinking about concerns but about encouraging companies to be more innovative. They felt they were very open to 'every which way' in terms of the nicotine delivery systems – anything that more closely mimics cigarettes and might be more effective (UK-POL-19).

The Rules

In discussing the difficulties that regulation creates for the development of new products, the importance and solidity of the regulations or 'the rules' is highlighted by those within the pharmaceutical industry.

> *'Well they don't take a different view on NRT – the rules are the same. NRT, if it is going to be a medicine, then you need to prove safety, efficacy, and there are all the reams and reams of European and UK national medicines law about how you get a product licensed. So those rules are no different from any other product. I think they are often interpreted... very often more pragmatically for NRT. And I would say there is political element to that."* (UK-PHA-08)

This comment both highlights that, as a medicine, NRT is enrolled into a network with set rules; however, the way these rules are interpreted is also identified as important. This separation of rules and interpretation is echoed below in the need for a different,

more pragmatic approach to NRT, again because it is seen as different to other chemical entities:

> *"And I mean it is of course important to emphasise that the regulations are quite clear. I mean it is not difficult to do it; it is just that it costs a lot of money to do it... But I mean it can be done. The regulations, they are applicable to all types of medicinal formulations not only NRT obviously. And I think my point here is that you need to work in a more pragmatic approach when you talk about NRT because it is not like any other new chemical entity that you have to document."* (SW-PHA-09)

Moreover, the positive stance of the MHRA is highlighted, along with their willingness to 'look at the data in a slightly softer way':

> *'The MHRA have been very forward thinking and very supportive and positive at managing the NRT licensing... Them recognising the public health need, us providing substantiating efficacy and safety data and also their willingness to look at the data in a slightly softer way than you would with a brand new chemical entity because these products have been established on the market for such a long time. And the specific public health situation."* (UK-PHA-16)

Whilst the rules are presented as solid and constant, flexibility is introduced by the separation of these rules and the way they are interpreted allowing the particularities of the NRT assemblage to be taken into account. NRT is allowed to perform ambiguously as both typical medicine and unique product.

Going National

One of the ways in which the MHRA is seen as being able to introduce flexibility into the network is through by-passing the centralised European licensing procedures. The EU decentralised procedure causes difficulties in the context of NRT because the indication and labelling requirements (in terms of contraindications and cautions) vary considerably between European medicines regulators. It was suggested that, to bypass this potential barrier, the MHRA encourages national applications for NRT products:

> *"So* [the MHRA] *kind of, let's say, encourage us to go national in the UK... We go national in the UK and we go DCP* [Decentralised Procedure] *elsewhere. The whole idea... with the Decentralised Procedure is of course to have everything common in the union:* [the EU] *don't encourage national applications. So it is really operating in a grey zone, where we are not really allowed to do that."* (SW-PHA-09)

And that whether an application is national or enrols other European regulators shapes their approach:

> *"...it is interesting, when you go and see the MHRA about an application the first question they will often ask you is: is this a national application or do you have any intention of taking it into Europe? And if it is the latter, you know... they become a lot more cautious."* (UK-PHA-08)

The consideration of whether to 'go national' rather than utilise a European procedure, is highlighted as particularly important in terms of harm reduction discussions. A representative of the MHRA also agreed that, since NRT is mostly done by national license, this makes things easier, also suggesting that the interests of public health in the EU is something that has not really been taken up, and that this is an EU and a global problem.

A 'Go'er in the US'

However, it is not only European regulators who have an influence on the network – the situation in the U.S and the attitudes of the US FDA are considered to be very influential, although in quite different ways. Whilst the decisions of the FDA do not impact directly on the behaviour of the MHRA or the ways that NRTs are regulated in the UK, its attitude towards NRT products does impact on the development of new products. The FDA's approach to the regulation of NRT is considered to be stricter than that of the MHRA, as an interviewee with experience of working on NRT in the US said: "*In the US the barriers to getting new forms of NRT approved are very, very high. There continues to be what I regard as an excess concern about both safety and abuse liability.*" He went on to expand on this comment: "*The emphasis is all on concern about any down-side... they have explicitly renounced any sense of comparing the risk of a therapeutic product with the countervailing risk of continued tobacco use.*" (NA-RES-11) These criticisms are echoed in the views of a UK academic:

> "*...the FDA in the US has taken a very... they would see it as cautious and I would see it as reckless view of what nicotine replacement products it would be willing to tolerate – particularly for sales over the counter... So what that means is that because the US is by far the biggest market, the big pharmaceutical companies are not really very strongly emphasised to spend a lot of money developing more efficient and effective nicotine delivery systems that could be a genuine substitute for smoking in the long term.*" (UK-RES-18)

This also has repercussions for the UK market, as several interviewees outline. Since the US is a large market the demands of the FDA carry weight:

> "*They are perhaps, or have been at least, one of the more strict agencies... if we have anything outside the current benchmark we have to document that in a very traditional way: I mean phase three studies. And since the US is one of the bigger markets, that is what we have to do. Of course that is affecting whether we actually venture into a development that is outside the benchmark because that would trigger three studies.*" (SW-PHA-09)

Moreover, companies must consider the whole market when they develop new products:

> "[Our brand of NRT] *is a global brand so when we develop a product it is a global product and of course the US is one of our key markets so, yes, the FDA would certainly*

shape technology and what NPD we were able to go for... To develop a new product, if you are investing in it, it is going to have to be a go'er in North America, in the US particularly, so if the FDA aren't sympathetic that shapes our NPD – our New Products Development" (UK-PHA-08)

A representative of the MHRA suggested that the FDA 'are in a totally different position' from the UK regulator, in that they regulate NRTs as 'new drugs', which puts up certain hurdles, and they also regulate tobacco. She noted that, with the incremental approach that the MHRA have taken, they are able to take a flexible approach to known entities. She also noted that the approach to NRTs has to be logical and science based and that it will not eradicate tobacco or stop people becoming addicted – 'the regulatory framework can't do this' (UK-POL-19).

Regulating the borders: *the grey area*

A final issue I wish to highlight in this section is that of the borders between different types of nicotine products – tobacco/pure, recreational/medicinal. These are undermined and policed in interesting ways. This issue is highlighted particularly, and discussed with vigour, by those in the pharmaceutical industry, particularly in relation to e-cigarettes. It is also brought to the fore by discussions on harm reduction. One representative of the pharmaceutical industry outlined these issues as he saw them:

"We are coming from a strictly regulated situation where we are heavily regulated in what we can do and say and so forth. And the cigarette companies are coming from the totally opposite area with no regulation at all and we are both approaching the area in between, the grey area, with very similar claims for harm reduction, total substitution with safer alternatives, and things like that. And if they can do that without regulation and we can't do it – or we can do it but with the whole burden of documentation and things like that – that is of course a big concern for us. And there is also then other players coming in from totally different areas, or angles, not from the tobacco industry but e-cigarettes, for example, and nicotine water or whatever. And they are – I guess there is even less control over these companies than the tobacco industry... as long as they are not making any medicinal claims, they can sell pure, clean nicotine products and it is quite clear to the consumer that they can use those for the same purpose." (SW-PHA-09)

Another participant suggested that the legislation creating smoke-free public places has played a large part in bringing this issue to the fore:

"And because smoke-free legislation is now a reality here and in so many other places, and it is kind of getting closer in so many places, there is a market opportunity for people making these products that wasn't always there, because now you've got people who can't smoke – they want to keep smoking but they can't smoke in a variety of places – so that is a significant opportunity for these products that wasn't there before. We still feel that a lot of them are making health claims through the back door and getting away with it." (UK-PHA-07)

Whilst in other areas the representatives of pharmaceutical companies felt the relationship with the MHRA was good, they emphasise this area as one where, in the past, their views have diverged significantly:

> *"And they* [the MHRA Borderlines Department] *don't believe nicotine per say is medicinal and they believe claims to encourage smoking cessation are medicinal claims but they don't believe that any other indication is necessarily medicinal. And we disagree fundamentally with that. Our position is that if it has nicotine in and you are putting it out there as some kind of cigarette substitute; you are treating nicotine addiction and that is indisputably a medicinal condition – an adverse condition."* (UK-PHA-08)

Again we see that the claims made are crucial in defining the border between what is and is not medicinal nicotine. It is clear that, for the pharmaceutical companies, the right step would be to regulate all products containing pure nicotine as medicines – this relates again to the self image of the companies:

> *"Our perspective is that, probably because we are coming at this as healthcare companies, we see this as very much medicines and healthcare products to help people obtain improvement in their health which takes us into different regulatory environment that general sales products, which are regulated by consumer standards and those sorts of things."* (UK-PHA-16)

It is argued that the current situation allows some products on the market without meeting relevant safety, efficacy and manufacturing standards; however, it should be noted that the market for pure nicotine products is very much dominated by large powerful pharmaceutical companies. As a representative of a small Swedish NRT manufacturer noted at a meeting with members of the UK tobacco control community, it is difficult for small companies like his to stand up to the big pharmaceutical companies.

Discussion

This exploration of the innovation of new NRT products highlights various areas of instability within the NRT network, as well as the importance of wider connections to the cigarette network, Europe, and the US. Nicotine is again and again revealed as an unstable and problematic actor; its addictiveness is a key stabilising feature in the network but causes great concern for some actors, particularly pharmaceutical companies and the government. Many actors fail to perceive it in the 'correct' way and therefore do not engage with NRT. It does not fit comfortably within networks of pharmaceutical regulation in terms of its connection with a leisure product, cigarettes, and the patenting framework. This chapter raises numerous important questions: who are smokers? What do they want? What would a better NRT product look like? Who should be allowed to produce and sell it? Is it acceptable to maintain addiction with

industry and government backing and NHS finance? Not all actors in the network are answering these questions in the same way, or even asking the same questions.

Chapter Seven: The Future for Nicotine Regulation

Introduction

This final chapter shifts focus from examining the historical evolution and current impacts of the frameworks regulating nicotine products to explore the question: *'Are there alternative approaches to the regulation of nicotine that would be more efficient and effective?'* I move from describing the construction and shape of the networks nicotine regulation is concerned with to a consideration of how these networks might be reshaped. Although the focus of this investigation has been primarily on NRTs, how they are regulated and what impacts this has, it is clear from the previous chapters that any discussion of this area must widen its focus to consider the ways that other nicotine products, particularly tobacco products, are regulated.

As outlined in Chapter one, tobacco and medicinal nicotine are the main categories of nicotine product. Smoked tobacco products are subject to regulation on price (duty and taxes), promotion and the product (yields and additives), as well as rules on health warnings and the minimum age of purchase. Smokeless tobacco products for oral use (that are not chewed) are prohibited. Chewed smokeless tobacco products are regulated in similar ways to smoked tobacco products, although they are exempt from some of the regulations. Medicinal nicotine products are regulated within the medicines regulatory framework which involves strict regulation of the product, place of sale, promotion and price. Various tobacco companies have developed modified cigarette-like devices: these are not yet available in the UK and it is not yet clear how they will be regulated if they are launched. Other novel products that are neither tobacco nor medicinal, such as e-cigarettes and nicotine water currently come under consumer protection regulations.

Tracing nicotine products through time has shown that NRTs have gradually become more firmly enrolled in networks of medical practice with the stabilisation of nicotine addiction and their removal from the black list; however, at the same time as they have become seen as efficacious treatments, they have also been positioned as different from normal medical products and flexibility has been introduced into the way regulations are applied to them. Tobacco products (smoked and smokeless) have gone from circulating freely to being enrolled in first a network of soft law over a period of around 50 years

and, over the last 20 years, have increasingly been controlled by legislation. Whilst non-chewed smokeless tobacco products have been excluded from the network altogether for some time, cigarette-like devices and recreational nicotine products, as more recent actors in the network and neither quite tobacco nor medicine, have an uncertain place.

This may change in the near future. The EC is currently considering revising the tobacco products Directive in five areas:

1. Adjusting the scope of the directive by including further tobacco products and paraphernalia.
2. Changes to the labelling requirements for producers.
3. Introducing reporting and registration requirements and market control fees.
4. Defining the ingredients of tobacco products.
5. Revising the sales arrangements for tobacco products. (Tiessen et al. 2010, p.xxii)

The options they consulted on in late 2010 (DG Sanco 2010) ranged from no change to revising the directive to strengthen product regulation, with the possibility of extending the scope of the directive to include non-regulated nicotine products. Possible changes include mandating/enlarging picture warnings, introducing generic packaging, replacing quantitative labelling with qualitative information on contents, emissions and quit-lines, making reporting formats for product ingredients compulsory, introducing some sort of fees, banning carcinogenic additives, and setting and reduction of maximum yields, setting up an EC laboratory to investigate tobacco and smoking products, harmonising the legal buying age and banning point of sale display (Tiessen et al. 2010). In February 2010, having received an application to expand the use of the *Nicorette* inhalator, the MHRA licensed a 'harm reduction' indication for NRT:

> "...to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and **as a safer alternative to smoking for smokers and those around them.**" (MHRA 2010b, p.5, emphasis mine)

By definition, this shift brought all non-tobacco nicotine products within the regulatory remit of the MHRA. They launched a parallel consultation to address unlicensed nicotine products. The MHRA (2010a) note that because of the regulatory status of these products, it is difficult to get information on quality, safety and efficacy, and the data that are available suggests that acceptable standards are not guaranteed. The three options outlined in their consultation letter are 'whether products containing nicotine should be considered by the Agency to be medicinal products by function and, if so':

1) 'whether all unlicensed NCPs [*Nicotine-Containing Products*] should be removed from the market within 21 days', or

2) 'a notice should be issued to manufacturers that all marketing must cease by a certain date', or

3) 'do nothing and allow these unregulated products containing nicotine that have not been assessed for safety, quality and efficacy to remain on the market'. (MHRA 2010a, p.5)

They note that their 'preferred option is option one, which is in line with current practice' (MHRA 2010a).

Discourses on tobacco and nicotine regulation

Tobacco product regulation

Controlling tobacco products has been on the public health agenda since the RCP made their recommendations in *Smoking and Health* (1962). The areas selected for control were the sale of tobacco to children, tobacco advertising, and smoking in public places as well as price increases through taxation. As has been described, the age at which one can buy tobacco, how tobacco products are promoted, how tobacco is priced and where smoking is allowed have remained key areas of activity and have come under legal control. As with harm reduction, as the network stabilised around the concept of nicotine addiction, the regulatory situation for tobacco products themselves has become increasingly of interest in tobacco control. Over the last decade, articles have appeared in tobacco control and public health journals commenting on the problem of regulation and proposing solutions (e.g. Britton & Edwards 2008; McNeill et al. 2001; Sweanor 2000), whilst reports from a number of influential bodies have tackled this problem, e.g. the RCP (2000, 2002, 2007, 2008), WHO (2000) and the US Institute of Medicine (2001). Work is ongoing on guidelines for Articles 9 and 10 of the FCTC, which concern regulation of the contents of tobacco products and tobacco product disclosures. There has been an increased focus on the regulation of the product itself as well as discussion about the broader regulatory strategy for tobacco.

One argument that runs through most of these discussions is that cigarettes are not regulated strongly enough in light of the health risks they pose (to both smokers and non smokers) and their impact on public health, as well as health inequalities. The use of 'soft law' – particularly voluntary agreements – is seen as an unsuccessful strategy. As the UK Health Select Committee suggested after an investigation into smoking and health during the 1999-2000 session:

> "It seemed astonishing to us that, almost 50 years after Government recognised the dangers inherent in smoking, tobacco products remained on sale in a remarkably unregulated fashion". (2000, p.xvi)

The nature of tobacco as a product was also highlighted:

> "We believe that the extraordinarily dangerous nature of the product being marketed means that tobacco companies cannot expect to operate in the same commercial environment as most other industries." (House of Commons Health Committee 2000, p.xiv)

Comparisons are made to other consumer products (such as food, medicines and vehicles), and the regulations that are applied to these products to protect the people who use them from the undue risk of harm:

> "Tobacco products have enjoyed an unprecedented degree of freedom from the safety regulations that apply to virtually every other food or drug product available in Britain" (RCP 2000, p.186).

The WHO has also compared tobacco regulation to that of other consumer products, highlighting the way tobacco deviates from the normal purposes of this type of regulation:

> "Regulation of consumer products including medications, manufactured food products, beverages, household devices, and automobiles, share at least two common purposes: one is to facilitate fair commercial trade and marketing, the second is to protect people from undue risk of harm caused by the products... It has become increasingly apparent that the regulation of tobacco products is severely deficient. It has fostered trade and marketing practices that would not be allowed for other products and led to the development of products that are harmful." (2000, p.59)

Despite the EU product and advertising Directives these issues are still highlighted as problematic: "...no other industry from nicotine replacement therapy to toothpaste manufacturers is allowed the regulatory anarchy enjoyed today by the tobacco industry." (Gray 2006, p.145)

The question of how best to regulate the tobacco products themselves (in terms of content, design and emissions) remains problematic. As described in Chapter five, EU Directives were introduced in 1989 and 1992 legislating on warnings and product labelling based on the advice of a high-level cancer-expert committee. The committee advised controlling additives, reducing tar and nicotine content, and strengthening labelling requirements. These recommendations were criticised for focussing on 'further reductions in tar and nicotine yields as measured by the International Standards Organisation/Federal Trade Commission method' [smoking machine measured yields], which 'will be largely cosmetic and certainly misleading to consumers' (Bates et al.

1999). In particular, the method for controlling additives and whether the level of nicotine ought to be lowered were questioned – echoing disagreements between the ISCSH and the ARU in the 1980s (Chapter four). In 2001 EU legislation was introduced concerning the manufacture, presentation and sale of tobacco products (Chapter five). A review of the implementation of the Directive commissioned by ASH (McNeill et al. 2004) critiqued the use of the International Organization for Standardization method as well as the use of the word 'tar'[67], arguing that 'there is an urgent need to put in place a comprehensive framework for regulating the harmfulness of tobacco products' (2004, p.4). It highlighted the need for compliance with ingredient disclosure, measuring of emissions when the product is used by consumers, exposure of users and non-users to toxicants, monitoring of dependence potential, disease risks and population impact. The International Organization for Standardization test method and the display of yields of tar and nicotine on packs are generally agreed to have been discredited, but are proving difficult to rescind despite consensus within the tobacco control community. This is one of the issues that was considered in the recent EC consultation on the Directive.

In the quote below the RCP reflect on progress in tobacco product regulation:

> "Nicotine regulation in the UK has so far mainly served the interests of the tobacco industry rather than those of public health. Low tar cigarettes, additives and health warnings have all been turned to the industry's advantage, despite the best intentions of government. The voluntary agreement approach has been discredited. European directives were a step forward in that they were mandatory, but they were built on measures such as the FTC/ISO *[Federal Trace Commission/ International Organization for Standardization]* test, which is now known to be crucially flawed as a guide to cigarette toxicity." (RCP 2000, p.170)

There is a strong feeling in the tobacco control community that attempts at product regulation have been undermined. Gray and Kozlowski, in a review of the regulation of tobacco smoke, highlight some key questions for tobacco product regulation:

> "Should limits for carcinogens and toxins be set as low as possible? Can it possibly be justified to add, or allow, higher levels of carcinogens for 'flavour' or other purposes? ...Should the dose [of nicotine] per cigarette be standardised as far as is practicable? Should the nicotine dose be 'satisfying' without the need for deep and frequent inhalation, which brings with it a larger dose of contaminants? If a 'satisfying' dose is to be delivered, how should this be measured for regulatory purposes? How should the dose be measured (and communicated) for consumer purposes? Should additives be allowed without testing for toxicity in both burnt

[67] "Tar is not a homogeneous substance. Instead there should be a focus on particular constituents of tobacco and tobacco smoke." (2004, p.4)

> and un-burnt form? Should each additive be justified on public health grounds?..." (2003, p.354)

Their discussion underlines the complexity of regulating in this area. A key problem that arises is lack of knowledge about tobacco products outside industry (in areas such as drug bioavailability, toxicology, performance of drug delivery testing). The FCTC considers product regulation in Articles 9 and 10. A working group was set up by the first session of the Conference of the Parties in 2006 to develop guidelines on these Articles; however this has been a complex and contested process. A briefing paper by the Framework Convention Alliance in 2007 highlights some of the key issues, suggesting that: 'considerable work is required before the public health benefits of implementing Articles 9 and 10 become clear'. They note that:

> "It is not yet understood how tobacco products can best be regulated to reduce the harm they cause. For example, there are no existing regulations or scientific consensus on measures that result in significant reductions in the health risks of inhaling cigarette smoke or in the addictiveness of cigarettes." (Framework Convention Alliance 2007, p.5)

It also highlights the resources required for this undertaking and the opportunity costs in diverting resources away from other strategies (Article 11 on packaging and labelling is particularly highlighted as a greater priority). Nevertheless, Article 9 and 10 guidelines on restricting or prohibiting flavourings were adopted at the fourth Conference of the Parties in November 2010 and the working group on these guidelines has been mandated to move on to examine addictiveness and toxicity.

The profitability and harm nexus

Various, more radical, approaches have been proposed for regulating tobacco. One strand of these focuses on the nature of the tobacco industry and what role it ought to be allowed within the network. I focus here on three papers by Jonathan Liberman (2003), Ron Borland (2003), and Cynthia Callard and colleagues (2005). These authors locate the central problem in the 'nexus between profit and causing of harm', as Liberman puts it:

> "For all the debate that has raged about tobacco and the tobacco industry and how they should be regulated, one constant appears to have been left peculiarly unchallenged. That is that the tobacco industry should be left to operate in circumstances where, subject to certain specified legislative restrictions upon its conduct, the more products it is able to sell, the more people it addicts and kills, the more money it makes." (2003, p.463)

Callard et al (2005) note that the tobacco control strategies supported by the WHO, the World Bank, and codified in the FCTC 'are principally aimed at reducing the demand for tobacco', underlining the need to address:

> "...the problems caused by the supply of cigarettes being managed by business corporations which are designed, built, managed, governed, and mandated to maximise profits, and which are programmed to continue to maximise profits even when doing so may result in human harm." (Callard et al. 2005, p.279)

These approaches suggest that instead of seeing the tobacco industry's behaviour as wrong, immoral and unethical, it ought to be viewed as the rational, calculated and profit-motivated behaviour of a business corporation.

The three papers suggest different solutions to this problem. Liberman (2003) underlines the need to structure a regulatory system where the incentive is to contribute to the reduction of harm. He suggests an: "...agency with responsibility for ensuring that products are made available to users but... in circumstances where all operating forces and influences are moving, as far as possible, towards the minimization of harm" (2003, p.466). Following on from these arguments, Borland (2003) proposes a 'regulated market model' where marketing of tobacco products is controlled by a 'monopsonistic' Tobacco Products Agency with a charter to service the existing market but shape it to reduce harm. In this model, licensed manufacturers would tender for market share to the agency which would control wholesale distribution to retailers, and particularly the marketing of products. Liberman envisages an agency with the capacity to withdraw or discourage use of more harmful products, control additives and set standards for toxic compounds, acting like the 'ideal informed consumer' and incentivising manufacturers to create less harmful products. Callard et al (2005), on the other hand, suggest that business corporations are the wrong entities to supply tobacco and that other forms of business institutions that are not necessarily designed to maximise share holder value and profits – e.g. partnerships, publicly owned enterprises, private non-profit enterprises or cooperatives – ought to used. They suggest that a public interest manufacturer, with structures that enable and compel it to reduce tobacco use, would be able to undertake initiatives such as plain packaging and designing their cigarettes in ways that reduce attractiveness and addictiveness. In a similar vein, Gilmore et al (2010) argue that gradual increases in specific taxes have had the unintended consequence of benefiting major cigarette manufacturers by enabling them to subtly increase their prices and,

therefore, profits. They suggest a system of price cap regulation as a solution to this concentration of market power, which caps manufacturers prices but not price at retail.

From tobacco to nicotine delivery devices

A further important shift in discussions within the tobacco control community about regulation has been from a focus on tobacco regulation to the regulation of nicotine. The key concept that these discussions centre around is 'regulatory imbalance'. As with harm reduction, the starting point is that nicotine is the addictive but not the harmful component of tobacco. A report from a meeting convened by the Health Education Authority was one of the first to outline this perspective on regulation (see also Warner et al. 1997). It focussed on 'nicotine delivery devices', suggesting that '...we should draw a distinction between the delivery device – cigarettes/other tobacco products – and the drug delivered – nicotine' (Raw 1997, p.3). Raw (1997) notes that product regulation could be a significant additional strategy for reducing disease if the premise that some nicotine users will not give up is accepted; further, that the tobacco industry is experimenting with 'low/no smoke products' and that there is a need to decide how to regulate such products. In their report on nicotine addiction the RCP outlined similar issues:

> "Tobacco products, particularly cigarettes, are an exceedingly 'dirty' delivery system for nicotine. The existing regulatory structures give huge market-place advantages to tobacco products, effectively creating a 'nicotine maintenance monopoly." (RCP 2000, p.171)

The idea of regulatory imbalance enrols the *nicotine addiction* and *harm reduction* assemblages; it suggests that we construct a category of things, products used to get nicotine, and prioritise their relative harm in order to distinguish between them.

Replacing tobacco regulation with nicotine regulation leads to the comparison of the regulations for cigarettes and NRTs (and sometimes novel products and *snus*), and highlights that the current regulatory situation regulates the least harmful nicotine product most strictly. As one interviewee pointed out:

> *"We have given the greatest latitude to the most hazardous delivery system and we treat delivery systems entirely differently whether they are tobacco or something else. So you have the insanity of greatly restricting or banning the least hazardous delivery systems and leaving the most hazardous delivery system as a de facto nicotine maintenance monopoly."* (NA-POL-10)

The RCP also highlight this issue in their report on *Harm Reduction*, focussing on the difference in hazard levels:

> "Overall, combustible tobacco products are the least regulated and medicinal nicotine products are the most highly regulated. Given the huge differences in the proven or likely hazards of these products to individual and public health, this represents a substantial and illogical regulatory imbalance." (RCP 2007, p.180)

As in harm reduction debates, harmfulness and addictiveness become the most important attributes of products.

Levelling the playing field

This regulatory imbalance necessitates a new approach to the regulation of nicotine, a more liberalised approach for some products as one interviewee suggested:

> *"Always the starting point for me is that the dominant form of nicotine delivery is the most harmful and most unregulated and therefore you have a reasonably strong argument for a much more liberalised approach for those forms which might be useful for cutting down or quitting."* (UK-POL-01)

The solution outlined for this problem of regulatory imbalance is often referred to as the need for a 'level playing field' for all nicotine products.

> "A common thread [in proposals for more effective regulation of nicotine] is the recognition of the need to level the regulatory playing field, as between consumer and pharmaceutical nicotine products, as well as the need to ensure that the future market for nicotine does not continue to be dominated by the most contaminated product, the cigarette ." (WHO SACTob 2002, p.2)

To level the playing field it is suggested that the product demonstrated to be most harmful to health (the cigarette) ought to be regulated most strictly, whilst the product demonstrated to be least harmful to health (medicinal nicotine) ought to be regulated least strictly:

> "A more rational regulatory approach might be to advantage less toxic products, instead of honoring accidents of history, as at present. All currently available nicotine-delivery devices would continue to be sold, but the least toxic would be the most easily available and attractively presented." (Warner et al. 1997, p.1093)

Levelling the playing field involves applying the 'continuum of risk' to the products regulated, an approach that again involves organising actors by harmfulness, and making the least harmful most attractive to consumers.

A nicotine regulatory authority

One tool for 'levelling the playing field', that has gained a great deal of support within the tobacco control community in the UK, is establishing a 'nicotine regulatory authority'. For example Raw suggests that:

> "What is really needed is a regulatory framework for all nicotine delivery systems, which would eventually make it possible to minimise harm by encouraging the

> production and marketing of less harmful forms of nicotine. A **Nicotine Regulation Authority** (NRA)." (1997, p.8, emphasis in original)

The RCP recommended that all nicotine products be brought under the same agency in their 2000 report (2000). The Health Select Committee report of 2000 'concurred' with this recommendation, although they suggested a tobacco rather than a nicotine regulatory authority. The RCP have underlined their support for this idea in several recent publications (2002, 2007, 2008). They have suggested four approaches that could be used to do this: move existing functions to a new agency, as with the formation of the MHRA: introduce new enabling legislation and powers to create a new agency, as with the formation of the Food Standards Agency; add tobacco regulation to the mandate of an existing body, e.g. the Food Standards Agency or the MHRA; re-examination of existing legislation to create specific powers to regulate tobacco, e.g. the Consumer Protection Act 1987 or the General Product Safety Regulations 1994 (RCP 2002).

A number of articles by academics prominent in tobacco control have appeared in health journals advocating this approach (e.g. Britton & McNeill 2001; Gilmore et al. 2008; Martinet et al. 2006; West 2000). For example John Britton and Ann McNeill argue that:

> To meet the needs of the estimated 13 million current smokers in Britain, many of whom will never overcome their nicotine addiction, we also need legislation that explicitly encourages the development of alternative products that can deliver uncontaminated nicotine at a dose and rate comparable with cigarettes and in a way that is commercially and socially acceptable... Achieving this, while maintaining reasonable safeguards for consumers and society, is not feasible within current legislation on the development, marketing, and distribution of new nicotine products. We need a single regulatory authority to take responsibility for all nicotine products and establish a regulatory balance that favours clean nicotine delivery devices over cigarettes and other tobacco combustion products. (2001, p.1078)

However, problems are raised with the concept of a nicotine regulatory authority. One interviewee highlighted the importance of the remit and powers given to a nicotine regulatory authority:

> *"...of course it's not THE solution because you could have a nicotine regulatory authority and have it do absolutely fuck all. That's what's happened in Canada. They have a legal regulatory framework, and, you know, you would be hard pressed to see anything useful coming out of it. They gather shed-loads of data and information, which they don't quite know what to do with. And they've not been at all innovative and they don't have a strategic vision. So the actual remit of any regulatory authority will be crucial, and it's powers. And I suspect it will always be the case that it will need political support to get any*

kind of strategic vision realised. So the fear with regulation is that it can lead to stasis rather than change. (UK-RES-06)

A representative of the DH felt that setting up a new agency was a politically unpopular idea:

> *"I don't think that it would be practical to be setting up a new agency in today's economic and political climate, especially a new agency that would have such a narrow remit, is my personal opinion. And of course we have seen the RCP have made calls for setting up such an authority and it is not an idea that has won political favour."* (UK-POL-17)

Two major issues are raised here: that the impact of a nicotine regulatory authority would not in itself change a great deal but would depend on the remit it is given and the resources and powers at its disposal; furthermore, that a great deal of resources and energy would be required to set up and run a new agency and this does not make it an idea that is appealing politically. Becker's (1963) writing on moral entrepreneurs reveals another potential concern to setting up a new regulatory agency. He suggests that organisations devoted to the enforcement of rules need to both justify the existence of their position and win the respect of those they deal with. He goes on to outline an important problem with the former:

> In justifying the existence of his position, the rule enforcer faces a double problem. On the one hand, he must demonstrate to others that problem still exists: the rules he is supposed to enforce have some point, because infractions occur. On the other hand, he must show that is attempts at enforcement are effective and worthwhile, that the evil he is supposed to deal with is in fact being dealt with adequately." (1963, p.157)

The important point here is that a regulatory agency has a stake in the continuance of the problem they control, in this case the use of nicotine, and an interest in managing rather than eliminating the problem.

What a 'level playing field' might look like varies by who is visualising it. Some, in particular the pharmaceutical industry, envisage a level playing field for all pure nicotine products, with tobacco excluded and all other actors (i.e. e-cigarettes) submitting to the regulatory demands that the pharmaceutical industry are subject to. Representatives of the pharmaceutical industry were not supportive of the idea of an authority regulating both tobacco and NRT, as one said: '*how can you regulate the cure and the poison at the same time?*' (UK-PHA-08) In arguing for the separation of tobacco and pure nicotine products, the medical nature of pure nicotine products was emphasised:

> *"We see this as very much medicines and healthcare products to help people obtain improvement in their health which takes us into different regulatory environment than general sales products."* (UK-PHA-16)

From this viewpoint, pure nicotine products should obviously come under the jurisdiction of medicines regulators: *"Anything that has nicotine in it or claims to have nicotine in it, to my mind, should come under their aegis"* (UK-RES-18). For others this is a strategy to enrol support:

> *"I think the strategy, the sort of cautious incremental strategy that Deborah* [Arnott, Director of ASH] *is pursuing is probably, politically, the wise one. That is likely to start off with ...if they become available, the more effective nicotine things being prescribed. My personal view is in the long term it probably wants to be a market-led thing rather than medically driven ...You want consumer nicotine products that will compete in the marketplace, that will sell and sell ...that gets people absolutely apoplectic at the thought of it.*
>
> Int.: So this is taking in smokeless?
>
> *I am a bit sceptical that it can all be contained within a medically driven prescription market. I don't think that is the way that smokers in millions are going to be won over."* (UK-RES-06)

In the previous government's recent tobacco strategy, the DH embraced the idea of a level playing field but only for pure nicotine products:

> "To create a level playing field the MHRA will consult on regulating all nicotine-containing products (with the exception of tobacco products, which are governed through specific legislation)." (DH 2010a, p.12)

As noted above, the MHRA is currently consulting on the regulation of pure nicotine products.

A concern that underlies all of these discussions on the regulation of tobacco/nicotine products is the role of the tobacco industry. The tobacco industry have historically challenged and delayed attempts to control their activity:

> "One persistent element common to both Canadian and U.S. attempts to regulate the tobacco industry is that, regardless of the action taken, the industry has challenged the government's action in court, thereby delaying, and sometimes preventing, implementation for many years. Consequently, regulation in both countries has taken significant periods of time to accomplish. As a result, federal regulators in both countries have increasingly premised their regulatory action on extraordinarily complete research and investigations in order to increase their chances of prevailing in court." (WHO 2000, p.90)

It is suggested that this has had an effect on the evidence deemed necessary to justify regulatory intervention. The industry has most commonly opposed product regulation on the grounds of trade secrets and intellectual property rights. That the industry cannot be trusted or worked with is a common and strongly held belief for many of those in tobacco control:

> *"The tobacco industry has already demonstrated itself to have a single minded pursuit of what it is supposed to do for its shareholders, which is maximise profits, and if that means killing*

large numbers of people it's willing to do that and it does do that. The tobacco industry has also shown itself to be completely duplicitous and to lie about issues and to pretend that it is doing one thing and it is actually doing something else." (UK-RES-18)

Suspicion about tobacco industry motives and a belief in the need to exclude tobacco companies from the process underlie discussions about regulation within the tobacco control community. Moreover, the FCTC codifies the exclusion of tobacco industry from public health policy making in Article 5.3:

> "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law." (WHO 2005, p.7)

The guidelines to this article (WHO 2008a) crystallise this as an obligation on Parties to protect public health policies with respect to tobacco control from the commercial and vested interests of the tobacco industry and, in particular, include the principle that 'there is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests' and the recommendation to 'reject partnerships and non-binding or non-enforceable agreements with the tobacco industry' (WHO 2008a). A further potential problem that is raised is that regulation could give tobacco companies legitimacy.

Underlying many of these debates is the issue of prohibition. One interviewee pointed out the 'contradiction in the middle of it all', that if invented today cigarettes would not be allowed on the market:

> *'There is of course a complete contradiction in that middle of it all, which is that if there was no such thing as cigarettes and if somebody discovered it and came along and said to a regulator: 'I want to market this stuff, it's wonderful, it gives people a high, happens to kill half of them, but we may as well make a profit in the mean time' – who would ever allow it to be marketed? The answer is no one. So my problem is that if you campaign, as we do in the tobacco control movement, for the proper regulation of tobacco itself – what do we mean by that? The logic is that we would ban it. You can't regulate it in the sense of making it safe because there is no such thing as a safe cigarette. So you are asking for authority to regulate a product without knowing meaningfully what we would do if we got that authority."* (UK-POL-20)

This touches on two issues that are not always explicitly discussed within tobacco control debates on regulation: what the aim of regulation is and the possibility of banning the sale of tobacco. Some commentators, however, do raise these issues. Liberman, for example states that he is 'explicitly rejecting the prohibition of use of tobacco as a regulatory alternative' (2003, p.465). He argues that depriving addicts of nicotine is morally problematic and that prohibition would result in 'significant levels of

illicit use and, therefore, in all likelihood, in additional forms of harm to society – through transforming tobacco into a law and order issue' (2003, p.465).

Imagining regulatory futures; building regulatory networks

It is suggested, in the context of scientific and technological innovation, that the generation of expectations and imagining of futures is performative. Brown and Michael (2003) state that there is a need, in analysing futures, to 'shift the analytical angle from looking into the future to looking at the future, or how the future is mobilized in real time to marshal resources, coordinate activities and manage uncertainty' (2003, p.4). The important point here is the emphasis on looking at how representations of the future are mobilised: how they are used and what they do. They are 'potent resources in constituting the present and the future' (N. Brown & Michael 2003, p.7), as Hedgecoe and Martin outline:

> "Expectation statements are a resource for actors involved in innovation, in that they can help to: legitimize, justify, back their arguments, give reasons in general; mobilize funds, attention of other actors; allow decision-making and reduce the uncertainty inherent in technological developments." (2003, p.330)

Brown and Michael go on to say that, as resources, futures are 'also highly unreliable – the past is littered with failed futures' (2003, p.7); imagined futures can only be realised if practical and material elements 'play along'. Moreover, futures are mobilised to facilitate building some technoscientific worlds and impede others; to include some actors and exclude others:

> "Constructions of the future are aimed at 'making' a particular present (in the sense of persuading other actors to align themselves with that future in the present by, for example, investing venture capital, or easing regulatory conditions, or contributing relevant knowledge), which facilitates the 'fruition' of that particular future." (Rosengarten & Michael 2009, p.1050)

Similarly, Hedgecoe and Martin suggest that, in building coalitions around particular futures:

> "The manner in which each group problematizes different technical options, and the extent to which their support can be enrolled, will ultimately decide the fate of a particular vision. If a key actor cannot be 'won over' then that vision will have great difficulty being successfully translated into material and social reality." (2003, p.356)

As for networks more generally, key actors must be enrolled in a particular future-vision for it to be translated into material reality.

Considering the discourses on regulation I have outlined, it is clear that, even within the tobacco control community, different futures are being presented, which involve different rearrangements of the actors within the network. There are some common elements within these visions: that more control over tobacco products is needed; that legal instruments should be introduced as opposed to 'soft law'; that tobacco industry involvement in building networks of control in the past has been unhelpful; that tobacco companies should be excluded from building future regulatory networks, as required by the FCTC. Past attempts to un-black box and stabilise the cigarette, and particularly cigarette smoke, have been problematic, which leads to difficulty in envisaging a coherent framework to regulate the content of cigarettes: which constituents of cigarette smoke are the most harmful? How much of these substances are acceptable? How can the amount of these substances that is inhaled be tested? What impact does changing the levels of these constituents have on health? Is the aim to reduce addiction, attractiveness or harm? Any expertise the tobacco industry might have in these matters is viewed with suspicion. One approach problematises the tobacco industry, suggesting that the problem lies in the orientation of business corporations to the maximisation of profit and proposing that the tobacco industry either not be allowed to market (envisaging instead a new actor – a 'Tobacco Products Agency') or sell (envisaging translating tobacco companies into different forms of business institution) tobacco. These approaches have enrolled little support, perhaps because their vision of radically reshaping the network appeals to few other actors.

A different approach, more widespread within the UK tobacco control community, problematises the object of regulatory discussions, suggesting that the problem is not one of tobacco product regulation but of regulatory imbalance between different categories of nicotine delivery device. Here the solution proposed is to have one actor regulating all nicotine products: either by extending the remit of an existing agency (the MHRA, the Food Standards Agency) or creating a new agency. Whilst a new agency is popular within the tobacco control community, it has proved difficult to mobilise other key actors (i.e. the MHRA, the DH, pharmaceutical companies) around this future-vision. Many actors are invested in the medicine/tobacco divide. For current regulatory agencies a new, challenging area of responsibility is not desirable. Again, this future requires major reshaping of the network and investment of resources.

Having outlined the main debates on tobacco/nicotine regulation within the tobacco control community, I will now consider current scholarship on regulation to compare how these two bodies of work tackle similar issues and how regulation scholarship might contribute to discussions of regulation within tobacco control.

Contemporary scholarship on regulation

Explaining regulation

One encounters the study of regulation at the boundary of a variety of disciplines with the larger contributions coming from public law, economics and political science, and some sociological input (Baldwin & Cave 1999). Regulation has come to constitute a field of study in its own right, which draws on and merges with wider areas such as the study of the changing nature and role of the state; governance, governmentality and control; risk and conceptions of modernity. The growth in the study of regulation can be linked to changes in modes of state government and the relationship between the public and private spheres that emerged from the US, with government through regulation becoming widespread particularly from the 1980s. This new form of government is often referred to as the 'regulatory state', a shift from the 'welfare state' (Scott 2004), and is described as the idea that '...a new institutional and policy style has emerged, in which government's role as regulator advances while its role as a direct employer or property-owner may decline through privatization and bureaucratic downsizing' (Hood et al. 2001, p.4). Moran (2002) notes that the US 'virtually invented the modern regulatory state' and correspondingly the first and largest literatures around regulation originated there.

Moran (2002) suggests that the US literature has been concentrated around two main agendas. First, the problem of regulatory 'capture': or whether regulatory agencies are properly independent from those they regulate. The second agenda is concerned with the purpose of and justification for regulation. It focuses on regulatory failure due to an over-reliance on 'command' styles of regulation – 'regulation by the state through the use of legal rules backed by sanctions' (Black 2002a, p.2) – and legal formalism – 'the use of clearly defined, highly administrable rules, an emphasis on uniformity, consistency and predictability, on the legal form of transactions and relationships and on literal interpretation' (McBarnet & Whelan 1991, p.849). A key issue is how to overcome this failure, with debates over regulation vs. deregulation. Moran (2002) underlines the

linkages between theories of regulation and the national context from which they emerge, suggesting that the British literature has been more concerned with the 'travails' of self-regulation. More broadly, it has been suggested that scholarship on regulation has tended to focus on two main discussions which explore the 'natural history of regulation' and the 'various species of regulation' (in the words of Baldwin et al. 1998; see also Morgan & Yeung 2007). Along with, and bound up in, these two major issues are other questions relating to the definition of regulation, reasons for using regulation and how best to regulate.

A large volume of writing has occupied itself with explaining and theorising the emergence, shifts in and decline of regulation in a variety of contexts. Theories can also be typified as to whether they differentiate between the public and private sphere and whether they are economically or more broadly politically based. It is common to classify these theories into three main groups according to their main explanatory mechanism as either focussing on public interest, interest groups or institutions/systems (Baldwin et al. 1998; Morgan & Yeung 2007). Public interest theories see regulation emerging as a way of securing collective goals for a community. These more traditional accounts see regulation as driven by market failures and carried out according to the nature of the task in hand by disinterested actors engaged in the pursuit of the public interest. Critiques by 'interest group' theorists underlined that the observed effects of regulatory systems were consistent with capture by powerful economic interests and suggested that regulation arises from conflict between different interest groups pursuing their own ends. Institution or system based approaches see regulation as arising from relationships between and within systems, with the public and private spheres more interrelated. Public interest theories have been criticised for being too idealistic, with no feeling of interplay between different groups with different goals or power relations, whilst private interest theories are said to lack a notion of public interest and have an over-simplistic explanatory mechanism (i.e. actors or groups rationally pursuing self-interest).

Examples of the third type of approach, characterised by a focus on the role of institutions and systems, include ideas about regulatory space, cultures and regimes. Hancher and Moran (1989) introduced the concept of 'regulatory space' into their work to address what they see as a lack of comparative work and underdeveloped middle

range theory. They find previous work, in which public authority is seen as controlling private interests, problematic for its assumption that private influence over the regulatory process is illegitimate. At the centre of their analysis is the point that in advanced capitalist societies economic regulation is dominated by relations between 'large, sophisticated and administratively complex organizations performing wide-ranging economic and social tasks' (Hancher & Moran 1989, p.272), against a background of extensive state intervention and increasing mixing of public and private. It is, therefore, necessary for analysis to understand the nature of the space shared by different actors and its political, legal and cultural attributes. Hancher and Moran (1989) emphasise that power – who is included in and excluded from regulatory space – is at the centre of the process. This type of approach tends to produce detailed analyses of particular contexts as opposed to a general theory of regulation. Their ideas have been criticised for their broad definition of regulation and lack of attention to the role of law (Daintith 1989).

As with regulatory space, studies of 'governmentality' (see for example P. Miller & Rose 1990; Rose 1999), drawing on Foucault's ideas about government as techniques and procedures for directing human behaviour (Rose et al. 2006), also see power as central to an analysis of regulation. Analyses which draw on Foucauldian ideas have been one of the key approaches to the British regulatory state (Moran 2002; Scott 2004). In general, in understanding regulation there is a move away from the centrality of law and the state to an emphasis on the 'disparate practices and technologies that control and govern in contemporary states' (Scott 2004, p.10), with law as one tactic amongst many. In this approach power is seen as diffuse as opposed to centralised and alternate sources of power such as professional expertise are emphasised. Further, attention is paid to the historical origins of regulatory structures. Miller and Rose focus on the role of language in their exploration of governmentality, suggesting that, as an 'intellectual technology', language renders reality thinkable and 'amenable to certain kinds of action' (1990, p.7). Moran (2002) notes that regulation is seen as a project that involves the reconstruction of social understanding so that effective systems of control are those that entail the internalisation of control norms. Scott points out that:

> "The governmentality literature is less strong, perhaps less interested, in suggesting how this reconception of ordering might be deployed in future regulatory policy... It is a literature which is at its most effective in reformulating our understanding through the analysis of the micro-detail of particular social and institutional practices." (Scott 2004, p.12)

With their focus on examining the context in which actors involved in regulation interact and are included or excluded, and the multiplicity of regulatory practises and technologies, these approaches point in the direction of an approach to regulation compatible with ANT.

Several authors (for example: Baldwin & Cave 1999; Braithwaite & Drahos 2000; M. Clarke 2000; Moran 2002) suggest that risk is central to discussing regulation. Risk has a key place in the literature on governmentality, in which it is understood as a particular way in which problems are conceptualised and managed (Rose et al. 2006). In contrast, Beck's influential work on the 'risk society' (1992) proposes that the scientific and technological developments in modern industrial society have created a new type of risk – global, collective and unpredictable – that leads to demands for regulation. Clarke's (2000) analysis of 'regulatory society' sees risk as both addressed and caused by business. He argues that there is the tendency for more and more areas of life, especially economic and business life, to be regulated – the 'rise of the regulatory society' – and that this trend appears set to continue. There is, therefore, a need for business to engage with regulation rather than denying the problem, and the 'service oriented and ethical side of business' ought to be built upon. Clarke (2000) also notes the need to manage populations' expectations of what to expect from regulation: "Regulation regulates, that is, it moderates and brings matters to explicit attention that were neglected; it does not, in the majority of cases, eliminate the problem" (2000, p.231).

In contrast, Hood's (1998) analysis of public management draws on Mary Douglas' anthropological typology of grid/group theory to suggest that risk is a cultural construction. He argues that the plurality of possible ways of regulating are rooted in two fundamental dimensions of human organisation, 'grid' and 'group':

> "'Grid' denotes the degree to which our lives are circumscribed by conventions or rules, reducing the area of life that is open to individual negotiation...'Group', by contrast, denotes the extent to which individual choice is constrained by group choice, by binding the individual into a collective body." (Hood 1998, p.8)

He goes on to outline four generic types of control and regulation which are linked to different views of what keeps groups together and what constitutes good government. His approach, like Foucauldian analyses, introduces a broader historical context to explore the underlying patterns of control and regulation. Moran (2002) suggests that this cultural approach to regulation is valuable in that it opens up the 'black-box' of

regulation with its focus on organisation rituals; however it neglects the political environment in which regulation occurs.

Hood et al (2001) also consider risk with their concept of 'risk regulation regimes', which bears some similarity to 'regulatory space' (Hancher & Moran 1989). They define these regimes as a 'complex of institutional geography, rules, practice and animating ideas that are associated with a particular risk or hazard' (Hood et al. 2001, p.9). This again moves away from notions of public/private interests to consider context and process. The idea of risk regulation regimes is used to analyse the variety of risks chosen for regulation and the way regulation works within and between states. They suggest this enables them to move beyond generalising principles (such as that of Beck's 'risk society' and Hood's 'grid-group') to a more 'meso-level' analysis that looks at the variation between one domain and another. Theirs is a type of institutional approach which focuses on, 'rules, conventions and organisations'. The highlighting of risk described in the preceding conceptualisations of regulation points to the important of considering how certain phenomena are constituted as risky, and how these conceptualisations are enrolled into and deployed within regulatory networks.

Cave et al (2010) describe the shift in approach outlined above as a move in regulatory scholarship away from pure interest group driven analysis towards a growing emphasis on institutional design, with a more detailed differentiation of the motivations and behaviours of actors. This movement is often referred to as a 'decentring' of regulatory scholarship (e.g. Black 2002a, Black 2002b). The idea of decentred regulation, implicit in many of the institutional approaches I have described, moves the state from the centre of analysis and asks what other actors and processes are involved in regulation. As Parker underlines:

> "The dominant current in contemporary regulation and governance scholarship is to argue that law itself should be intentionally and profoundly pluralised in ways that recognise its own (severe) limitations." (2008, p.350)

Black (2002b) points out that the notion of decentring, implicitly or explicitly, envisages an other which it defines itself against 'regulation by the State, which is often assumed to take a particular form, that is the use of legal rules backed by criminal sanctions: 'command and control' regulation' (2002b, p.105). Command and control is generally agreed to be the classic type of regulation and, as noted earlier, debates about the failure of this approach have preoccupied those studying regulation both in the US and

Europe. According to Black (2002b) a decentred understanding problematises various aspects of regulation: the complexity of interactions between actors; the fragmentation and construction of knowledge (that no actor has all the knowledge needed); fragmentation in the exercise of power and control; the autonomy of social actors; the existence and complexity of interactions and interdependencies between social actors in the process of regulation; the collapse of the public/private distinction; and the rethinking of formal authority. Moran (2002) argues that the focus in much regulatory scholarship on the 'perceived crisis of command regulation' highlights an important issue in the study of the regulatory state:

> "Public policymakers responded to the pathologies of command by deregulating. But the academic literature has fastened on to a different issue: given that, whatever particular episodes of deregulation take place, regulation of complex social processes will be needed, what kind of spirit should animate this regulation?" (2002, p.397)

Before further considering this question, I want to want to take a step back and consider what exactly we mean by regulation, why we want to regulate in the first place, and what the decentring of regulation means for these questions.

What is regulation?

At first glance the word regulation and what the study of it might involve seem fairly straight-forward; however, the definition and scope of what constitutes 'regulation' are contested matters. The lines within which the scope of the study of regulation ought to lie are drawn with different breadth depending on the perspective taken (Baldwin et al. 1998). Three general levels seem to be recognised which see regulation as either a specific set of commands, deliberate state influence, or as all forms of social control (Baldwin & Cave 1999). The legal perspective tends to use a narrower conception seeing a 'statute promulgated by a sovereign legislature as the paradigmatic form of regulation' (Morgan & Yeung 2007, p.3). Economic theories of regulation also tend to see a sharp distinction between markets and regulation and consider regulation to be deployed in order to correct market failures (Scott 2004). A sociological approach moves away from a narrow focus on the state and rules as command to viewing all forms of social control as regulation. Clarke (2000) proposes seeing regulation as 'a process whereby order is achieved in an area which has shown a propensity to disorder to an extent that demands attention' (2000, p.2); whilst Morgan and Yeung (2007) suggest that a three part functional approach comprising standard setting, information gathering and behaviour

modification is widely accepted. Black, considering the implications for a decentred view of regulation, suggests that a productive approach is to see regulation as:

> "...the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification." (2002b, p.20)

She suggests that this definition of regulation extends it beyond state activity but distinguishes it from any system of social control, delimits regulation as an 'intentional, systematic attempt at problem-solving' and marks it out as a specific site of social activity.

Why regulate?

Along with a shift in definition, the decentring of regulation has prompted broader reflection on the motivations for regulating. Black notes that:

> "For many, the goal of regulation is the project of welfare economics: the correction of market failure... In the standard treatments of 'regulation', the 'why regulate?' question is nearly always answered in terms of the correction of market failures, with the occasional nod to distributional or other ancillary aims." (2002a, p.7)

Market failure is when an uncontrolled marketplace will fail to produce results in the public interest. Regulation is often justified by reference to various technical issues related to market failure, for example: monopolies, where one seller produces for the whole market; externalities, where the price of a product does not reflect the true price to society of producing the good; information inadequacies – consumers need to be sufficiently informed for a competitive market to work; and moral hazard, where someone other than the consumer pays for the service (Baldwin & Cave 1999). Baldwin and Cave (1999) outline possible regulatory aims other than market failure: scarcity and rationing in order to allocate certain commodities that are in short supply; distributional justice where regulation is used to redistribute wealth; social policy or paternalism, where the rationality of individuals is not trusted and their preferences overruled; or planning, where regulation intervenes to meet the demands of future generations. They underline that the case for regulation is often based on a combination of rationales and that both the failings of the market and of regulation ought to be weighed up.

In a paper exploring justifications for regulation, Prosser (2006) outlines three bases for regulation: economic principles, individual rights and social solidarity. He suggests that the market failure approach, drawing on economic reasoning, dominates the debate. For

Prosser, market failure is inadequate 'to either explain or to justify normatively the range of regulatory tasks currently undertaken' (2006, p.364) as it assumes that market solutions are always the first-best outcomes when making decisions on the allocation of goods and services, and that other justifications are arbitrary. He goes on to argue that in this divide between market allocations and social justice there is a radical separation of economics and politics which is questionable given the increasingly wide definitions of regulation in use. He suggests that Black's (2002a) definition of regulation (quoted above) is useful for its recognition of the pervasiveness of regulation and opening up of the plurality of different regulatory objectives. Prosser argues that the danger of the market failure approach is:

> "Seeing the task of regulation as essentially a technical matter of making rules; these rules are then seen as constraints on the freedom of business to compete in open markets, and so to be minimised... Yet the issues raised... in fact revolve around deep conflicts of values and are not merely a matter of technicality." (2006, p.371)

Instead he emphasises that regulation is 'an organic process that requires a balancing of competing values setting out the sort of society we wish to live in' (2006, p.375). Prosser (2006) argues that that there is a much broader tradition of thinking about regulation in social rather than economic terms, but that many of these accounts lack developed social theory: a general philosophy of what is required for a good society. His proposal for an alternative approach to regulation is based on Durkheim's work on social solidarity. Prosser suggests that a major role for regulation is 'to provide the essential social underpinning of mutual trust and expectation which is necessary for markets to function' and to 'prevent or limit the socially fragmenting role of markets' (2006, p.382). The approach should ask which rationale is most appropriate in different areas of regulation depending on whether maximising efficiency, protecting human rights or maintaining social solidarity is needed.

Shearing's (1993) 'constitutive conception' of regulation has similar implications. He critiques the regulation/deregulation debate, suggesting that arguments for deregulation should be seen as political moves in a struggle over regulation. Instead he argues that this debate is rooted in a conception of regulation he calls 'control', which envisages social order as creating itself through the interaction of innate human characteristics and sees the order created as providing the most efficient distribution of goods (1993, p.68). Seeing regulation this way creates a debate over 'when, whether and to what extent market ordering alone will promote the public interest' (1993, p.69). In opposition to

this, Shearing outlines the constitutive conception of regulation in which 'markets are always regulated by careful constitutive work rather than simply given' (1993, p.70) and ordering is a political activity. For Shearing (1993), rather than the control conception that sees the market as productive and regulation as restrictive, regulation constitutes the market and should be seen as productive. He goes on to explain that:

> "One way of thinking about this is to imagine regulation as taking place in a space in which different regulatory schemes operate simultaneously. The occupants of this space may change but it is never empty. If one set of regulatory influences diminishes this simply changes the relationship between the occupants of this space." (1993, p.72)

Regulatory schemes, therefore, often compete with each other for control of the ordering process and in this process state regulation may try to limit the effects of other schemes. This way of conceptualising regulation allows us to think about how different regulatory schemes, with their different underlying rationales or values, interact and shape nicotine regulatory networks.

The above discussions are connected with a large body of work that examines adequate justifications for the restriction of individual freedoms, particularly by the state. Beauchamp (1980) suggests that because there is a presumption for liberty in our society, limiting liberty has to be justified. Gostin (2007) notes that government intervention to promote health often goes unjustified because health is viewed as an unmitigated good, yet interventions ought to be justified because they intrude on individual rights. Commonly, discussions about state intervention and liberty start from Mill's 'harm principle':

> "...the sole end for which mankind are warranted, individually or collectively, in interference with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others." (Mill 2001, p.18)

Gostin (2007) observes that harm to others is the most commonly asserted and well accepted justification for public health regulation. Two important conditions of the principle are that individuals are free from controlling influences and have sufficient understanding to make an informed choice. Mill underlines that the principle is not intended to apply to children, and emphasises the key role educating, informing and persuading people plays. Problems in applying the principle occur in defining key aspects including 'harm', 'freedom from controlling influences' and 'sufficient

understanding'. For Mill, indirect, remote or possible harm to others are not enough to restrict liberty (Bakalar & Grinspoon 1988).

Intervening to prevent an individual harming them self is far more contentious. This kind of intervention is commonly referred to as 'paternalism':

> "...the interference of a state or an individual with another person, against their will, and defended or motivated by a claim that the person interfered with will be better off or protected from harm." (Dworkin 2010)

Gostin (2007) notes that regulation of self-regarding behaviour is pervasive in law and widely judicially sanctioned, but is usually justified as protecting against harm to others. Pope (2000) distinguishes between 'soft' and 'hard' paternalism, where soft paternalism involves intervention when an individual is considered to lack decision-making capacity; assuming a risk without adequate information, maturity or freedom is considered to be insufficiently autonomous. Arguments for paternalistic regulation suggest that in a complex industrial society, where far more needs to be known that any single person can learn, there are some things the average person is simply incapable of making an informed and rational choice about (Bakalar & Grinspoon 1988). The question of autonomy is complicated by the argument that choices are socially and culturally embedded. As the Nuffield Council on Bioethics point out (2007), information-only approaches may be inadequate because making sustainable changes in behaviour is difficult, even for those who would like to act differently. In the case of tobacco use, as Goodin (1989) outlines, there is the need to consider whether smokers fully appreciate the risks they undertake; furthermore, even if they continue smoking in full knowledge of the risks, whether they accepted the risks in a sense that is fully voluntary and whether the addictive nature of smoking constitute a loss of the capacity to consent to the risks of smoking.

'Hard' paternalism, on the other hand, justifies constraining individuals' decisions, even when they are informed and voluntary, for their own benefit. Pope argues that 'hard paternalism is frequently the unrecognized but fundamental ethical justification of much public health law' (2000, p.477). He notes that it is widely criticised because it forces a conception of the 'the good' on people. Pope (2000) also observes that both soft and hard paternalism are subject to the problem of limitless expansion (where do you draw the line in protecting people?); however, he suggests that this is not necessarily a problem for smoking. Drawing on Rabin (1991), Pope argues that smoking can be

distinguished from other voluntarily assumed risks by the nature of the harm it imposes: smokers are at risk of serious physiological consequences; there is a high probability of harm as smoking is intrinsically and always harmful; smoking pervades life activities (2000, pp.496-7). Further smoking is largely taken up by young people before they reach adulthood.

Recently, models have been suggested which try to balance some of these concerns. Thaler & Sunstein (2003) introduce a modified version of paternalism they call 'libertarian paternalism'. Two observations underlie their framework. They argue that the environments in which people make choices are never value-free but will always make some choices easier than others. They also suggest that people often do not make the most rational choice and that many people do not want to expend the time and effort involved in making a choice. Libertarian paternalism proposes that environments be designed in order to steer people in directions that will promote their welfare. The Nuffield Council on Bioethics (2007), noting that libertarian paternalism 'may allow too much choice, and it might also absolve the state from some important responsibilities' (2007, p.25), suggest, instead, a 'stewardship model'. The notion of stewardship highlights the state's responsibilities to look after 'important needs of people both individually and collectively'; consequently, the state is seen as having a more active role in promoting the health of the public that allowed in the harm principle (2007, p.25). Their report (Nuffield Council on Bioethics 2007) emphasises that public policies should actively promote health, whilst recognising the importance of open and transparent participatory procedures as a necessary condition for public health policy making.

A related question is whether society is entitled to use the law to uphold conventional moral standards. This question was raised through the discussion of Hasson's (2003, 2006) work in Chapter six. A debate between jurist Lord Devlin and legal theorist H.L.A. Hart is well known for its exploration of this question. In response to a report by the Wolfenden Committee on the legalising of homosexuality and prostitution which claimed that it is not the duty of the law to concern itself with immorality, Devlin (1965) defended laws against homosexual acts, suggesting that society has the right to punish any act, which in the opinion of any 'right-minded man' is immoral. He views society as a community of ideas and suggests that regulation is justified as a defence of public

morality and therefore social cohesion. This view was criticised by Hart (1967), who countered that feelings of intolerance and disgust do not constitute a moral conviction and that Devlin assumes a social solidarity that does not exist in modern society, and questioned whether immoral acts threaten society's survival. Becker makes the important observation that:

> 'Deviance is not a quality of the act the person commits, but rather a consequence of the application by others of rules and sanctions to an "offender". The deviant is one to whom that label has been successfully applied; deviant behaviour is behaviour that people so label.' (1963, p.9)

Duster (1970), drawing on this definition of deviance, discusses how legislating against a behaviour can change its moral status and how legislation tends to control behaviours associated with the less powerful. This highlights an important link between social status and moral positions; the way that the values of groups with power can affect the content and operation of the law. This point is particularly relevant to smoking where a trend for the increasing use of harder legal measures as the population of smokers has become more deprived can be noted.

How should we regulate? Current theories

Returning to the question of 'what kind of spirit should animate' regulation? There are various approaches that attempt to move beyond either-or debates on re-regulation versus de-regulation. Moran suggests that these solutions have '...increasingly converged on the idea of intervening to shape both the structures and cultures of systems of self-regulation' (2002, p.398). Different emphases emerge within this convergence. The 'self regulation school' sees the spread of command styles of regulation as the symptom of a problem rather than a solution and argues that industry self regulation is the most effective form of regulation (Moran 2002). Proponents argue that self regulatory agencies have greater expertise and technical knowledge, reduce monitoring and enforcing costs, require less formal rules making amending standards less costly, and regimes normally involve the internalisation of administrative costs (Ogus 1995). However, complexities emerge in the variety of forms of self regulation discussed as well as with defining what exactly self regulation is (for a discussion see Black 2002b). Ogus (1995) notes that self regulation is not always preferable to other forms of intervention: where externalities are widespread, a conventional, centralised regulatory regime may be more efficient. For him, 'the appropriate forms of self regulation will vary depending on transaction costs in different arenas' (Ogus 1995). The focus in

recent discussions is on how to intervene to shape the structures and cultures of self regulation (e.g. Ogus 1995; Black 2002b; Gunningham & Rees 1997). For Gunningham and Rees (1997), the most important hurdles to effective self regulation are the extent to which it is possible to build an 'industry morality' and the extent to which responsibility can be institutionalised. Moran (2002) argues that at the heart of discussion about self regulation is a 'Durkheimian problem':

> "How can the non-contractual elements of contract be fostered? How, in complex economic structures with actors pursuing strategic interests, can a sense of common obligation and willingness to comply with commonly agreed rules, be created?" (2002, p.398)

Moreover, Black notes that '...government initiated regulation of firms relies for its effectiveness in part on firms having not only the will to comply but also the organisational capacity to do so' (2002b, p.126) and proposes that the key question is how to harness this capacity for public policy ends.

A further problem that self regulation raises is 'what happens if the culture of the regulated is so opportunistic that regulations are routinely viewed as obstacles to be surmounted in the search for advantage in markets...?' (Moran 2002, p.399) McBarnet and Whelan (1991) investigate this problem of 'creative compliance' where the subjects of legal control manipulate the law to serve their own interests and to evade unwanted control. They focus on the role of those who are regulated and on the 'two sided nature of law, as a means of controlling and a means of escaping control' (McBarnet & Whelan 1991, p.848). They investigate 'anti-formalism', a strategy which is commonly used in response to the undermining of legal formalism by creative compliance. In conclusion they observe that:

> "...there is an irony in introducing anti-formalism to control the creative compliance of sophisticated regulatees backed by resources of finance and expertise. Creative compliance is stimulated by strong motivations for resisting control. These motivations do not disappear with the first threat of a different form of control. On the contrary, they become motivations for resisting and undermining anti-formalism." (McBarnet & Whelan 1991, p.870)

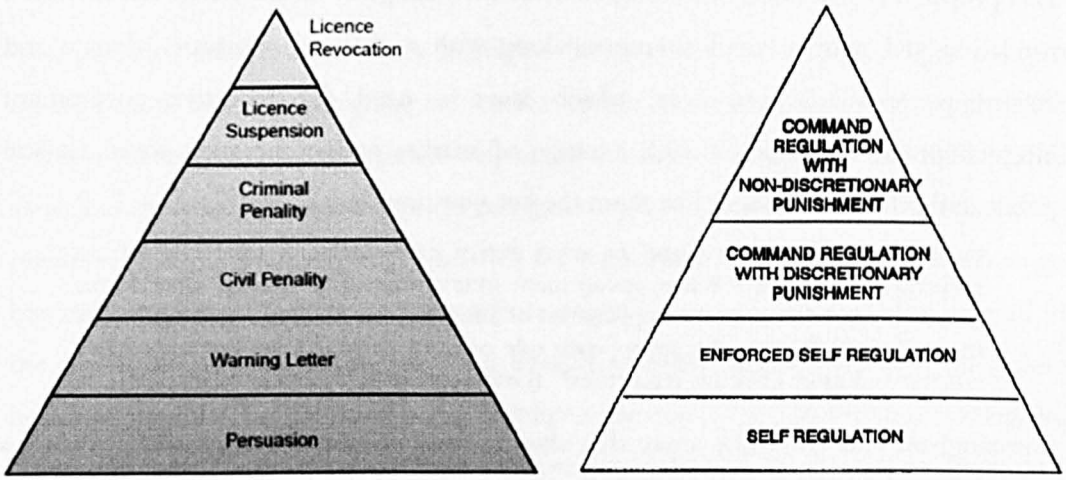
Rational actors with conscious strategic goals, such as the tobacco industry, will continue to have strong motivations for resisting control, even in the absence of formal legal control.

Two particularly influential decentred approaches to how we might better regulate are Ayres and Braithwaite's (1992) 'responsive regulation' and Gunningham and Grabosky's (1998) 'smart regulation'. Ayres and Braithwaite start from the idea that:

> "If we accept that sound policy analysis is about understanding private regulation – by industry associations, by firms, by peers, and by individual conscience – and how it is interdependent with state regulation, then interesting possibilities open up to steer the mix of private and public regulation. It is this mix, this interplay, that works to assist or impede solution of the policy problem." (1992, p.3)

They propose that regulation should be responsive to industry structure, taking into account the differing motivations and conduct of regulated actors and highlighting the importance of context, regulatory culture and history. The potential for delegating regulation to public interest groups, unregulated competitors and firms is explored. At the heart of their model is the idea of escalating forms of intervention. Regulation is conceptualised as a pyramid of activities, with persuasion at the base of the pyramid and penalties at top. Ayers and Braithwaite (1992) suggest this strategy is able to speak to diverse motivations for complying with regulation within firms and highlights the importance of constant dialogue between regulated and regulatee. They envisage pyramids containing sanctions for a single firm (from persuasion up to license revocation – Figure 3, left) and regulatory strategies for a whole industry (from self-regulation to command regulation with nondiscretionary punishment – Figure 3, right).

Figure 3: Compliance (left) and enforcement (right) pyramids



Source: Ayers and Braithwaite (1992, pp.35 (left) & 39 (right))

The importance of looking beyond a single firm in regulatory strategies is underlined:

> "The importance of business subcultures of resistance to regulation means that we must understand the significance of industry-wide forces beyond the agency of the single firm. In some respects industry associations can be more important regulatory players than single firms. For example, individual firms will often follow the advice of the industry association to cooperate on a particular regulatory requirement because if the industry does not make this requirement work, it will confront a political backlash that may lead to a more interventionist regulatory regime." (Ayres & Braithwaite 1992, p.39)

Ayers and Braithwaite (1992) also highlight the importance of the greater powers at the top of the pyramid for increasing the likelihood of more cooperation at the base of the pyramid; the effectiveness of 'benign big guns', as they put it. Their approach suggests that effective regulation depends on fostering norms among those regulated so that they will voluntarily comply (Moran, 2002).

Gunningham and Grabosky (1998) also focus on the need to harness governments, business and third parties in their exploration of regulatory strategies in the context of environmental regulation. They advocate redesigning environmental regulation so it will perform optimally in terms of efficiently and effectively delivering policy goals, equity, administrative viability and political acceptability. Their key contention is that:

> "...in the majority of circumstances, the use of multiple rather than single policy instruments, and a broader range of regulatory actors, will produce better regulation ...a far more imaginative, flexible, and pluralistic approach to

environmental regulation... smart regulation." (Gunningham & Grabosky 1998, p.4)

This proposal is grounded in a recognition of the failings of traditional government-led regulation and market-based solutions, along with a changed regulatory climate and limited governmental resources, which leave a need for 'selective government intervention in combination with a range of market and non-market solutions and public and private orderings'. For them the key questions are:

> "...in what circumstances and to what extent can regulation safely be left to industries themselves? When government intervention is necessary, what forms should it take? What are the implications of adopting one form of regulation rather than another? What is the appropriate role of third parties? How can we achieve smarter and more effective regulation?" (Gunningham & Grabosky 1998, p.23)

Gunningham and Grabosky argue that sharing responsibility for regulation between a range of actors lessens the impact of one actor pursuing an agenda that is not in the public interest. They explore the variety of available instruments – command and control regulation, self-regulation, voluntarism, education and information instruments, economic instruments – and their strengths and weaknesses, along with the groups of actors that might be enrolled and the ways they may interact. For them, policy design should work to the following broad principles: design a complementary instrument mix, prefer less interventionist measures or escalate the response up an instrument pyramid, empower third parties, and encourage business to go beyond compliance (Gunningham & Grabosky 1998, p.377).

Bridging the gap?

Taken as a whole, regulatory strategies advocated by this decentred approach are, according to Black (2002b), hybrid, multi-faceted and indirect, with an emphasis on the involvement of multiple actors and strategies. Black argues that regulation:

> "...should be a process of co-ordinating, steering, influencing, and balancing interactions between actors/systems to organize themselves, using feedback loops, redundancy, and above all, countering variety with variety." (2002b, p.11)

Similarly, Moran re-conceptualises the regulatory state as part of a new governing paradigm that focuses on governance and 'steering networks rather than commanding a single vessel called the state' (Moran 2002, p.412). Moreover, Scott underlines the importance of taking into account existing regimes and capacities:

> "Perhaps the most important policy implication is to suggest that wherever governments are considering a policy problem – be it unsafe food, passive smoking or poor quality university research – what they are considering is **an existing regime which cannot be swept away and replaced by a regulatory**

> **agency. A more fruitful approach would be to seek to understand where the capacities lie within the existing regimes,** and perhaps to strengthen those which appear to pull in the right direction and seek to inhibit those that pull the wrong way." (Scott 2008, p.22)

This passage perhaps most clearly highlights the gap between these conceptualisations of regulation and those highlighted earlier within the tobacco control community. Current theories on how to regulate emphasise the role of companies and third parties as well as the state; the use of a range of regulatory tools; preferring less interventionist measures; the importance of dialogue with the regulated actor to encourage them to go beyond compliance; that the existing regime ought to be evaluated and then steered in the desired direction. The discussion on tobacco/nicotine regulation within the public health community, on the other hand, highlights the role of the state in controlling the tobacco industry, and the increasingly deprived population of smokers, through formal legal instruments; the tobacco companies as objects of regulation rather than partners in a regulatory dialogue; a preference for strongly interventionist action; and the creation of a new regulatory body. In the former, the values of efficiency, administrative viability and political acceptability are emphasised alongside effectiveness and equity, whilst in public health the effectiveness of a regulatory strategy in improving the health of the public is key. The future-visions of the public health community draw on a regulatory discourse that has been relegated to the past by the regulatory policy and scholarship communities.

How can we understand this gap? I suggest that the pivotal difference in these constructions is the role and image of the regulated company/industry. In 'responsive' or 'smart' regulation the regulatee is, at least initially, envisaged as a partner who can bring unique knowledge and skills to the regulatory process. There is considered to be potential for the creation of a 'sense of common obligation and willingness to comply with commonly agreed rules' (Moran 2002), and command regulation with non-discretionary punishment is seen as a last resort. Within the public health community, the tobacco industry is perceived as a devious and untrustworthy adversary. There is a growing literature investigating the conduct of the tobacco industry, which highlights their influence on, and manipulation of, policy making in the UK and EU (e.g. ASH 2010b; Smith et al. 2010; Smith et al. 2009). Previous, less interventionist measures such as voluntary agreements are seen as profoundly discredited within the public health community. Working with the tobacco industry is, at least for much of the public health

community, highly problematic – as can be seen from reactions to the FDA regulation of tobacco in the US and particularly to Philip Morris' support for the move. Can this gap be bridged? Has the right kind of less interventionist regulation not been tried in the field of tobacco? Would responsive or smart regulation be suitable for reshaping the tobacco/nicotine regulatory network? Or is the situation already past the base section of the regulatory pyramid? Is the tobacco control community right – is the tobacco industry best excluded from the process? Is the culture of the regulated too opportunistic?

Understanding where the capacities lie: where is the network flexible?

In my concluding chapter I will examine these questions more fully. Here I want to briefly consider where, as Scott (2008) suggests, the capacities might lie in the tobacco/nicotine regime, so those that pull in the right direction can be strengthened: where is the network rigid and where might it be flexible? In terms of rigidities, the place of *snus* outside the network is likely to be difficult to reverse. The medical/tobacco divide will also be challenging to blur as a number of powerful actors are committed to it, although the continuum of risk does seem to be a powerful conceptual tool. New products such as e-cigarettes and other forms of nicotine that are currently neither defined as tobacco nor medicine could possibly open up a new space in the regulatory network and it is crucial to consider whether regulating them as medicines is the most effective step. The revision of the EU tobacco products directive is a chance to reshape the network.

Conclusions

This thesis took as its starting point an anomaly identified by commentators within the tobacco control community: why are different types of nicotine products regulated differently? I was also interested in how this situation came to be seen as problematic; how nicotine regulation was formulated as a problem. To explore this situation, entailing as it does a heterogeneous range of technological artefacts, medico-scientific ideas and regulatory regimes, I drew on ideas from STS, particularly those inspired by ANT. ANT was seen as particularly appropriate for its open approach to what will count in the world being investigated and its insistence on following the actors and tracing the associations they make rather than imposing a pre-formed framework. I will begin this concluding chapter by summarising the key findings of the thesis and relating these back to the first two research questions on the development of nicotine regulation and its effects. I will then turn to the final research question and discuss how regulation might best be used to restructure the networks I have described, as well as considering the implications of recent developments. Finally, I will offer some closing thoughts on using ANT.

Summary of findings

I have elected to arrange this summary thematically rather than providing a summary of each chapter. I propose that this will more readily enable me to draw together the key processes running through my descriptions. I focus on four processes that I suggest have emerged as key as the thesis has unfolded: i) the un-black boxing of the cigarette; ii) the construction, 'packaging and extending through time and space' (Prout 1996) of nicotine addiction; iii) the concept of medicalisation and the enrolment of medical networks; and iv) regulatory intervention and orderings.

I. Un-black boxing the cigarette

In Chapter four I sketched out the early history of tobacco use. I suggested that, until the end of the nineteenth century, tobacco was embedded within a wide variety of practices and relationships. I recounted the variety of practices through which tobacco was consumed: its positioning as a humoral essence to keep the body in balance, and as a 'loathsome' and harmful habit; its use by different groups in society and the different practices adopted; the construction of production networks in the US, and trade

relations between the US and the UK, and the UK and Europe in which tobacco was constituted as a valuable commodity. Tobacco's multiplicity was highlighted. Then, by tracing the 'invention' of the modern cigarette, I brought into view the multitude of heterogeneous elements that had to be associated and held together for the cigarette to exist, and to translate the previous multiplicity of tobacco practices into cigarette smoking. The carton of cigarettes packaged a long network of actors and practices – 'American Bright' tobacco, paper, 'flue-curing' practices, blending practices, milder, acidic smoke, the Bonsack machine, consumers who prefer a way of smoking tobacco that is clean, easy to use and affordable, matches, the sliding box, branding, package design and advertising – and, with enormous success, extended the network through time and space. It was able to 'delegate a 'network', standing in for it, repeating and performing its work in times and places remote from its origination (Prout 1996, p.202).

Whilst tobacco use has a long history of being defined as both good and bad (medically and morally), following the observation of a conspicuous rise in lung cancer during the 1920s and 30s and the nomination of smoking as a hypothetical cause, the relationship between smoking and lung cancer began to be examined using epidemiological tools. This incorporation of cigarette smoking into modern medical networks through the use of epidemiological techniques to position it as a risk factor can be seen as the start of a process of un-black boxing. It instigated a rapidly expanding body of medico-scientific work examining the relationship of smoking to a variety of bodily disorders and the effects of cigarette smoke on the bodies of smokers, and later non-smokers.

Throughout Chapters four and five I described how the un-black boxing of the cigarette – a process of problematising and intervening in various aspects of the cigarette-network – continued from the 1970s. Through the last four decades, the expanding anti-tobacco coalition has used various tools including public education, research and media campaigns to redefine the cigarette as dangerous for its users and, through the concept of passive smoking, non-smokers. It has investigated and problematised diverse aspects of the cigarette network: the constituents of tobacco and tobacco smoke (particularly tar, nicotine and CO) have been measured, their actions examined and some have been altered; the packet has been inscribed with the new understanding of smoking and the ways in which it communicates examined and proscribed; the effects of advertising and marketing practices have been scrutinised and gradually limited, then cut out of the

network; the areas in which smoking is accepted and allowed have been restricted so that now smoking is no longer allowed in enclosed public spaces. The circulation of tobacco industry documents during the 1990s further opened the black box, making public glimpses of the workings of some tobacco companies and their understandings and manipulations of their product.

There is now increasing interest in how the tobacco product itself is regulated. The magnitude of the health risk of smoking and the amount of control over the product are compared to other consumer, food and drug products. There is a great deal of debate over how to measure and regulate the content, emissions, presentation, addictiveness and harmfulness of tobacco products and their constituents. These discussions are made more complex by the widespread distrust of the tobacco industry's, likely greater, expertise in this area and disillusionment with any industry involvement in the regulatory process, as well as doubt over whether it is possible to reduce the harm of (particularly smoked) tobacco use significantly.

One particular constituent of tobacco, nicotine, has, as we shall see in the next section, taken on a central role in the understanding of smoking and, therefore, in this process of un-black boxing. It has stimulated increasing interest in intervening in the constitution of the cigarette itself, its packaging and promotion. It has also shaped the solutions that are considered appropriate to the problem of smoking.

II. Translating nicotine addiction/treatment

In Chapter four, I described research, led by Michael Russell, that investigated the role that one particular constituent of tobacco, nicotine, plays in smoking behaviour. Russell – and Murray Jarvik in the US – drew together previous research on the actions of nicotine on the central nervous system and the possible rewarding effects of nicotine, and began investigations with the premise that nicotine plays an important role in smoking. Russell was keen to expand on this work and produce further evidence for, and understanding of, nicotine's role. Russell and his team utilised various inscription devices to transform observations about the activity of nicotine in the body and people's smoking patterns into accounts that underline nicotine's addictiveness and its centrality to understanding smoking behaviour. For these researchers, nicotine was not a harmful component of cigarette smoke but the reason that people smoke. The group at the ARU

worked at linking their accounts of the role of nicotine to the smoking problem, and how it could best be tackled.

Nicotine was also central in developing a new type of tobacco substitute. From previous observations that some smokers might find nicotine injections an acceptable alternative to smoking and the use of chewing tobacco by Swedish submariners as a substitute for smoking, Ove Fernö took the idea of oral use of tobacco as detaching nicotine from the harmful cigarette smoke, and set out to investigate how pure nicotine could best be configured for oral use. Fernö's solution delegated biomedical work to a device in order to combine control of the therapeutic substance and patient access (Prout 1996); however, taking into account the actions of nicotine led Fernö to enrol a less conventional device: chewing gum. Other elements needed to be brought together to accommodate the nicotine: an ion exchange resin so the nicotine was only released when the gum was chewed; methods for demonstrating whether the gum was working and enough nicotine could be absorbed, and to compare it to cigarettes and snuff; a 'buffering agent to improve the absorption when it proved not to be; a chewing gum manufacturer; flavouring to mask the taste of nicotine. The team at the ARU were interested in nicotine gum as a potential aid to giving up smoking, embodying as it did the same understanding of the nature of the smoking problem, and undertook tests in order to establish whether it worked. They studied the absorption of nicotine from the gum, and its safety and efficacy. These tests played a role in establishing nicotine as an addictive drug. In this way the disease and treatment can be seen as having been co-produced (i.e. Jasanoff 2004).

Despite the work that had been done constructing both disease and treatment, a great deal more work was required to stabilise and extend the network; nicotine gum remained a very uncertain entity. For Leo Pharmaceuticals the gum was not a *'scientific, sophisticated product for a research-oriented pharmaceutical company'* (SW-RES-02). Instead it was chewing gum that contained a poison and was intended for an indication that did not exist; smoking was widely understood as a habit requiring willpower to break. Studies demonstrating the gum's safety and efficacy were crucial in enrolling Leo. As a regulated pharmaceutical company, Leo was enmeshed in complex networks of pharmaceutical regulation. Nicotine gum, enrolled by its positioning within Leo into these networks, required regulatory approval. In Sweden the gum was initially able neither to fit into the

category of food nor drug; it was unable to extend the nicotine addiction network and required more work, including the creation of an indication, to be configured as a medicine. In the UK, although there were concerns about the safety of nicotine and its cardiovascular effects, the gum was more successfully able to extend the nicotine addiction network and was translated into *Nicorette*: a licensed, 'prescribable drug to help people give up smoking'. This translation was destabilised by the ACBS who defined *Nicorette* as a drug-in-the-making, questioning the manufacturers' right to define it as a drug. They queried whether it had a significant benefit to health, whether it was 'something that cured smoking' and whether there had been enough testing; as far as the NHS was concerned it was 'not a drug' and not, therefore, available on NHS prescription. *Nicorette* was translated as it entered new networks and was not able to extend the nicotine addiction/treatment network fully. Nicotine was an addictive drug, and *Nicorette* an effective treatment, only in certain places.

The networks in which nicotine addiction existed continued to produce accounts in order to convince others to accept their arguments. Fernö, Russell and colleagues continued extending the *Nicorette* network: they struggled to convince pharmaceutical companies to further develop NRT products and expand circulation. This work produced a gradual shift in NRT formulations and strengths. The incorporation of 'tobacco dependence' into terminological standards marks the success of this work within medical-scientific networks and, through ensuring 'stability of meaning over different sites and times' (Timmermans & Berg 2003), stabilised tobacco dependence as a psychiatric diagnosis. However, it was *Smoking Kills* (DH 1998), an important 'co-ordinating tool' within UK tobacco control, that significantly strengthened and lengthened the nicotine addiction network. Further, *Smoking Kills* stated that smoking was an addiction. Moreover, it enacted new schemes of organisation (Prior 2008) such as NHS smoking cessation services and the availability of NRT on NHS prescription and general sale, new actors (smoking cessation services and specialists) and designated new roles for the NHS, GPs, pharmacists, other healthcare professionals, the pharmaceutical industry and the MHRA.

The nicotine addiction network, extended as it was through work in medical-scientific networks, adoption by the tobacco control community and particularly as enacted through *Smoking Kills* (1998), has configured and translated other actors in various ways.

The MHRA previously positioned *Nicorette* within their framework of rules as a typical medicine, isolated from the tobacco network except for its relationship as treatment, and highlighted concerns about the safety of nicotine. The stabilisation of nicotine addiction within the tobacco control community led to criticism of this position for not taking the harm caused by smoking into account. The MHRA followed their designated role in *Smoking Kills* by reclassifying nicotine gum as a GSL product, and later reconsidering restrictions on the set-up within which NRT is enacted. Significantly, they weighed any risks from using NRT with the benefits of quitting smoking. The pharmaceutical companies who produced NRT had been rather tenuously enrolled in the network. NRTs were not seen as particularly profitable and developing stronger, potentially more addictive products raised concerns about company image and the reactions of regulatory authorities. With the shifting framing of NRTs from abrupt cessation to harm reduction, it seems that some pharmaceutical companies have started redefining the potential users of their products and how the products themselves might be used. Within both the tobacco control community and pharmaceutical companies smokers have been redefined during this time. Some, if not all smokers have increasingly been constructed as unable or unwilling to stop using nicotine, and seen in terms of the categories of social deprivation or mental illness.

Although nicotine addiction has been extended and stabilised to the point that it is now predominantly a taken for granted tenet of tobacco control, there remain contradictions and ambiguities in the network. NRT is performed both as treatment and as consumer product. 'Better' NRTs are envisaged by some as providing nicotine more rapidly and in bigger doses to users, and allowing greater user control over nicotine; as more like cigarettes and more addictive. Various other aspects of the network are compared to cigarettes: the way NRTs are presented and packaged, ease of use, and price. However, there are debates about how the treatment set-up ought to be configured, over whether NRT can be effective if detached from this set-up with its support and counselling, and whether a less medical NRT is more consumer friendly; moreover, whether pure nicotine can adequately satisfy smokers (drawing *snus* into the network as a possible cigarette-replacement). Addictiveness is problematised in relation to regulators, companies and consumers. Moving away from a treatment framing creates problems for the pharmaceutical companies' 'license to operate' (Gunningham et al. 2004) as

'healthcare' companies, whilst consumers are found to de-script NRTs in various ways and to not appreciate the role of nicotine, instead positioning nicotine as hazardous.

III. Medicalisation

The concept of *medicalisation* was introduced at the end of Chapter four. It denotes the process through which areas previously outside the remit of medicine come to be treated as medical problems and defined in medical terms: a shift from badness to sickness. I introduced some of the literature that has discussed how to define medicalisation and conceptualise these processes: from an expansion of the medical profession's jurisdiction, to medicalisation as 'complex, multi-sited and multidirectional' and involving other actors such as consumers and the pharmaceutical industry. Throughout Chapters four, five and six I have drawn attention to elements of medicalisation in tobacco control. I suggested that cigarette smoking was drawn into modern medical networks through the work of medical scientists using epidemiological techniques to investigate the relationship between smoking and lung cancer. This work positioned it as a risk factor for lung cancer. This, at first contested, definition was gradually strengthened by an accumulation of accounts of the effects of smoking to a leading cause of lung cancer and expanded to include other diseases such as cardiovascular disease and chronic obstructive pulmonary disease. *Smoking and Health* (RCP 1962) played a key role in stabilising this definition through its summarising and distilling (Faulkner 2010) of previous accounts. It stated that smoking is an 'important cause of lung cancer' and delineated new roles for the medical profession in dealing with the problem.

The concept of nicotine addiction introduced a physio-pharmacological understanding of smoking behaviour that drew on medical explanations and medical ways of thinking. As it was extended and strengthened, smoking was translated into a disease in itself as well as a risk factor for other diseases. Further, the development of a treatment for the new disease within a pharmaceutical company both enrolled and strengthened this new understanding. Although groups of researchers and practitioners became involved through their work with smokers, the medical profession was more fully enrolled in the nicotine/addiction network through its recognition by key actors (the US Surgeon General and RCP) and incorporation into classificatory schemes (the ICD and DSM). With the support of a DH keen to take action on public health issues, the tobacco control network was significantly reshaped around the disease-treatment set of ideas.

The programme of action set out in *Smoking Kills* positioned pharmaceutical companies and a range of medical professionals in more central roles in the network, and outlined the creation of new treatment settings and practices within the NHS. The enactment of this programme has enabled tobacco use as a disease, a medical problem, to become the dominant framing in the English tobacco control network, and treatment with counselling or drugs an important solution.

In parallel to these later shifts, the concept of harm reduction has been mobilised by some actors within tobacco control in order to further reshape the network. In Chapter five, I described the ways that harm reduction is used to mobilise and translate a range of different actors. Harm reduction can be seen as a *co-ordinating strategy* (Law 2002b): it is often used to delineate a set of actors as drug delivery devices and arranges them according to selected attributes (speed of nicotine delivery and risk to health). The significance of other attributes is disputed; whether an actor is tobacco or medicine remains a crucial distinction for some actors. The harm reduction network that is being assembled in England, by including the tobacco/nicotine category, is translating NRT into 'medicinal nicotine' and positioning it as a central actor. This 'medicalised harm reduction' strategy, by co-ordinating which nicotine delivery devices are included in the tobacco control network (NRT, the pharmaceutical industry, not smoked or smokeless tobacco products, not the tobacco industry) is also able to more successfully mobilise the tobacco control community. Harm reduction, which with the enrolment of products such as *snus* has the potential to push the tobacco control network in quite different directions, has been used in England to further stabilise the enrolment of medical networks into tobacco control. It has enrolled the pharmaceutical industry as an increasingly important actor in the tobacco control network, changing how the industry conceives of its products, customers and its role in tobacco control.

On the other hand, the medicalisation of smoking remains partial and tenuous. In Chapter six we saw that some of those involved in the development of NRT argue that smokers do not see themselves as ill and in need of treatment; therefore NRT products need to be made less medicinal and more recreational. The treatment services enacted by *Smoking Kills* (1998) have been used by a minority of smokers (see for example West 2007; although Gibson et al. 2010 report that UK smokers are more likely to use support when quitting and to achieve short- term abstinence, compared to those in the

US, Canada and Australia), whilst there is evidence that some medical professionals resist the new roles and their delegation of responsibility for smoking by not discussing their patients' smoking/giving advice about smoking cessation (e.g. Coleman et al. 2001; whilst Pilnick and Coleman report various problems GPs face in discussing patients' smoking, including resistance from patients (2003), fear of damaging the relationship with the patient (2006), and difficulty in talking about how to stop (2010). Changes made by the MHRA to how NRTs are controlled also push in the opposite direction: the move to general sale status means NRT can be accessed and used out-with healthcare settings and practices, and allows them to act more like consumer products; the use of NRT for longer periods, for cutting down, temporary abstinence and harm reduction position NRT as an anomalous medical product. Whilst harm reduction has been enrolled to further stabilise the medicalisation of smoking, it can be seen as simultaneously pushing in the opposite direction by opening up a space for cigarette-like products (tobacco and electronic) and some smokeless types of tobacco as harm reduction products. This shift has also been criticised internationally for discouraging smokers from making unsupported quit attempts by medicalising quitting and not putting enough resources into other areas of tobacco control (e.g. Chapman 2007; Chapman & MacKenzie 2010).

The concept of medicalisation is clearly useful for understanding how the construction of smoking as a problem has shifted; equally, both the case study of smoking and the use of an ANT approach can illuminate processes of medicalisation. In the example of smoking, many of the groups often identified as expanding the boundaries of the medical have been quite resistant to this framing. Far from the 'disease-mongering' described in some areas of psychopharmaceutical development (e.g. Healy 2004, 2006; Lexchin 2006; Moynihan 2003; Tiefer 2006), until recently the pharmaceutical industry has, for the most part, resisted, or at least been apathetic to, playing a role in the smoking problem. Although there is evidence that, to some extent, smokers have taken up the idea and language of addiction (Bancroft et al. 2003; Katainen 2010), there has been no organisation around[68] or identification with a disease category as in the 'patient-activist' groups for diseases such as AIDS (Epstein 1996). It seems that smokers often

[68] Other than tobacco industry funded pressure groups that campaign against restrictions on smoking such as the Freedom Organisation for the Right to Enjoy Smoking Tobacco (FOREST).

reject the definition of themselves as ill and in need of treatment, and seek non-medical explanations and solutions for their continued smoking. The medical profession have had a complex role in relation to smoking. They were the first group in which smoking rates dropped, and played an important role in the acceptance of smoking's relation to many diseases and in the tobacco control community; however, as for other addictions, there remains resistance to, and difficulties in dealing with, the positioning of smoking as a problem for medical professionals to manage (see McKeganey 1989 on opiate addiction; and Strong 1980 on alcoholism). An ANT approach highlights the gradual and tenuous process of piecing together a network in which smoking is viewed as a psycho-pharmaceutical problem of nicotine addiction; where treatment is an acceptable solution; that incorporates a pharmaceutical treatment that is widely thought to work and is widely available; where the provision of smoking cessation services is government policy and healthcare professionals have been designated a key role in this programme of action. Although the 'definitional issue' is essential here, it did not in itself turn smoking into a medical problem, nor did the inscription of this understanding into a treatment device. The enrolment and support of many existing networks – the pharmaceutical industry, the DH, the MHRA, the NHS – was required, along with the creation of new actors and practices. Although some actors played a pivotal role in bringing aspects of the network together it was a not a case of concerted professional expansion or a series of moves choreographed in advance (by a centred engineer), but a series of disparate movements connected through an attention to the effects of a particular actor: nicotine.

IV. Regulatory ordering, intervention and effects

The final theme I wish to discuss is that of processes of regulatory intervention and ordering within tobacco control networks. In the past cigarette products were, for the most part, treated like any other consumer product. As Chapters four and five outlined, since the 1960s various tools have been used to intervene in the cigarette network. The RCP intervened through *Smoking and Health* (1962), which stabilised the epidemiological fact 'smoking-as-health-risk' and translated the existing studies into a programme of action that delegated roles to doctors and the government. The government initially enacted a limited part of this programme, focussing on disseminating the new fact through public education and shifting responsibility for change to smokers. This was followed by the creation of external organisations, which were delegated various roles: providing scientific advice (ISCSH), changing public opinion and lobbying for change

(ASH). The government began working with the tobacco industry to modify the cigarette network using voluntary agreements and codes of practice (focussing on health warnings, restrictions on advertising, promotion and sponsorship and lowering tar and nicotine levels). Other actors were also involved in controlling cigarettes through increasing restrictions on smoking in public transport and cinemas. The stabilisation of the *passive smoking* concept translated the discussion about smoking in public places into a medical issue and created an innocent victim of smoking. This led to increasing restrictions on smoking in workplaces. Rather than use the available legal mechanisms, the government produced recommendations, guidelines and targets, and restrictions were enacted through voluntary action by employers. Economic penalties in the form of tax increases were justified on health grounds.

In summary, until the end of the 1980s the government enrolled various soft law mechanisms and actors in ordering the cigarette network; public education, product modification and collaboration with other stakeholders, particularly the industry were emphasised. As part of the 1970s product modification programme, the Medicines Act 1968 was proposed as a possible legal mechanism for intervening in the cigarette network and controlling the industry; however, this move failed to enrol sufficient support. Although this period is commonly seen as one of 'denial and delay' by the government, others (Berridge 2007, 1998; Brandt 1990; Hilton 2000) underline the rather different shape of the network at this time: the authority of epidemiological methods was not fully accepted, the tobacco industry was able to successfully lobby government officials, concerns about the financial implications of restricting smoking dominated, and smoking was seen as a personal habit which lead to a focus on educating smokers so they could decide for themselves and an unwillingness to further intervene.

In the late 1980s an ASH Scotland campaign against 'Skoal Bandits', directed at the protection of children, was able to mobilise widespread support. This, and the lack of any tradition of oral snuff use, compelled the government into the use of legislation, first banning the sale of tobacco to children under 16 and then banning oral snuff. The EU's desire to take a more active role in tobacco control policy, and the greater weight given to health in the Community, significantly shaped regulatory orderings in the UK during this time. A series of Directives forced the government to begin a shift from a

range of non-legal regulatory orderings to legislative intervention. The election of a Labour government in 1997 who, through *Smoking Kills* (1998), put tobacco control at the centre of its public health campaign, continued and pushed forward this more centralised and legalistic intervention in the tobacco network. The adoption of the FCTC in 2005 marked another shift in the scale of tobacco interventions. In the last 20 years there has been a 'hardening' within the regulatory regime controlling tobacco, in the form of a gradual translation of voluntary agreements and codes of practice into legal control through rules and sanctions. Berridge notes that:

> "...smoking was beginning to satisfy the criteria for a deviant or marginalised activity – in particular through the lower social class and gender associations which had emerged. It was easier to mount a more consistent attack on the existence of a habit associated primarily with women and the poor." (1999c, p.1188)

Currently the law prohibits tobacco advertising, misleading descriptors on packaging, the sale of tobacco products to person under 18 and smoking in enclosed public spaces; it requires health warnings on packaging (and proscribes the size and the inclusion of pictures), the disclosure of ingredients, sets maximum tar, nicotine and CO yields.

I have suggested that, through the positioning of NRT in a pharmaceutical company, law played a role in enrolling NRT into medical networks and thus shaping it: to act as a medicine NRT needed a disease to treat, indications it would be licensed for, to have its safety and its efficacy compared to placebo, patient information and appropriate packaging. My first research question asked:

- ⇨ *How did different nicotine products come to be regulated in different ways: in particular, how did NRT fall primarily within the scope of pharmaceutical regulation?*

It seems that different nicotine products were regulated in different ways precisely because they were in different categories – tobacco/medicine – and seen as quite different types of thing. It is only recently that 'nicotine products' has become a meaningful category. In 1980, when nicotine gum was licensed in the UK, there were tobacco products and there were anti-smoking preparations. As we have seen, the category of 'medical treatment for smoking' was gradually assembled and strengthened throughout the late 1970s and 80s, as was the idea that nicotine was the key actor linking different types of products. A regulatory regime for the tobacco products in circulation, therefore with the main focus on cigarettes, was gradually put together and solidified as the health impacts of tobacco use became more widely accepted, public support for these measures increased, the status of the smoking population declined and

the tobacco control community became more influential. Conversely, the success of nicotine gum, developed within a pharmaceutical company, depended on its categorisation as a medicine, and since there was a pre-existing regime in which medicines were regulated, it was enrolled into this regime.

Therefore, from the medicines regulators' position, NRTs had to orient themselves to the same rules as any other medicine. With pressure from the 1990s onwards exerted by tobacco control community and, later, enrolment into the government's *Smoking Kills* (1998) programme of action, flexibility was introduced into the way the rules are enacted for NRT: they were reclassified as GSL products removing the requirement for medical oversight; moreover, unlike for other drugs, the MHRA accepted that use of NRT should be compared with the risks of continued smoking rather than assessed as an isolated medical product. Restrictions on the sale and use of NRT have been significantly relaxed over the last ten years: they can be used for up to nine months, by people of twelve years and older, to help quit, cut down, or temporarily abstain from smoking; some may be sold in any lockable premises, advertising of NRT is allowed (as long as the advertising conforms to strict standards); and NRTs have reduced in price.

What of the implications of these two regulatory regimes whose assembly I have described? My second set of research questions asked:

- ⇨ *Does the current approach to regulation:*
  - *a. Impede the effectiveness of harm reduction goals?*
  - *b. Constitute a barrier to the innovation of a greater variety of, and more effective, products?*

Bearing in the mind the way both harm reduction and regulation have been conceptualised here, these questions require some rethinking before an answer can be attempted. In some ways, whether the current approach to regulation has impeded the effectiveness of harm reduction goals is the wrong question to ask, or rather the wrong way of asking the question. As summarized in section III, harm reduction can be conceptualised as a coordinating strategy as well as an outcome; the concept of harm reduction has shaped the network in significant ways and enabled new courses of action. Growing support for a shift away from a focus on abrupt smoking cessation to a harm reduction approach – particularly from the MHRA – has, to some extent, shifted the way that pharmaceutical companies see their product and its potential users: products for longer term use and temporary abstinence, smokers who are less sure about quitting

and a more supportive regulator. However, harm reduction, along with smoke-free legislation, has created a 'grey area'; a space where large, multinational pharmaceutical and tobacco companies, and smaller companies selling recreational nicotine products make similar claims and compete for the same customers. Harm reduction has created greater opportunities for, and more interest in, the innovation of new medicinal nicotine products but has also created more competition for these products. The concept of harm reduction has brought the tobacco and medicinal nicotine regulatory orderings into the same space and is being used to reframe both as addressing the same problem: how ought nicotine delivery devices be ordered? It has produced an 'asymmetry' between tobacco and NRT regulation: the costs of producing a nicotine product within the medicinal regime, of developing its legal component, and the restrictions over its use are greater than in the tobacco regime. Although in some areas, particularly promotion, the tobacco regime imposes more restrictions.

It is important to emphasise that exploring regulation through the lens of ANT along with insights from the decentred approaches to regulation described in Chapter seven, underline that regulatory regimes shape and are shaped by the heterogeneous networks they are embedded in – that regulation is constitutive. Rather than ask whether regulation is a barrier, my research has again demonstrated that it is more useful to ask a different question: how is product innovation shaped by a range of actors and strategies within the network, including regulatory orderings and interventions? As previously recounted, harm reduction has enrolled some pharmaceutical companies more centrally into the treatment network and shaped their conceptions of what kind of products would be acceptable. It seems to have stimulated thinking in these companies about how NRTs might be developed. The incorporation of these ideas into the regulatory process, through the acceptance of smoking as a comparator and then licensing of 'cutting down', 'temporary abstinence' and 'harm reduction' as indications for some NRTs, has reinforced this rethinking.

What a more effective product might be, and what direction innovation needs to go in are not stable, but are found to be affected by one's positioning in the network. Whilst academics working on smoking behaviour and dependence (along with pharmaceutical industry representatives whose focus is research and development) focussed on the need for products to produce some kind of 'positive reward', in other words to be more

addictive, some actors in the pharmaceutical industry were concerned with getting products licensed and whether products would be acceptable to consumers. Concerns were raised about whether these new devices would be too expensive and whether, if they felt more like cigarettes, they would seem incongruous or even dangerous to consumers looking for something to help them stop smoking. The orientation of those in the pharmaceutical industry towards 'healthcare' and producing 'treatments' is incompatible with the intentional production of products that have the potential for 'lifestyle' use. Other aspects of a potentially more effective product are linked to more complex and changing understandings of tobacco dependence: the importance of a product allowing its user to regulate their blood nicotine concentrations and the additional 'aesthetic' characteristics of smoking a cigarette discussed in Chapter six that work with nicotine's action as a pleasure amplifier. Additionally, this discussion points to the difficulties of discussing pleasure in this context. Other parts of the cigarette network are also highlighted: the price of a packet of NRT compared to that for cigarettes, the ability of pharmaceutical companies' distribution networks to place NRT in all the places that consumers can access cigarettes, and the possible impact of the inscription of nicotine yields on cigarette packets on perceptions of nicotine and as a result NRT.

As noted earlier, the cost of producing a nicotine product within the medical regime, specifically of developing its legal component, is greater. Pharmaceutical companies must produce safety and efficacy data for each new product and apply for it to be licensed. They are concerned that going outside current nicotine delivery boundaries would increase the amount of documentation required. Lack of patent protection is also raised as one barrier to making the investment back. However, an academic commentator reframed doing basic safety and quality checks for products containing what is a potentially toxic drug, as well as checking the claims made about their value, as simply prudent. Although the medicines regulations themselves are seen as fixed and consistent, flexibility is introduced into the way NRTs interact with them by the way the rules are interpreted. The ability, through utilising the national procedure, to remain detached from European networks of medicines regulation is one way of retaining flexibility. Nevertheless, other regulatory centres, particularly the FDA whose approach

to NRT remains 'traditional'[69], are still able to affect what products are available in the UK by shaping what products pharmaceutical companies deem likely to be widely approved. Because NRTs circulate through many regulatory sites, the ability of the MHRA to influence them through its own rules is limited.

Here we see the very real effects of categorisations within the network, and how classification as a medical or recreational or tobacco product enrols different expectations and associations. The attractiveness and availability of NRTs is often compared to that of cigarettes; however, their status as medicines constrains them from acting in some of the ways cigarettes do. The increasing flexibility in the way NRTs are controlled, along with the emergence of harm reduction ideas and products, has played an important role in reorienting the pharmaceutical companies. It has also has worked to destabilise the tobacco/drug, medicinal/recreational categories and bring tobacco and pharmaceutical companies into the same network. Whilst there is much discussion of how the medicines regulatory regime constrains the circulation of NRT, it is also clear that the status of NRTs as medicines is valued by many actors. Actors in the pharmaceutical industry were found to engage in 'boundary work' (Gieryn 1995) to underscore the drug/tobacco boundary. There are moves to close down the 'grey area' by incorporating all non-tobacco, nicotine products into the medicines category; however, defining recreational nicotine products as medicines would place restrictions on them and perhaps change the way they are perceived.

Implications for nicotine regulatory policy

Now I turn to the final research question this project sought to address:

- ⇨ *Are there alternative approaches to regulation that might be more efficient and effective?*

I will discuss how the regulation of nicotine containing products might be reshaped. However, before it is possible to discuss what alternative approaches to regulation might be considered, it is again necessary to give further thought to the question that has been asked, chiefly: what do we mean by efficient and effective regulation?

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[69] Although, there is some evidence that the FDA, who now regulate both NRTs and tobacco, although in separate centres, are engaging more in this area: representatives of the MHRA met with the FDA early in 2010 to discuss the UK experience with NRT (McNeill, personal communication) and the FDA Center for Drug Evaluation and Research held a public workshop on the 'Risks and benefits of long-term use of NRT' in October 2010.

Returning to Prosser's (2006) point in the previous chapter, the issues raised in regulation 'revolve around deep conflicts of values and are not merely a matter of technicality'; further, regulation 'requires a balancing of competing values setting out the sort of society we wish to live in' (Prosser 2006, p.371). At the heart of debates around the regulation of nicotine products are complex questions including: is addiction a problem in of itself? Is it acceptable to use drugs for recreation and pleasure? How far ought the state to go in intervening in the consumption practices of individuals? Is it acceptable to restrict freedom in order to prevent individuals harming others, and far more contentiously, themselves? What responsibilities and rights should powerful, multinational corporations expect? How far ought the public health community to go in prescribing what kind of lives people lead? As outlined in Chapter five, two distinct positions, which answer these questions rather differently, co-exist uneasily in the tobacco control community. As for other recreational drug use, particularly opiates, a harm reduction orientation whose focus is the minimisation of physical harm from the use of drugs clashes with a more puritanical position that disapproves of the recreational use of drugs and drug addiction per sey and is directed towards eliminating their use.

There is a great deal of legal and philosophical discussion over whether the law has principled limits: whether or not the law ought to be used to preserve morality, as embodied in the debate between Devlin and Hart mentioned in the previous chapter. If, as a society, we view harming oneself by smoking as wrong, do we have the right to use the law to compel smokers to conform to this view? Or is protecting others from harm the only purpose for which the law ought to be used to interfere with the liberty of action of individuals, as Mill suggested. With regulations banning smoking tobacco within confined public spaces it may be that we are approaching the limit of what is justifiable under Mill's arguments. Certainly justifications for going further are much less widely agreed upon. The issues in tobacco control are further complicated by the interests of powerful, multi-national corporations with considerable lobbying power and sophisticated marketing techniques at their disposal, an element that is not always adequately considered within this literature. Stanton-Ife (2009), in a review of these debates, concludes:

> "Principled limits beyond means-ends or practical limits are elusive and hard to justify. The central dilemma revolves around the question of recourse on the part of law-makers to moral truth." (2009, p.35)

I do not purport to attempt this elusive task here. Instead, I will examine the values underlying some of the current debates within the nicotine regulatory network, and consider how the divergent aims of harm reduction and elimination of tobacco use might be differently addressed by regulation.

I concluded the previous chapter by underlining the gap between the tobacco control and regulation studies literatures on how to regulate. Within tobacco control the discussion emphasises greater control over tobacco products, the role of the state, the use of legal instruments and the need to exclude the tobacco industry from regulatory networks. Conversely, decentred approaches in the regulation literature highlight the need for involvement of multiple actors and a range of regulatory tools, a preference for less interventionist measures, dialogue with the regulated actor, and the role of the state as one of co-ordinating and steering. I suggested that the pivotal difference in these constructions is the role and image of the regulated industry: in 'responsive' or 'smart' regulation, industry is envisaged as a partner who can bring unique knowledge and skills to the regulatory process; whilst within the public health community the tobacco industry is perceived as an untrustworthy adversary. Despite these rather divergent approaches, potential points of overlap between the two literatures can be identified. For example, Ogus (1995), in arguing for the advantages of self-regulation, notes that it is not universally preferable, i.e. in situations where externalities are widespread. Gunningham and Rees (1997) suggest that the extent to which it is possible to build an industry morality is an important hurdle to self-regulation, whilst McBarnet and Whelan (1991) emphasise that if the culture of the regulated industry is too opportunistic, rational actors with conscious strategic goals will continue to have strong motivations for resisting control of all kinds. From the history of tobacco control, it seems clear that all these issues would be barriers to implementing a regulatory regime that seeks to shape the structures and cultures of tobacco industry self-regulation. Furthermore, Ayers and Braithwaite (1992) highlight the importance of greater power at the top of the pyramid for co-operation, which points to the need for an agency with sufficient powers for more flexible regulation to be feasible.

Nevertheless, the role of the tobacco companies is not necessarily as easily dismissed as it is sometimes in tobacco control discussions. If the aim of tobacco control efforts is to eliminate the use of, and addiction to, all tobacco products, then it seems fairly clear that

the pharmaceutical industry is the only industry to have a role within the network. However, if the aim is to reduce harm to users of nicotine-containing products, then the situation is more complicated. Although the tobacco control community has good reason to be wary of tobacco industry involvement in regulatory policy, and the uncertainties around reducing the harm from smoked tobacco are formidable, there is evidence that the risks of using some forms of smokeless tobacco are far less than for smoking cigarettes, and that it is now possible to reduce the levels of carcinogens in some forms of smokeless tobacco (e.g. Gartner, Hall, Vos, et al. 2007; Henningfield & Fagerström 2001; Luo et al. 2007; RCP 2007). Some smaller tobacco companies particularly have made considerable efforts in the harm reduction area (for example, Swedish Match has developed a quality standard for *snus* – 'Gothia Tek', whilst Star Scientific claim to have devised a curing technology that interferes with the formation of tobacco specific nitrosamines). Where the elimination of tobacco use is highlighted, there is a tendency to group together all tobacco products with minimal consideration of the differential harmfulness. If the reduction of harm to users is the policy objective, then some smokeless tobacco products and the companies that manufacture them are likely to have a role to play in the regulatory network. This is a direction the government is heading in food regulation, where major fast food, snack and confectionery manufacturers are being allowed to join public health networks.

The network is being shifted away from the possibility of a role for the tobacco industry at present. As noted in Chapter seven, the FCTC codifies the exclusion of the tobacco industry from public health policy making. A recent report by the FCTC Conference of the Parties Convention Secretariat on smokeless tobacco and electronic nicotine delivery devices focuses on the risks of their use with little discussion of their potential for harm reduction (2010), whilst in the US, where all smokeless tobacco types are legal, the public health community has tended to oppose tobacco industry innovations in, and promotion of, smokeless tobacco products on the grounds that they appeal to children. Work on FCTC Articles 9 and 10 has focussed on identifying best practices in reporting to regulators as regards contents, emissions, and product characteristics, methods for testing and measuring cigarette contents and emissions, and drafting guidelines on the attractiveness of tobacco products. If tobacco companies are opposed and excluded, then opportunities may be lost to shape the tobacco market. It is possible that common ground could be found between the public health community and the tobacco industry

in devising a regulatory regime that minimises the risks of smokeless tobacco use and promotes switching from smoked to smokeless tobacco products.

As outlined in section III above, a strong network has been built in the UK round the treatment of tobacco dependence. NHS treatment services and staff, the pharmaceutical industry and the MHRA are key actor-networks to have been enrolled into this programme of action, whilst the 'medicalised harm reduction strategy' has been used to exclude the tobacco industry. There is tension within this new network between prohibition and harm reduction orientations. These tensions are currently being balanced by incorporating some harm reduction ideas whilst focussing on medicinal nicotine and clearly maintaining cessation of nicotine use as the ultimate goal of treatment activities. As previously noted, this medical framing in the network has various positive effects: NRT has been shown to be more effective within the treatment set-up, some pharmaceutical companies have shown more interest in developing new nicotine products, and it has been successful in enrolling a wide range of actors. The regulatory framework continues to evolve. With the recent licensing of a harm reduction indication and subsequent MHRA consultation, it is probable that all non-tobacco nicotine products will in future be included in this regime. As Chapter six outlined, the fact that products such as e-cigarettes come under consumer protection regulations only, has raised concerns. Many highlight that products containing nicotine ought to meet safety and quality standards, and do relevant testing. Pharmaceutical industry representatives underline that it is unfair that similar products must undergo a far less burdensome regulatory process than NRT. If the MHRA applied the same rules to all pure nicotine products, this would 'level the playing field' for all non-tobacco products and deal with issues of purity and safety for recreational nicotine products.

There are some issues to consider with this potential shift, as well as the increasing medicalisation within the network. As noted previously, the approach taken in the UK has been criticised for discouraging smokers from making unsupported quit attempts by making quitting seem more difficult and not putting enough resources into other areas of tobacco control such as mass media campaigns. There may be downsides with the regulating recreational products under medicines regulation in terms of the innovation of less harmful recreational nicotine products and consumer perceptions of these products: the smaller companies that manufacture these products may not have the

capacity to meet the requirements of medical regulation; problems may emerge in licensing products designed to maintain nicotine use; further, smokers may view products as being in the medical category rather than as replacements for cigarettes and find them to be less attractive for recreational use. It is possible that some of these issues may be dealt with within the medicines regulatory regime, depending on how much flexibility the MHRA can create. As noted by pharmaceutical industry representatives, establishing the efficacy of products for smoking cessation and providing data to support the claims made produce the largest data burden. For recreational nicotine products, efficacy in these terms is not relevant. MHRA regulation of recreational nicotine products opens up questions about the suitability of medicines regulation for recreational drugs as well as more difficult questions such as whether use of, and even addiction to, recreational drugs that do not pose greatly elevated health risks should be accepted, and how we decide what magnitude of risk to health is acceptable. If policy is focussed on the elimination of all nicotine use, the availability of recreational nicotine products is more problematic than if the aim is persuading consumers to switch to less harmful forms of nicotine delivery.

As the last chapter outlined, an option that has proved popular within the tobacco control literature is the creation of a 'nicotine regulatory authority'. Various arguments for this approach have been outlined including: the challenges developments in the nicotine market pose, the complexity of policy responses, the strength of commercial interests involved, the current lack of resources, and the ability to regulate products in direct relation to their health impact and monitor measures. This idea has, however, failed to gather widespread support. Despite the commitment of the previous government to tobacco control, a nicotine regulatory authority, and the resources required to set it up, was not seen as a viable option by the DH. The current government's focus on spending cuts, local control, and shifting away from the use of legislative measures in public health policy suggest that it is improbable that they can be enrolled: the recent public health White Paper emphasised 'empowering individuals to make healthy choices'; authority for nutrition policy has recently been moved from the Food Standards Agency to the DH, as the centre for public health; whilst the Irish Office of Tobacco Control, often used as an example within tobacco control (e.g. RCP 2008), is to be merged into the Health Service Executive this year. A further issue I touched on in Chapter seven is Becker's (1963) observation that, in order to justify the

existence of their position, rule-enforcers need to demonstrate that the problem still exists; a nicotine regulatory authority would have a stake in the continuance of nicotine use. Consequently, the creation of a nicotine regulatory authority would raise problems from a prohibitionist standpoint.

Going back to Scott's (2008) point about policy problems being existing regimes that cannot be easily swept away, it is clear that there would be significant resistance to moving NRT out of the medicines regulatory regime, as a long network of actors has been enrolled round the medical categorisation. Although some pharmaceutical companies have become significantly more engaged in the area of tobacco control since *Smoking Kills* (1998), and particularly the shift in attitude of the MHRA, the extent to which the pharmaceutical industry can be enrolled into a harm reduction approach may be restricted. The image they project and the way they are perceived are very important to pharmaceutical companies, particularly in relation to the medical profession. Therefore, a shift towards recreational use of nicotine and maintenance of addiction may well be further than the industry is willing to go in this direction. If the provision of reduced risk nicotine products that are satisfying to smokers is the aim, input may be needed from actors other than the multinational pharmaceutical companies, including tobacco companies and smaller companies who perhaps have more freedom to be innovative.

I suggest that there is a need for more debate about the difficult ethical questions that underpin many of the policies in tobacco control, particularly in terms of the limits to intervening in individuals' lives to prevent harm. The tobacco control community has tended to let the tobacco lobby dominate debates about the State's interference with individuals' smoking, with over-simplified arguments that all measures introduced interfere with smokers' freedom to choose to smoke. My own sense is that there is becoming too great a disparity between the regulation of tobacco products and of smokers, with the potential for too much of the regulatory burden falling on the most disadvantaged. There is a need for industry to bear more of the burdens of regulation, and for discussions about interventions to control smoking in homes and cars to consider whether these may be unduly intrusive and in conflict with important personal values such as private space.

The measures currently being discussed by the UK Government and the EU – placing tobacco products out of sight and introducing plain packaging – seem to me to offer good ways to continue 'levelling the playing field' for nicotine products whilst placing more of the burdens on the industry than smokers. Minimising the impact on retailers is a consideration, although less of one than the tobacco industry suggests. Suggestions such as introducing a licensing system for tobacco retailers to control selling to under 18s would be in line with Mill's principle. I also find that there are good arguments for making the choice to use less harmful smokeless tobacco products available to consumers. Importantly, the use of these products would eliminate the risk of the most common smoking-related diseases. Furthermore, the uncertainties in reducing exposure to the harmful constituents in smokeless tobacco are far less problematic than for tobacco smoke, making regulation of the product contents a great deal less challenging. Of course, many difficult questions surround introducing products like *snus* – e.g. how to communicate about reduced harm to smokers and control the much more harmful forms of smokeless tobacco – and, without the means of strictly controlling the circumstances (particularly limits on harmful constituents), in which it is made available, it may be unwise. Moreover, whether medical professionals ought to promote a tobacco product is a difficult question, but regulatory levers such as lower taxation in comparison to cigarettes could provide alternate ways of shaping consumption. Perhaps more important than these practical questions, is the underlying disagreement on whether it ought to be done. A crucial aspect of this is the level of risk that is acceptable from using tobacco (whilst the use of *snus* elevates the risk of some diseases, it greatly lowers the risk of all diseases caused by smoking). The current review of the tobacco products Directive is a key opportunity to significantly shape the network with the possibility of exerting control over packaging, display and contents of products. The inclusion of recreational nicotine products under tobacco regulation potentially raises more concerns than the medical regime, including problems with limiting marketing of, and access to, potentially less harmful products, the applicability of labelling, and whether the Directive would deal adequately with safety and quality issues. However, as noted, reconsidering the position of *snus* in the network is a potential opportunity.

My aim in these last few pages has been to highlight some of the complex questions underpinning the issue of nicotine regulation, and suggest that there is a need for more debate around them. The emergence of, and increase of interest in, public health ethics

as a field of study (see for example Daniels 2006; Faden & Shebaya 2010; Nuffield Council on Bioethics 2007; Verweij & Dawson 2009) may create opportunities to engage in some of these debates. Daniels (2006, 2001) underlines that healthcare is special because it protects normal functioning, which protects the range of opportunities open to people. Further, drawing on Rawls (1971) theory of justice he argues that:

> "...by establishing equal liberties, robustly equal opportunity, a fair distribution of resources and support for out self-respect – the basics of Rawlsian justice – we would go a long way towards eliminating the most important injustices in health outcomes" (Daniels 2006, p.6)

Daniels' proposals would be useful for the public health community in formulating ethical arguments for smoking interventions. In light of some of the issues raised, further research examining in more detail how smokers use and understand NRTs and other products such as e-cigarettes and what impacts the increasing medicalisation of tobacco use and cessation has on smokers' perspectives and experiences, particularly of quitting, would be valuable. One issue that was briefly illuminated in Chapter five was the question of how smokers who are often spoken for, but not enrolled as actors, within the addiction/treatment network, confront, undermine or engage with the network, and the aforementioned questions would help to further understand this.

Using ANT to explore regulatory networks

I will bring my conclusions to a close with some final thoughts on what the use of ANT in this thesis has achieved and some problems identified in deploying it. Returning to a comment made in Chapter three, the lack of accounts of how to actually do ANT (Gad & Bruun Jensen 2010; McLean & Hassard 2004) is a problem for the inexperienced. As Law notes (2004, 1999a), the production of 'how-to' guides for ANT would prove problematic by limiting and fixing ways of doing it; moreover, Lee and Hassard (1999) argue that ANT's 'antipathy to self-definition' and resistance to forging its own internal and external boundaries are key to its success. However, the inclusion of more detailed discussion in ANT accounts about how the research was actually carried out (for example Bonner & Chiasson 2005; Latour 1987), in particular how decisions were made about which actors to follow, what actors to include and exclude, which actor-networks to unpick and which bit of the network to focus on, would be beneficial.

Another issue that I think continues to trouble the ANT approach, is undertaking the symmetrical treatment of humans and non-humans. As I traced the nicotine addiction and tobacco control networks, I found myself primarily understanding these networks through the eyes of the human actors enmeshed in them and their spoken and written accounts. As much as I tried to deal with humans and non-humans in a symmetrical way, the networks I described tended to focus more on human action and meaning. Perhaps I have failed to push my ANT analysis far enough; however, I would argue that this highlights a broader problem. On this point, Murdoch suggests that:

> "...might it not be prudent to assume that, while humans are enmeshed within networks of heterogeneous relations, they retain distinctive qualities as members of such networks?" (2001, pp.126-7)

He goes on to argue that Hacking's (1999) distinction between 'interactive' and 'indifferent' kinds allows us to:

> "...accompany ANT into non-dualistic terrain so that we can describe the heterogeneous relations that comprise complex ecosystems. At the same time, however, he insists we take note of a fundamental distinction between natural and social actors, one that is based upon their differing abilities to reflect upon, and thus change, the social arrangements in which they are enmeshed." (Murdoch 2001, p.127)

This way of recognising human distinctiveness in reflecting on their incorporation into networks whilst maintaining an emphasis on the heterogeneity of these networks and the understanding of action as the performance of a specific collective (McLean & Hassard 2004), seems to me to be a potentially fruitful way forward.

Whilst difficulties remain with putting ANT into practice, this study demonstrates that the approach has much to offer. ANT has allowed me to highlight the work needed to gradually put together, extend and dismantle actor-networks: to trace the successful extension and punctualisation of the cigarette network; the gradual making of new, and dismantling of established, associations needed to redefine the cigarette; and the ongoing work needed to assemble and extend the nicotine addiction/NRT networks. States of affairs that seem obvious now, when stable, are shown to be painstakingly assembled and held together. It also underlines the requirement for the gradual enrolment and support of new and existing actor-networks of medical practices and actors in the process of medicalisation. Using the notion of translation I have been able to trace how actors have been enrolled into the current network and their interests aligned around the 'medicalised harm reduction' strategy. This also reveals the weak points in the current network and the actors that could easily detach themselves and

destabilise the network (pharmaceutical companies, the DH, some public health actors). It also allowed me to investigate what the harm reduction strategy is doing in the network – how it is being used to translate the interests of various actors. Furthermore, by striving to maintain an awareness of those the network marginalises, I have been able to point to the ways in which smokers are centrally enrolled in the network by spokespersons and spoken for in various ways, but also marginalised and silenced. This introduces the question of how smokers confront and undermine the network, as well as participating in it.

ANT offered a different perspective on regulation that aligns more with the constitutive conception of regulation described in Chapter seven. Instead of seeing regulation as a technical issue of addressing market failures, and concentrating on the ways that regulation restricts actors, ANT leads one to focus on regulations as actors in heterogeneous networks that both shape and are shaped by the networks of which they are part. Furthermore, regulation can be seen as stabilising networks and actors. Enrolment into a regulatory regime stabilised nicotine gum as a medicine, whilst the gradual piecing together of the tobacco regulatory regime has played a key role in stabilising the definition of cigarettes. However, regulation on its own does not stabilise actors. In the case of nicotine gum, other actors also needed to be enrolled before it could act as a medicine, whilst a broad range of actors have had to be enrolled to stabilise the tobacco regulatory regime. I was also able to demonstrate the very different processes involved when an actor confronts an established regulatory regime than when it is gradually enmeshed in an emergent one, where the reshaping of strong network is required. Finally, the important question was raised about how values are negotiated and aligned into regulatory networks. Whilst not necessarily straightforward to put into practice, ANT provides powerful resources for analysing the building, stabilisation and effects of regulatory networks.

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The Medicines Act 1968

Health and Safety at Work Act 1974

Protection of Children (Tobacco) Act 1986

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Environmental Protection Bill 1990

The Children and Young Persons (Protection from Tobacco) Act 1991

The Finance Act 2001

The Tobacco Advertising and Promotion Act 2002

The Health Act 2006

UK secondary legislation

The Tobacco for Oral Use (Safety) Regulations SI 1992/445

The General Product Safety Regulations SI 1994/2328

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The Smoke-free (Premises and Enforcement) Regulations SI 2006/ 3368

The Children and Young Persons (Sale of Tobacco etc.) Order SI 2007/ 767

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English secondary legislation

The Tobacco Advertising and Promotion (Display) (England) Regulations 2010

The Protection from Tobacco (Sales from Vending Machines (England) Regulations SI 2010/864

Scottish secondary legislation

The Prohibition of Smoking in Certain Premises (Scotland) Regulations SI 2006/90

Appendix I: Abbreviations

ACBS	Advisory Committee on Borderline Substances
ANT	Actor-network theory
ARU	Addiction Research Unit
ASH	Action on Smoking and Health
CO	Carbon monoxide
CSM	Committee on the Safety of Medicines (Now Commission on Human Medicines)
DH	Department of Health
DSM	Diagnostic and Statistical Manual of Mental Disorders
EC	European Commission
EU	European Union
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drugs Administration (US)
GP	General Practitioner
GSL	General Sales List
HEC	Health Education Council (now the Health Education Authority)
ICD	International Classification of Diseases
ISCSH	Independent Scientific Committee on Smoking & Health
MHRA	Medicines and Healthcare products Regulatory Agency (previously the Medicines Control Agency)
NICE	National Institute for health and Clinical Excellence
NHS	National Health Service
NRT	Nicotine Replacement Therapy
RCP	Royal College of Physicians
SSK	Sociology of scientific knowledge
STS	Science & technology studies
TRIPS	Trade-related aspects of intellectual property rights
UK	United Kingdom
US	United States
WHO	World Health Organisation

Appendix II: List of Codes

The following is a list of key themes and connections generated during analysis. They are presented in no particular order.

Change
Outside/inside
Stabilisation
'A sea change'/Smoking Kills

Harm reduction
'Safer smoking'
Alternative strategies: 'what else have you got?'
'The Swedish experience'/snus
Tobacco industry developments
'The low tar lie'
'Divides the field'/pragmatists vs. moralists
Defining harm reduction (continuity/radical)
'Continuum of risk' (nicotine/harm/speed)
'Nicotine delivery devices' (tobacco/medicine boundary)
Mobilising harm reduction (medicalised harm reduction)

Medicalisation
Risk factor
Nicotine addiction as disease
Coproduction of treatment/disease
Smoking kills and medical associations
Harm reduction and medicinal nicotine

NRT as assemblage
Form
Role of nicotine
Being a medicine (disease/indication/licensing/NHS prescription)
Pharmaceutical companies (healthcare)
How NRTs are used (abrupt cessation – harm reduction/indications)
Treatment settings/set-up
Users/smokers
Packaging & Advertising (communicating with users)
Distribution networks
Cigarettes (comparator)

A better product
Understanding nicotine (cigarettes)
Faster/stronger
More cigarette-like
Perception of nicotine – compliance/usage
Cessation/harm reduction
What do consumers want?
Being too medicinal (consumer friendliness)
Snus

Imagining smokers/users
Why do people smoke?
The way that people think of themselves (not sick/ill)
What do smokers want/need?
Unable to stop using nicotine
The 'remaining' smokers
Desire to quit
Perceptions of nicotine/user compliance

Image of pharmaceutical companies
Creating addictive products
Company values, healthcare companies
Inertia, not pushing the envelope
A change of mindset – positioning in harm reduction debates

Regulation
Company image
Asymmetry – a level playing field
Responsibility
'The rules'
Getting a product registered
Cigarettes as comparator
Going national
A go'er in the US
The grey area

Regulatory futures
Health risk and strength of regulation (other products/nature of tobacco)
Uncertainty/complexity
The profitability and harm nexus
Nicotine delivery devices/continuum of risk
Regulatory imbalance/Levelling the playing field
A nicotine regulatory authority
Role of industry