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E-Cigarettes and the Comparative Politics of Harm Reduction

History, Evidence, and Policy

Edited by
Virginia Berridge · Ronald Bayer
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Abbreviations

ACMD	Advisory Council on the Misuse of Drugs
ACT	Australian Capital Territory
AMA	American Medical Association
AP	Authorised Prescribers
ASH	Action on Smoking and Health
BAT	British American Tobacco
BMA	British Medical Association
BUGA UP	Billboard Utilising Graffitists Against Unhealthy Promotions
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CMO	Chief Medical Officer
COT	Committee on Toxicity in Food Consumer Products and the Environment
EMCDDA	European Monitoring Centre on Drugs and Drug Addiction
ENDS	Electronic Nicotine Delivery Systems
EU	European Union
EVALI	E-cigarette and Vaping Associated Lung Injury
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
HR	Harm Reduction
IOM	Institute of Medicine
ISCSH	Independent Scientific Committee on Smoking and Health
ITC	International Tobacco Control Policy Evaluation Project
LCP	Liberal Country Party
LSHTM	London School of Hygiene and Tropical Medicine
MHRA	Medicines and Healthcare Regulatory Authority

MoH	Medical Officer of Health
MRC	Medical Research Council
NASEM	National Academies of Science, Engineering and Medicine
NCI	National Cancer Institute
NDS	National Drug Strategy
NGO	Non-governmental organisation
NHMRC	National Health and Medical Research Council
NICE	National Institute of Clinical and Healthcare Excellence
NNAA	New Nicotine Alliance Australia
NRT	Nicotine Replacement Therapy
NSM	New Smoking Material
NSP	Needle and Syringe Programme
ONS	Office of National Statistics
PHE	Public Health England
PMTA	Pre Market Tobacco Product Application
RCP	Royal College of Physicians
SAS	Special Access Scheme
SCHEER	Scientific Committee on Health, Environment and Emerging Risks
SUDP	Standard for Uniform Scheduling of Drugs and Poisons
TCA	Tobacco Control Act
TGA	Therapeutic Goods Administration
THC	Tetrahydrocannabinol
THR	Tobacco Harm Reduction
TPD	Tobacco Products Directive
TPRT	Tobacco Products Research Trust
TRC	Tobacco Research Council
TSANZ	Thoracic Society of Australia and New Zealand
WHO	World Health Organisation

CHAPTER 1

Introduction: Before E-Cigarettes—The Pre-history of Public Health, Tobacco and Nicotine in the UK, Australia and the US

Virginia Berridge, Amy L. Fairchild, Kylie Morphett, Coral Gartner, Wayne Hall, and Ronald Bayer

Abstract The comparative study arose from our curiosity about why policies towards e-cigarettes were so different in the UK and Australia, two countries with a shared public health history. The US was added as a case study to see how its unique history of tobacco activism and anti-tobacco activism prefigured and influenced its e-cigarette policy. We outline the history of tobacco policy in the context of public health in each country,

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showing that a major change occurred after World War II, when tobacco became a key issue of public health concern. All the countries developed stances hostile to tobacco smoking and to the tobacco industry, but differences in the way this was done helped to inform their policies towards e-cigarettes, which cover a spectrum of tolerance. An important source of divergence between the three countries was a history of policy in the UK favouring a harm reduction approach to nicotine. In the US and Australia, while nicotine was used as individual therapy, it was in pursuit of a cession-only strategy.

Keywords Tobacco · Nicotine · Public health · History · UK · Australia · US

E-cigarettes entered the global tobacco and nicotine market between 2003 and 2008. Within a decade, they had spawned a battle royal focused on both evidence and values. This book focuses on the three countries that have played a central role in global debate over e-cigarettes. It is an examination of three different, influential countries that shaped debate in a way that gives us a more granular view of how policy climates develop and evolve (Montez, 2020). Indeed, it has its origins in a more distant history of tobacco policy. Those who were familiar with public health

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histories saw a paradox in country policy responses to e-cigarettes. The UK and Australia have had a long history of cross fertilisation of public health policy. Australian responses to HIV, for example, influenced those in the UK while British anti-smoking policies and culture influenced those in Australia. There was also movement of leading public health personnel between Australia and the UK. Why then, did Australia's response to e-cigarettes differ so much from that in the UK? The UK welcomed e-cigarettes as a form of harm reduction while Australia imposed stringent restrictions on smokers' access to protect youth. Discussion of why this was brought the British and Australian authors together. We then called on our collaborators in the US for an analysis of e-cigarette policy in a comparator country with a long history of both anti-tobacco activism and a "war" on illicit drugs. How did the US response to e-cigarettes fit within its history of policy responses to different types of substance use?

1 A Note on Our Methods and Analysis

Our approach used a combination of the methodology of historians and policy analysts. We used contemporary history approaches that use documentary sources to analyse the story of debate in each country. We also reviewed the arguments and evidence cited in major reports and policy statements by government agencies and in submissions to government inquiries. We examined public statements made by leading public health bodies and non-government organisations (e.g. cancer councils, medical organisations and heart foundations) in each country and supplemented these with analyses of arguments presented for and against ENDS policies in the media and leading medical journals in each country. Finally, we conducted key informant interviews with leading figures in policy in each country to understand their perspectives on the challenges and the evidence.

The discussion of policy in this area has often been framed in terms of "the evidence" which is assumed to be a value-free concept and the use of the precautionary principle or the concept of harm reduction to deal with the uncertainty left by evidence gaps or contradictions. While both evidence and values have been key in both national and global debate, we show that they intersected in different countries in different ways: very different responses and constellations of arguments arose within specific national contexts and histories. Our analysis accordingly emphasises the pre-history, the historical context, of the policy issues raised by

e-cigarettes and places the policy debate within the contexts of regulatory bodies and the networks of researchers and lobbyists who influenced policy. This opening chapter accordingly sets the scene for the events which have unfolded in each country in tobacco control in the twentieth century.

Our analysis focuses on the justifications provided for these policies by key policy actors. We also paid attention to the pre-history of harm reduction policies on HIV/AIDS and drugs and drew upon histories of tobacco control policy in each country to understand the origins of these differences in policy approaches to e-cigarettes (often called electronic nicotine delivery systems [ENDS]), between the three countries. Commonalities and differences between countries were compared in a multi-day face-to-face meeting between the investigators. The meeting arrived at a consensus through a discussion of commonalities and divergences in historical approaches to nicotine policy in Australia, the UK and the US. Summaries of the policy situation in each country were prepared and used to produce this book.

There have been different policy views in constituent countries of the UK, notably England and Scotland, so England is our main focus in the case of the UK. Some agencies are UK-wide and European Union (EU) regulation applies to the whole of the UK, so at times a UK policy perspective is unavoidably taken.

2 National Policies Towards E-Cigarettes

Electronic cigarettes remain the subject of public, media and regulatory attention in the UK, US and Australia. How much has evidence (of what kind, and with how much uncertainty) shaped public policy in these countries? Should e-cigarettes be banned? Should they be regulated, and if so, should they be regulated as recreational consumer products, tobacco products, medicines or some a combination of these approaches? These debates have centred on whether e-cigarettes encourage or discourage smoking in aggregate. Very different policies have been justified by invocations of precautionary and harm reduction principles depending on how countries framed risk to different groups within each country.

In the UK, the tradition of harm reduction using nicotine has shaped majority support for a policy that has endorsed e-cigarettes for smoking cessation and harm reduction. This has not been without considerable controversy in the public health field.

In the US, despite an abstinence-oriented, anti-tobacco agenda, there has been a debate about the trade-offs between the risks of youth vaping and the benefits to current smokers. Australia, by contrast, has effectively banned the sale of e-cigarette products containing nicotine by making them a "prescription only" medicine, a policy that has made it difficult for smokers to access e-cigarettes. Each nation has justified its policy by appeals to "evidence."

We use these countries to provide comparative case studies of how policies towards e-cigarettes have been made and why they have come to be so different. This book argues that their varied responses are the outcomes of the history of public health, and health policy more generally, and different policy making traditions and institutions in the three countries. This book thus throws light on the relationship between history and the role of evidence and science and policy more generally.

This introductory chapter of the book sets the scene for key events in tobacco policy in the three countries over the half century since the 1950s. We consider how thinking about public health has changed since World War II and how tobacco smoking came to be treated as a central public health problem. We then examine how nicotine as a harm reduction tactic figured in tobacco policy before the advent of the e-cigarette. We start by looking at public health and the role of tobacco and nicotine in the three countries.

3 The UK

Britain, as the world's first industrial nation, developed a public health movement in the mid-nineteenth century. This emphasised the role of sanitary reform in the prevention of infectious disease epidemics, such as cholera, via the provision of drains and the general improvement of the living environment. Such actions, which were limited until the third quarter on the nineteenth century, were underpinned by miasmatic or contagionist views of disease. After the Public Health Act of 1875, a cadre of state bureaucrats developed, the Medical Officers of Health (MoHs). They operated at the local level and were responsible for the removal of nuisances, building standards and the regulation of food production. From the late 1880s, they also enforced notification and isolation in the case of infectious diseases.

Germ theory emerged in the second half of the nineteenth century. It became the dominant explanation of infectious diseases and produced

a shift in the focus of public health away from improving the environment to improving the health of individuals, and especially mothers, in the home. Eugenic ideas focused on "racial poisons" such as venereal disease, alcoholism and tuberculosis. After World War I, a "public health empire" developed in the UK in which the MoH ran a whole range of local government-based services that in the inter-war years promised to form the basis for a new national health service.

But after World War II, the national health and welfare services that were introduced in the UK were not run by public health. Changing patterns of disease from infectious to chronic, known as the epidemiological transition, and changes in the organisation of health services, encouraged those in public health to seek a new way of thinking about health. The idea of social medicine as holistic way of thinking about public health began in the inter-war years and continued into the 1940s. It produced a more restricted vision of public health that focused on chronic diseases of lifestyle and the role of quantitative methods in investigating risk behaviours for these diseases. Public health practitioners focused on the role of long-term risk factors which might not cause disease immediately but would produce chronic ill health in the future. They began to use a new language, that of "lifestyle"—individual behaviour or habits—and to discuss how it might be modified (Berridge, 2016).

Tobacco smoking encapsulated the new approach to public health. The original research was carried out by Richard Doll and Sir Austin Bradford Hill at the London School of Hygiene and Tropical Medicine and by Wynder and Graham in the US. The rise in deaths from lung cancer led the British Medical Research Council to commission Doll and Hill to investigate the causes. A questionnaire administered to cancer patients in London hospitals revealed that heavy smoking was common in those with lung cancer but not in those with other forms of cancer. The American study produced similar findings. Doll and Hill then designed a prospective study of British doctors that related their chances of acquiring lung cancer and other diseases to their smoking habits. The final report from this doctors' study was published in 2005. By then, the health hazards of smoking were widely accepted.

The publication of the Royal College of Physicians (RCP) report, *Smoking and Health* in 1962, was the first to bring the issue to worldwide attention, with the assistance of television coverage. It was followed two years later in 1964 by the US Surgeon General's report on smoking in the US.

New techniques of health advocacy began to be used, and mass media campaigns were instituted that drew on behavioural science to influence the behaviour of populations. Activist groups such as ASH (Action on Smoking and Health) in the UK used the mass media in a self-conscious way, basing its tactics on the American consumer movement and the UK housing action movement.

The early tobacco activists in the UK were not anti-industry. In fact, members of the Royal College of Physicians committee worked with tobacco-funded organisations. The industry-funded Tobacco Research Council (TRC) provided the statistics for the first RCP report. A shared research and policy agenda that extended into the 1960s and 1970s aimed to identify the substances that caused harm in cigarettes and to remove them.

In the 1970s, this objective crystallised in the search for what was known as the "safer cigarette." Cigarette filters were investigated, as was a reduction of tar and nicotine levels with appropriate labelling. New Smoking Material (NSM) was launched in 1977 but proved a failure because it was unpopular with smokers and opposed by health agencies such as the Health Education Council. Anti-tobacco activism was stimulated by the discovery of "compensatory smoking," which involved smokers consuming more low-tar and low-nicotine cigarettes, potentially leading smokers to take in more rather than less tar.

By the end of the 1970s, public health support for cooperation with industry and for modification of smoking came to an end. The new public health position, common to other public health approaches such as diet and heart disease, aimed to eliminate smoking and opposed collaboration with industrial interests. This was a wider agenda for public health in the 1970s, shown in the British government's policy documents on prevention (Berridge, 2007).

Over the next twenty years, the aim of eliminating smoking was dominant. In many respects, hostility continued and deepened during the 1980s. The arrival of "passive smoking" as a scientific fact codified what had been a moral issue—the selfishness of smokers in polluting the atmosphere for non-smokers—into a scientific one. The publication of papers by Hirayama and others in the *British Medical Journal* in 1981 showing that the non-smoking wives of heavy smokers had a much higher risk of lung cancer provided an epidemiological case, a scientific justification for greater restrictions on smokers (Hirayama, 1981). The institution of a ban

on indoor smoking in commercial venues in 2007 was in some sense the culmination of the focus on the restriction of public space for smoking.

The arrival of passive smoking on the scene in the 1980s underpinned a more aggressive stance on the part of anti-tobacco campaigners, enabling them to draw attention to the widening of risk. This was risk to others rather than just to smokers. Smokers threatened others rather than just themselves. It involved "innocent victims", among them women and children. It was concerns such as this which led to the smoking ban in public places and to the UK's participation in the Framework Convention on Tobacco Control set up through WHO in 2003.

But alongside this public health stance on smoking, other developments within public health saw what was termed harm reduction come onto the policy scene. The advent of HIV/AIDS in the 1980s brought harm reduction overtly into drug policy, reversing the "war on drugs" stance adopted from the US at the beginning of that decade (Berridge, 1996). And the development of nicotine as a treatment therapy for smoking also saw the beginnings of harm reduction approaches within the smoking field, as will be discussed in Chapter 2.

4 Australia

As a former British colony, Australia's approach to public health in each of its states followed the lead of England well into the twentieth century (Lewis, 1989, 2007). After the colonies Federated in 1901, the Commonwealth government's responsibility for health was limited to border quarantine; state government health departments were primarily responsible for health services and public health (Lewis, 1989).

There was no Commonwealth Department of Health until 1921 (Lewis, 1989). State public health services ensured clean water and sanitation services, and food safety and were responsible for the detection, isolation and treatment of persons with infectious diseases (Lewis, 2007). The Commonwealth's health role expanded after World War II when it took responsibility for regulating and funding pharmaceuticals. In the 1970s, the Commonwealth also began to subsidise primary health care and private medical practice and fund state hospital services and to take a role in providing public health advice, including that on the risks of smoking.

Cigarette smoking in Australia, as in Britain and the US, was widely adopted by Australian troops in World War I and World War II (Tyrrell,

1999; Walker, 1980). Attitudes towards smoking by women changed in the 1920s as cigarette advertising began to target them. The large number of women in the workforce during World War II also increased cigarette smoking rates among women. By the end of World War II, three quarters of men and over a quarter of Australian women smoked cigarettes.

As in the UK, cigarette smoking was recognised as a major cause of premature mortality and morbidity in Australia in the late 1950s after the publication of Doll and Hill's epidemiological studies (Tyrrell, 1999). In 1957, the National Medical Research Council (NMRC) accepted that smoking caused lung cancer and called on the federal government to fund anti-smoking campaigns and ban tobacco advertising (Walker, 1984). The findings of the 1962 report of the Royal College of Physicians on tobacco smoking were endorsed by the Australian Colleges of Physicians, Pathologists and General Practitioners and the Australian Medical Association (Lewis, 2007; Tyrrell, 1999; Walker, 1984). These medical bodies accepted that cigarette smoking was a cause of lung and other cancers and heart disease. They advocated government-funded public education campaigns to inform smokers of these health risks on the optimistic assumption that this would be sufficient to encourage smokers to desist (Tyrrell, 1999). They also advocated for restrictions on tobacco advertising (Lewis, 2007).

A major obstacle to effective tobacco control policies in Australia was the Liberal-Country Party (LCP) coalition government that was in power federally from 1949 to 1972 (Tyrrell, 1999; Walker, 1984). The LCP government was ideologically opposed to "interfering" in smokers' "personal choices" and it was protective of the economic benefits of the tobacco industry (Walker, 1984). In 1965, for example, the Cabinet rejected a proposal from the Commonwealth Department of Health to fund public health campaigns to discourage smoking because the Department of Primary Industry argued that there were major economic benefits from tobacco production (Tyrrell, 1999).

The tobacco industry also enjoyed considerable protection from the Country Party (later the National Party) that represented the interests of tobacco growers (Tyrrell, 1999). The print and other media strongly opposed any advertising bans because tobacco advertising was a major source of their revenue; they refused to print anti-smoking advertisements into the 1970s to avoid offending the tobacco industry (Walker, 1984). Treasury also obtained a substantial amount of tax revenue from tobacco excise. For all these reasons, Australia lacked any effective public health

policies to reduce the prevalence of cigarette smoking until well after the end of conservative rule in 1972 (Walker, 1984).

In the 1960s, the Australian public health community followed the example of the UK in supporting a form of tobacco harm reduction. The Anti-Cancer Council of Victoria (now Cancer Council Victoria) campaigned to reduce cigarette tar yields (King et al., 2003), and the NMRC recommended that cigarette packs include information on tar content. The tobacco industry voluntarily implemented this policy in 1982, and the government made disclosure mandatory in 1994. The industry knew that low tar yields were misleading because filter ventilation (introduced in the 1970s) enabled smokers to engage in compensatory smoking (King et al., 2003). This early failure of tobacco harm reduction led the Australian public health community to follow the UK in focusing on encouraging smokers to quit and stopping adolescents from initiating smoking (Berridge et al., 2021).

Advocacy for more vigorous tobacco control in the 1970s and 1980s came from NGOs and activists who worked outside government (Chapman, 2008). They campaigned for bans on cigarette advertising on television and billboards; government-funded media campaigns to encourage smokers to quit bans on smoking in public places and workplaces; and higher tobacco taxes to encourage smokers to quit and discourage young people from smoking (Chapman & Wakefield, 2001, Tyrrell, 1999).

The campaign for more effective tobacco control policy in the 1970s was under the leadership of state cancer societies and Australian medical colleges (Walker, 1984). These bodies followed the UK lead in establishing an Australian Action on Smoking and Health (led by Steven Woodward) that campaigned for increased tobacco taxes and an end to cigarette promotions on television, in print advertising and via sports sponsorships.

The Victorian Anti-Cancer Council played a leading role under the leadership of the physician Nigel Gray and the psychologist David Hill (Tyrrell, 1999). Gray and Hill published data on the prevalence of smoking, the most influential of which included the "killer fact" that the preferred cigarette brand among Australian adolescent smokers in each of Australian states was the brand that sponsored the most popular football teams in each state (Gray, 1989). Gray also persuaded the Victorian State government to use state tobacco taxes to replace tobacco industry

sports sponsorship which helped to end tobacco industry use of sports to promote smoking (Tyrrell, 1999).

An Australian innovation in tobacco control was civil disobedience campaigns by the group Billboard Utilising Graffitists Against Unhealthy Promotions (BUGA-UP) founded in 1979. BUGA-UP activists attracted public attention by defacing cigarette billboard advertisements. Some were prosecuted but only lightly fined by sympathetic magistrates (Lewis, 2007; Tyrrell, 1999). In combination with the media advocacy of Simon Chapman, Nigel Gray, Steve Woodward and others, the tobacco control movement had their first victory in ending tobacco industry sports sponsorship, cigarette advertising on billboards and, much later, the print and television advertising of cigarettes (Chapman, 2008).

In the 1980s and 1990s, legal actions were successfully brought against employers for tobacco-related diseases in non-smokers who had been exposed to tobacco smoke in the workplace. These actions forced employers to ban smoking in workplaces. They later led governments to ban smoking in public transport and, later still, in public spaces such as restaurants and bars and public transport.

In the early 1990s, the Australian tobacco control community secured a ban on the commercial importation of smokeless tobacco products, such as chewing tobacco, oral snuff and snus (Greenhalgh & Hanley-Jones, 2023). During the 1980s, some states banned the sale of these products because their use had increased among young people in other countries (Gartner & Hall, 2009). In 1991, the federal government banned the sale of all smokeless tobacco products, including chewing tobacco, using the Trade Practices Act Greenhalgh and Hanley-Jones (2023). The ban aroused little opposition because very few Australians used these products. Individuals were allowed to import up to 1.5 kilograms of smokeless tobacco products for personal use, but tobacco import taxes made this very expensive (Greenhalgh & Hanley-Jones, 2023). In mid-2006 there was a significant increase in taxation on these products, from 2.30/kg to 300.39/kg, 3 taking the customs duty into line with that in all other tobacco products.

In Australia, smoking cessation support has been provided by general practitioners and state-based telephone counselling Quitlines. The main focus has been on motivating smokers to make a quit attempt without medication, an approach advocated by Simon Chapman who argued that quitting by going “cold turkey” was the most effective approach to cessation (Chapman, 1985; Chapman & MacKenzie, 2010). NRT has been

available for over-the-counter sale in Australia as a transdermal patch form since 1997 and in gum form since 1998. Bupropion and varenicline were publicly subsidised in 2000 and 2008, but NRT was only subsidised in 2011, in response to evidence that smoking was becoming concentrated among socially disadvantaged Australians (Greenhalgh et al., 2016).

In Australia, as in the US, the tobacco industry campaigned to undermine public health efforts to educate smokers about the health risks of smoking. Australian subsidiaries of US and British global tobacco companies used many of the same tactics to reassure Australian smokers and raise doubts about the health risks of smoking. These included marketing filtered, light and low nicotine cigarettes; using visiting "experts" to question the risks of cigarette smoking (Carter & Chapman, 2003); and opposing the introduction of smoke-free policies by attacking research on the risks of environmental tobacco smoke (Chapman & Penman, 2003). They also later opposed tobacco pack health warnings and took legal action in the High Court in a failed attempt to block mandated plain packaging of cigarettes.

Successful tobacco control policies reduced the adult prevalence of cigarette smoking from 35% in 1980 to just over 20% in 2010 before e-cigarettes became available and to 14.7% in 2019 (Greenhalgh et al., 2020). As we will show, the steady decline in the prevalence of cigarette smoking been used to argue that e-cigarettes other forms of tobacco harm reduction are not needed in Australia (Berridge et al., 2021).

5 US

The history of public health in the US in nineteenth century is not dissimilar from that of the UK. As in the UK, public health began to focus narrowly on the promise of bacteriology and the conquest of germs after 1900. Curing diseases in individuals, not broad social, occupational or environmental reform, would be, in the minds of a new breed of public health professionals, both cheaper and more effective (Fairchild et al., 2010). After World War II, biomedical research took on the promise of population protection (Scheffler, 2019) in a context in which consumer culture took on increased importance in American notions of democracy and freedom (Cohen, 2003).

At a moment in which cigarettes dominated consumer culture, the American public health saga regarding tobacco began with the 1964

Surgeon General's report linking cigarettes and lung cancer. No understanding of the contours of the political, scientific and public health dimensions of the bitter controversy regarding the promise and peril of e-cigarettes in the US is possible without an appreciation of the social context that had been created by a six-decade-long campaign, sometimes halting, against combustible cigarettes. It was a context marked by a legacy of deceit and manipulation by the tobacco industry one within which a challenge to smoking as a broadly accepted social behaviour had to confront the uniquely important role of anti-paternalism in American social discourse, a role that would, for years, necessitate the shaping of anti-tobacco policy in terms of the protection of the medical and social interests of non-smokers and of children.

But it was also a context marked by an increasing focus on individuals, their choices and their "treatment." Understanding the relationship between smoking, disease and death was central to the rise of "risk factor" thinking in epidemiology in the US in the 1950s and 1960s. Risk factor thinking is important because it focused attention on individuals and their behaviour and made it harder, in a context in which talking about race and class in the US was fraught, to focus attention or action on the social determinants of health (Oppenheimer). Most forcefully making the linkage between risk factor thinking and not just individual behaviour but rather individual responsibly for disease was John Knowles, a widely known physician and President of the Rockefeller Foundation. In a classic piece, Knowles captured American thinking on the role that public health had to play in combatting disease: "Over 99 percent of us are born healthy and suffer premature death or disability only as a result of personal misbehavior…." He can either "change his personal bad habits or stop complaining. … Beneficent Government cannot—indeed, should not—do it for him" (Knowles, 1977).

Within this landscape, the Office of the Surgeon General, the US Centers for Disease Control and Prevention (CDC), the Food and Drug Administration(FDA), national health-related NGOs (e.g. American Cancer Society, American Lung Association Campaign for Tobacco Free Kids Action on Smoking and Health, Foundation for Non-Smokers Rights) and researchers who played a major role in confronting the tobacco industry were the key stakeholders shaping the interpretation of evidence, appropriate policy targets and acceptable policy options.

It was only when the prevalence of smoking had dramatically declined and the social class composition of smoking became characterised by a

steep social gradient that public policy would take on an explicitly neo-prohibitionist dimension, one in which the goal of protecting smokers from their own behaviours was paramount. It was at that moment that e-cigarettes entered the market.

Considering this context, it is not surprising that even as his 1964 report spurred the American anti-tobacco movement, the Surgeon General described research into new, less threatening cigarettes as "a promising avenue for further development". In the early 1970s, the government spent $6 million a year to try to develop safer tobacco products. Even former US Secretary of Health, Education, and Welfare Joseph A. Califano Jr., who called smoking "Public Enemy No. 1," saw a place for "research aimed at creating a less hazardous cigarette" (Califano, 1978). As late as 1981, the Surgeon General advised smokers who could not or would not quit to switch to low-tar and low-nicotine brands. The American Cancer Society although worried that the development of less hazardous cigarettes might derail efforts to deter people from smoking or getting them to quit—supported "frank scientific discussion about the possibilities of developing cigarettes that will be less harmful and still satisfying to smokers" (Fairchild & Colgrove, 2004).

The AIDS epidemic in the 1980s compelled the US to confront its prohibitionist policy on injecting drug use. The evidence was clear that sharing injection equipment was an efficient means of HIV transmission. The Netherlands was the first to report that providing drug users with sterile equipment could reduce the incidence of infection. HIV activists in the US became strong proponents of such an approach even as heroin possession and use remained criminal. Advocates framed harm reduction as a pragmatic tactic for reducing but not eliminating all risks. The animating idea was that there were some who could not or would not stop drug use, regardless of whether it was legal or illicit. Harm reduction approaches, then, fell short of blanket prohibitions on behaviour or bans on products that carried any degree of risk needles and syringes we are condemning large numbers of addicts to death from AIDS".

Needle exchange was utterly unacceptable to those who saw addiction, in and of itself, as a threat to be confronted, not facilitated. For many in African American communities, this was especially true. It sent "the wrong message" to society that drug use is acceptable. It thereby risked undermining other messages that would reduce harm to a greater extent. As a corollary, critics charged that harm reduction activities encouraged the initiation or continuation of potentially risky behaviours. It thereby

perpetuated rather than attenuated harm. While individual harms might be reduced by efforts to make use safer, this reduction could be accompanied and even outweighed by an aggregate rise in harm (Fairchild & Colgrove, 2004). In the UK, the absence of a racial element to the debate was one factor which helped the adoption of a harm reduction approach (Berridge, 1993).

But even as the case for harm reduction in the case of injecting drug users was gaining wide scientific support, American optimism over tobacco harm reduction came to a halt in the 1980s. Stunning revelations from high-profile court cases demonstrated that the tobacco industry had, for decades, lied about the dangers of smoking and manipulated the levels of nicotine in its products to ensure that smokers stayed addicted. Opposition to anything less than total cessation became the new orthodoxy. It was reinforced by clinical guidelines describing smoking as a chronic disease, the availability of over-the-counter nicotine replacement therapies and a new focus on the protection of bystanders from second-hand smoke and children from tobacco advertising. As the head of the American Heart Association put it in 2000: "There is no such thing as a safer cigarette" (Fairchild & Colgrove, 2004). A solid "'zero tolerance' philosophy" regarding harm reduction involving safer cigarettes took hold (Warner, 1997).

It is against this backdrop that we can turn to the nearly six-decade effort on the part of anti-tobacco activists and public health officials to address the burdens of combustible cigarettes. To avoid the spectre of the nanny state, those who shaped anti-tobacco policy in the first decades after the Surgeon Generals 1964 Report made protection of non-smokers and children central while pursuing three broad strategies, namely the protection of youth and "innocent" bystanders (non-smokers unwillingly exposed to second-hand smoke), the denormalisation of smoking and taxation. In the course of pursuing these strategies over half a century, the CDC (Communicable Disease Center, now the Centers for Disease Control and Prevention) assumed a critically important federal role.

The protection of youth took on a new force in the late 1980s into the 1990s. The introduction of Joe Camel ads—clearly designed to appeal to the young—in 1988 drew widespread condemnation (Fairchild & Colgrove, 2004). Food and Drug Administration Commissioner David Kessler's sought to reframe smoking as a "paediatric disease." The 1994 Surgeon General's Report, Preventing Tobacco Use Among Young People, exemplified this stance in its claim that "When young people no

longer want to smoke the epidemic itself will die" (Department of Health and Human Services USA, 1994).

Ultimately, an anti-tobacco movement in the US determined that it had to challenge the normative culture that made smoking acceptable, even desirable. An analysis from the early 1990s vividly captured the underlying goal: "Increasing restrictions on smoking in public places to protect non-smokers from toxins in [environmental tobacco smoke] undermines the social acceptability of smoking. Decreasing the social acceptability and mandating restrictions on where and when one can smoke in turn discourages children from starting to smoke and facilitates adults' decisions to cut down or stop smoking. While generating significant health benefits for smokers and nonsmokers, this drop in cigarette consumption translates into fewer sales and lower profits for the tobacco industry" (Bayer & Feldman, 2004). California's campaign to denormalise tobacco consumption, which began in the early 1990s, sought to push tobacco out of "the charmed circle of the normal, desirable." Lauding these efforts, anti-tobacco activists wrote, "In a society where smoking is not viewed as an acceptable activity, fewer people will smoke, and as fewer people smoke, smoking will become ever more marginalized" (Gilpin et al., 2004).

Those committed to the reduction of tobacco-related mortality and morbidity came to explicitly endorse a strategy of marginalisation and stigmatisation, as apparent in a 2006 report in the *American Journal of Public Health* titled, "Effect of Increased Social Unacceptability of Cigarette Smoking on Reduction in Cigarette Consumption" (Alamar & Glantz, 2006). After noting that bans on smoking in restaurants, bars and homes were as effective as taxes in reducing tobacco consumption, the authors concluded, "Our results indicate that increasing the social unacceptability of smoking is a highly effective policy tool in reducing consumption. Tobacco control programmes should stress the dangers of environmental tobacco smoke and reinforce the nonsmoking norm" (Bayer, 2008).

The complex politics of tobacco policy was underscored by the ultimate failure of an FDA effort to impose graphic warnings on cigarette packages. Reflecting the unique American conception of the constitutional protection of advertising as a form of speech, federal courts held that requiring graphic messaging represented "compelled speech," violating the First Amendment to the US Constitution protecting freedom of speech.

Six decades of anti-tobacco efforts produced a radical transformation. In 1963, more than half of men and a third of women in the US smoked.

By 2019, only 14% of adults smoked. The gap between men and women had substantially closed: 15.3% of men and 12.7% of women smoked. Despite this progress, a sharp social gradient in tobacco use emerged, with people of low-income and less formal education the most likely to smoke (Feldman & Bayer, 2011). By 2016, 35.3% of those with a high school equivalence degree smoked in contrast to only 6.9% of college graduates and 4.0% of those with graduate degrees (CDC, n.d.).

The policy trajectory that produced this epidemiological tobacco transition would ultimately have a profound influence on the response to e-cigarettes.

6 Conclusion

Although all three countries had a similar history of hostility to tobacco as a central plank of public health policy, our summaries of the prehistory of e-cigarette policy underscore differences between them. Note for example: the US unwillingness to control advertising because of the right to freedom of speech and focus on individual smoker treatment; the Australian belief in the superiority of "cold turkey" for smoking cessation rather than treatment; and the important British tradition of harm reduction using nicotine.

Each of the three countries had, by the twenty-first century, embraced increasingly restrictive measures to limit the toll of tobacco cigarette smoking. Each in its own way moved in the direction of neo-prohibitionist policies that would have been unthinkable decades earlier. In each, years of confrontation with the tobacco industry transformed a formerly vibrant industry into a social pariah. In each nation, there was a dramatic decline in prevalence of smoking so that smoking which had been normative behaviour in the 1950s had become increasingly marginalised. For some, the policy question at hand was how the "tobacco end game" would be played out.

The ensuing policy battles over e-cigarettes in each country can only be understood with an appreciation of this public health context. What is striking, and what motivated us to write this volume, was the fact that each of these countries pursued differing public health policies while appealing to the same bodies of evidence. In the case of England and Australia, in particular, the difference in approach was dramatic. Yet, as influential as each was in the global debate, all three nations came to understand the promise and risk of e-cigarettes in radically different

ways. Each came to interpret the available evidence differently; each addressed the evidence from the perspectives of harm reduction and the precautionary principle in utterly divergent manners.

The national narratives to which we will now turn make it abundantly clear that it is inadequate to understand sound public health policy making as a matter of "implementation science." Only a direct recognition of the role that history and politics played in shaping public health policy can permit us to fully understand how and why very different policy determinations were made. Amassing scientific evidence on the public health effects of e-cigarettes is not the end of the story; it is just the beginning.

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CHAPTER 2

Outlier or Pioneer? the Development of Policy on E-Cigarettes in England

Virginia Berridge

Abstract In England, support for nicotine replacement therapy and for nicotine as a harm reduction agent expanded from the 1990s. The Labour government gave support as part of its anti-tobacco strategy and focus on inequalities. Action on Smoking and Health (ASH) the main anti-smoking activist organisation, also changed position. When e-cigarettes came on the scene ASH was important in including them within harm reduction and in assembling a coalition of support which included regulatory agencies. The coalition government also gave support. Medicinal licensing was intended but events in the European Parliament saw a consumer product approach adopted. The US EVALI epidemic did not affect England but shook public confidence. Recently, medicinal licensing has come back onto the agenda with a greater focus on young people.

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In England, policy makers have embraced the possibility of e-cigarettes (ENDS) to reduce tobacco-related harm by encouraging smokers to use them to quit smoking or as a long-term substitute for cigarettes. Regulation has been in ways which facilitate access by smokers. How did this come about? This chapter will examine how the tobacco policy arena developed in the 1980s and 1990s and the changing role of nicotine within that constellation. The acceptability of nicotine as a harm reduction strategy predated the arrival of e-cigarettes and this was a key factor in their initial reception. UK regulatory agencies also changed stance and the role of the EU was of importance in placing e-cigarettes within consumer regulation rather than medicinal licensing, at least initially. ASH, important as an activist organisation, changed stance before their arrival, and was crucial in building a coalition of support among influential organisations. So pre-history, the context of what had gone before, was of great importance in the English sphere. E-Cigarettes fitted into a welcoming policy context.

1 Nicotine From the 1970s

One area of tobacco research had diverged from the public health norm over several decades: this was the use of nicotine for tobacco harm reduction. There had been some early work on nicotine funded by the tobacco industry that was presented to the Royal College of Physicians committee in 1969 and published in *Nature*. The psychiatrist Michael Russell, based at the Addiction Research Unit at the Institute of Psychiatry, undertook research on nicotine with Medical Research Council (MRC) funding. Russell was a member of the third Royal College of Physicians committee in the 1970s, but his views differed from those of the other members. Russell argued that it would be more practical to make a much safer cigarette rather than to try to stop people from smoking. The minutes of the committee recorded "…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 laid on safer methods of smoking. *It was agreed* that this dilemma should be discussed in the report as the kind

of problem that doctors have to face in giving advice" (Royal College of Physicians, 1975).

Russell was interested in using nicotine as a smoking cessation treatment. He developed a strong link with the Swedish pharmacologist Ove Ferno, whose research on nicotine chewing gum for use by submariners (who could not smoke on board) had been presented to the second world conference on smoking in 1971. Russell and Ferno developed a nicotine replacement therapy (later renamed Nicorette) that slowly made its way into medical practice. Until the late 1980s, nicotine gum was only available on private rather than NHS prescription.

Russell and the psychologists who worked with him were outside the public health mainstream at this time. They were addiction scientists not public health researchers. In "Nicotine Use after the Year 2000" published in the *Lancet* in 1991, Russell argued for a nicotine addiction harm reduction model:

> What distinguishes nicotine from other widely abused drugs is that its effects are subtle and do not cause socially disruptive intoxication, provoke violence, or impair performance. Yet deaths due to tobacco far outnumber those caused by all other drugs. The central paradox is that, while people smoke for nicotine they die mainly from the tar and other unwanted components in the smoke. Why have governments persisted in allowing the manufacture, extensive advertising and promotion of such a lethally contaminated drug delivery system as the cigarette, while putting so little pressure on the tobacco industry to develop more purified forms of nicotine delivery? (Russell, 1991)

Russell's work was not popular within the public health smoking field because of his emphasis on the role of nicotine in harm reduction. But he developed a cadre of researchers that included Martin Jarvis, Ann McNeill, and Peter Hajek, who later became leaders in UK research and policy on nicotine and e-cigarettes. Russell's work was important also because of its location in a research setting, the Addiction Research Unit, which brought together researchers on drugs and alcohol as well as on tobacco.

Substantial research on nicotine took place in the UK from the 1980s onwards under the aegis of the Independent Scientific Committee on Smoking and Health (ISCSH), a Department of Health committee reporting directly to ministers. This was funded by the Tobacco Products Research Trust (TPRT) funded at arm's length by the tobacco industry

to do research on product modification. A major symposium organised by the CIBA Foundation the MRC and the TPRT in 1986 concluded that the toxicity of cigarettes would be reduced more if tar levels were reduced more than those of nicotine. Dependence or addiction to nicotine was recognised as a double edged concept. Nicotine levels in cigarettes could be maintained in order to reduce harm-or they could be lowered in order to wean smokers off the habit. This work marked the arrival of addiction as an important science/policy concept in the tobacco field (Berridge, 2005). It was of some use to the "stop all smoking" public health camp but also to those who favoured harm reduction, who clustered in a different scientific network. The recognition of a group of smokers who could not give up, who were generally among the poorer sections of the population, helped support the interest in strategies to combat this problem.

In the UK, the concept of nicotine addiction, and the use of nicotine for smoking cessation, benefitted from increased policy attention to social inequalities in health. By the mid-1990s, GPs could prescribe both Nicorette nasal spray and Nicotinell chewing gum on the NHS. Direct advertising of the gum was allowed in 1998, and gum of two strengths and transdermal patches were sold to the general public. In the Labour Government's White Paper, *Smoking Kills*, published in 1998, NRT was given a central role in reducing social inequalities. It played a similar role in a Royal College of Physicians report on *Nicotine Addiction* in 2000 and a government inquiry into health inequalities chaired by Sir Donald Acheson, the former Chief Medical Officer. There were also calls to establish a nicotine regulatory authority. These events, and the response to nicotine, shaped the subsequent development of policies on e-cigarettes.

Initially however, harm reduction was not to the fore. This was demonstrated by the case of Skoal Bandits in the 1980s. In 1985, Alison Hillhouse, director of ASH Scotland, heard that US Tobacco, with financial support from the British government, was to open a factory in Scotland to manufacture Skoal Bandits, a type of oral snuff. This prompted a campaign which ended five years later with the British government's announcement that it would ban oral snuff. Snus, a smokeless tobacco pouch popular in Sweden, was also banned by the EU in 1992 although Sweden was given an exemption for its use when it joined the EU in 1994 (Raw et al., 1990). ASH, the main activist organisation in the UK, resolutely anti-industry under the leadership of Mike Daube, its second Director in the 1970s, was in trouble in the early 1990s. There

were internal problems and personality difficulties after David Simpson, who had been a campaigning director, left in 1990. ASH adhered to its oppositional stance of the 1970s, but with more focus on information rather than campaigning. Hence, it was hostile to the model of addiction, which it thought could undermine the focus of the anti-tobacco movement on giving up or quitting. ASH also supported and advocated for the EU ban on snus. Anti-tobacco was now an international movement and there were moves at the international level which eventuated in 2003 in the Framework Convention on Tobacco Control (Reubi & Berridge, 2016). This had a harm reduction component but the elimination of tobacco was to the fore as the major goal (Reynolds, 2012).

The policy mood began to change quite significantly in the late 1990s. The election of the Labour government in 1997 and a heightened focus on inequalities was a crucial watershed. Even before the political change, researchers had begun to focus on nicotine and its role in combatting inequality. The Health Education Authority, which had been a bastion of abstentionist sentiment, organised an international conference and published a report on regulating nicotine delivery systems. In a paper given at the London School of Hygiene and Tropical Medicine (LSHTM) in 1996, the smoking researcher Martin Jarvis, a leading member of Russell's group, linked inequality, NRT and availability on NHS prescription.

> Deprived smokers are the most dependent smokers…What are the implications for treatment? There has been much thrust towards a health education message. Get the poor to take smoking seriously. That kind of idea is not supported by the data. We need to find interventions which target dependence more effectively. Make the prescription for nicotine reimbursable. (Jarvis, 1996)

By the mid-1990s, both Nicorette nasal spray and Nicotinell chewing gum were prescribable on the NHS, but GPs had to justify the circumstances under which the prescriptions were written. Direct advertising of the gum came in 1998; and gum, along with transdermal patches were on sale to the general public.

There was interest in the highest levels of public health. One researcher remembered the then Chief Medical Officer, Sir Kenneth Calman, encouraging moves on NRT and NHS prescription.

> Ken Calman, ….he challenged us because we were saying we're not quite sure what to do about nicotine replacement therapy and we were discussing it and then he said well why don't you ask for it to be on prescription and we said because we'll never get that and he said well aim high. And so we then as our working group came up with that recommendation. And although Smoking Kills didn't make it an NRT on prescription, it allowed for one week supplies for people who were getting behavioural support. It led the way I think, it paved the way to NRT being on prescription. There wasn't this kind of row then. I mean there were some people who didn't think treatment is important, who felt that population approaches were the way to go. But if you're in front of an addicted smoker, even if they haven't got a smoking related disease, or if they've got a smoking related disease, you want to throw the kitchen sink at them to get them to stop. (McNeill, 2018)

In the Labour government's White Paper *Smoking Kills*, published in 1998, NRT was given a central role in the battle against smoking and inequality, which were linked together. NRT was to be free for a limited period to those on low incomes and there was the possibility of NRT in pregnancy for the heaviest smokers. The Royal College of Physicians issued a report on nicotine addiction in 2000 (Royal College of Physicians, 2000). The public health field also began seriously to consider harm reduction as a strategy. Innovations such as the smokeless cigarette and nicotine delivery devices led to calls for a nicotine regulatory authority which would consider all these varied modes under one regulatory umbrella.

Part of the change of position was a sea change in the stance and positioning of ASH. The resolute opposition of that organisation to smoking and its adoption of an absolutist stance had been a central part of the anti-tobacco coalition established in the 1970s. But this position began to change in the 1990s. Clive Bates became its director in 1997 and took the Michael Russell view of nicotine and harm reduction, making a powerful intellectual case for harm reduction. He was supported by some on the ASH Board, in particular John Britton, who chaired the Royal College of Physician's Tobacco Advisory Group. But public health members of the Board such David Simpson, its former Director, and Jean King, of Cancer Research UK, were not comfortable with this stance. Bates left ASH and moved to the Policy Unit at Downing Street. He was succeeded in 2003 by Deborah Arnott, who came from the Financial Services Authority, where she had been head of Consumer Education. Her major focus

initially was on achieving smoke free legislation, which occupied her attention between 2003 and 2007. But she also continued policy support for harm reduction with highly effective alliance building. The main activist organisation in the UK had therefore completely changed stance on harm reduction and nicotine prior to the advent of e-cigarettes. Its powerful advocacy skills and skilful networking was exercised on behalf of the idea of harm reduction.

2 Harm Reduction Expands for NRT 2000–2010 and for E-Cigarettes

In the first decade of the twenty-first century, there was an expansion of indications for NRT under the aegis of the Medicines and Healthcare Regulatory Authority (MHRA) the licensing body for UK medicines. In February 2010, the MHRA published a report, *Nicotine Replacement therapy and harm reduction*, which was the product of an expert working group established in 2005. It stated clearly at the outset

> There is a new element to the indication of nicotine replacement therapy (NRT) of 'harm reduction' since it has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT. (MHRA, 2010)

The process by which the MHRA had moved to this position had been a gradual one. There had been moves to involve the agency before but without success. Deborah Arnott contacted Kent Woods, its new chief executive.

> …from a strategic point of view he got it and …as a result of that an expert committee was set up to look at how NRT was licensed and the MHRA changed its position significantly…..the particular thing we were pushing for was if people aren't using NRT they will go back to smoking….So you need to licence it in that context, not as you would a novel and potentially highly risky drug. (Arnott, 2018).

The expert working group was set up in 2005 to review the usage of NRT. Its membership included Ann McNeill, a member of Russell's group and an experienced public health researcher. It recommended that restrictions on NRT use should be minimised for pregnant and breast feeding women;

patients with heart disease; those with kidney and liver problems and with diabetes, and children aged 12–18 years. Then the indication for NRT was extended, such as by "cut down to quit," and "temporary abstinence" introduced in 2005 and 2006. This was supported by data from clinical trials showing NRT as an effective intervention in achieving sustained smoking abstinence for smokers who had no intention to stop completely or who were unable to quit abruptly. With advice from the Commission on Human Medicines (CHM) in October 2009, MHRA approved an extension to the indication to include a harm reduction element for a particular product—the Nicorette Inhalator—either as a complete or partial substitute for smoking. This harm reduction approach was a significant plank in the wider strategy on tobacco launched by the Department of Health at the same time.

The MHRA recognised that the extension of the indication for NRT to include harm reduction marked a major shift in medicines regulation. It concluded.

> NRT has to date not been licensed for harm reduction and the decision to do so raises the question of the regulation of other unlicensed nicotine containing products on the market such as electronic cigarettes, which have not been assessed for safety, quality and efficacy. (MHRA, 2010)

At the same time, as medicines regulation was moving to accommodate harm reduction for NRT, influential professional bodies were also moving in the same direction. In 2007, the Tobacco Advisory Group of the Royal College of Physicians (RCP) published its report, *Harm reduction in nicotine addiction; helping people who can't quit* (Royal College of Physicians, 2007). It explicitly tied this new direction to the RCP's pioneering work in the 1960s. The measures of the 1960s, however, did not address the problem of smokers who could not quit. The new report

> demonstrates that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.
>
> Harm reduction is a fundamental component of many aspects of medicine and indeed everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking.

The emergence of a coalition around the principle of harm reduction for nicotine was underlined by the composition of a UK delegation which went to Washington, DC in January 2010. There was US interest in e-cigarettes and the principle of harm reduction. The delegation contained representatives of the voluntary sector, academics and different branches of the government and regulatory institutions presenting a united front. It was hosted by Mitch Zeller of the FDA Tobacco Centre. Its members were Deborah Arnott, director of ASH, Martin Jarvis, long-term researcher with Michael Russell, June Raine, director of vigilance risk management of medicines for the MHRA and Oliver Smith, Deputy director of Tobacco, Health and Wellbeing Policy at the Department of Health. The delegation visited the FDA Centre for Tobacco Products; NIH; the Legacy Foundation; and the Department of Health and Human Services. June Raine presented the MHRA view.

> Tight regulation of medicinal nicotine imposes strict restriction on new product development. This clear and unjustifiable regulatory imbalance works against public health. The regulation of nicotine products needs to be radically overhauled.…UK regulatory controls on NRT products have evolved stepwise over the last decades, increasing choice and widening access.…The radical new approach now being developed in the UK uses regulation to encourage use of less harmful products and reduce use of more harmful sources of nicotine. (Raine, 2010)

Although this demonstrated the strength of the UK policy coalition, there was little change in US policy as a result.

Deborah Arnott was busy engaging with relevant interests and organisations in the field. Together with John Britton, she went to see Sir Michael Rawlins, head of NICE (National Institute of Clinical and Healthcare Excellence) the non-departmental public body which reviews evidence and produces guidelines. Rawlins was a smoker, known during his period at NICE for going out of the room to have a quick smoke. He understood the issue. NICE then organised one of their citizens' events discussing NRT and tobacco harm reduction and that led into guidance on tobacco harm reduction, published in 2013. Arnott also produced a paper for the Treasury in 2006 reviving the old issue of price differentials and VAT. These were revised so that NRT over the counter attracted only 5% VAT rather than 20%. In 2010, the organisation produced a report called *Beyond Smoking Kills* which marked the tenth anniversary of the

Labour government's smoking White Paper. It reviewed the field after the achievement of smoke free legislation and asked, what next? It examined alternatives to smoking and what the regulatory framework should be, whether it should be medicines regulation, light touch regulation by the Department of Health, food regulation, or retaining the existing situation which was no regulation. It came down on the side of medicines regulation (ASH, 2010).

By this time, the first e-cigarettes were starting to come on to the market in the UK. Deborah Arnott remembered.

> I went to a lunch in a casino in central London and they were being imported by enthusiasts and people with an eye to the main chance, from China, they knew they couldn't promote them as a way to help people quit, they had this sort of third rate nonentity celebrity, who kept saying this is great it's helped me stop smoking. And they had to keep saying, no, you mustn't say that, it's an alternative to smoking otherwise it gets caught by the legislation. (Arnott, 2018)

ASH was also talking to the Department of Health about increasing the number of routes to quit and so it was in the official strategy document which consulted on the way forward for tobacco control. Jeremy Mead who worked for the MHRA and then became the tobacco lead in the Department of Health was important in embedding this approach. David Graham who worked for Johnson and Johnson was important in persuading them to put in an application for a long-term licence for NRT, which was agreed in 2010. This discussion was what brought e-cigarettes into the regulatory field. Previously, they had been seen as a "borderline product," not of interest to the MHRA. But if long-term licensing was on the cards, then e-cigarettes would be caught up in the process. So MHRA consulted on whether e-cigarettes should be regulated or just taken off the market. They were seen than as "a bit of an oddity" costing £80 a device. They were big and clunky. ASH had asked about e-cigarette use in its regular annual YouGov survey about attitudes relating to smoking and nicotine in 2010. Usage was tiny, so the cigarettes were not mentioned in the 2011 survey. But after that matters started to change. MHRA consulted about the position on e-cigarettes and their potential regulation. Both ASH and the RCP stated that they should not be taken off the market but should be regulated. But there were also a large number of responses from e-cigarette users who were worried that they would no

longer be able to use products which they had found useful. They were alarmed at the prospect of medicines regulation which would make these products less accessible.

Political support also came into the equation. The psychologist David Halpern who was leading the Behavioural Insights Team in Downing Street (the "Nudge unit") under the coalition government, took up the issue. He was surprised to find people who might have been anti-tobacco—John Britton and ASH—in support of e-cigarettes. The unit's new year document on health behaviour in 2011 was to include a section on the case for e-cigarettes but at the last minute this had to be taken out on the insistence of the Department of Health. Then a battle opened within government with most of the mainstream public health community, including the Chief Medical Officer, coming out against e-cigarettes. The Unit took the issue to the Prime Minister, David Cameron, who had been a smoker and had even tried an e-cigarette. Cameron supported their line and they decided to stick to the objective of light touch regulation to ensure the product was free of toxins but had enough nicotine to satisfy smokers' cravings, and to legislate to ensure they were not sold to under 18s (Halpern, 2019).

So the first decade of the twenty-first century in England, even prior to the arrival of e-cigarettes on the scene, had seen significant advances in the role of nicotine and NRT as a harm reduction strategy in the tobacco control field. Key influences here were the changing attitudes of the leading activist organisation and the skills of its leadership; the growth of an coalition involving researchers, ASH, and government regulatory agencies such as MHRA and (to a lesser extent) NICE. E-Cigarettes fitted into this framework and political support helped. In June 2013, on advice from the MHRA the government proposed to regulate all non-tobacco nicotine products, including e-cigarettes, as medicines.

3 The Role of Europe

However, there was another aspect to regulation. This was Europe and the EU. Membership of the EU required the UK to comply with regulations mandated under the EU Tobacco Products Directives (TPD). These regulations also fitted with the preference of the Conservative government under David Cameron (on the advice of the Behavioural Insights team, the "nudge unit") for the use of "light touch" regulation to encourage smokers to use e-cigarettes as cessation aids and long-term

smoking substitutes (Halpern, 2015). It was during this process that a significant change to regulation occurred.

The European Commission had also intended to use medicinal licensing as the entry point, but this approach was voted down by the European Parliament on 8 October 2013. The Parliament decided that e-cigarettes would be regulated like tobacco. The policy change in the Parliament was brought about by an alliance of vaper activists, who made good use of social media, and obtained the support of MEPs, in particular, those from Italy and Germany. In 2014, passage of the European TPD (2014/40/EU) placed limits on the sale and merchandising of tobacco and tobacco-related products in the EU. In 2016, a revised TPD updated regulations on tobacco products and set new regulations. These required medicinal licensing if therapeutic claims were made for these products or if they contained more than 20 mg/ml of nicotine. They also placed limits on the sale and merchandising of tobacco and tobacco-related products in the EU. The European Parliament approved these regulations in February 2014. They prohibited the use of health or cessation claims when advertising these products and set limits on the maximum concentration of nicotine in products (20 mg) and the maximum volumes of liquid which could be sold. They also required child proof packaging of e liquids, specified purity of ingredients, devices that delivered constant doses of vapour and disclosure of ingredients and nicotine content. Regulators were empowered to act if these regulations were not met (European Union, 2014). The Tobacco Products Directive prohibited all forms of advertising capable of crossing borders. The English committee on advertising practice produced guidelines which balanced the protection of minors and the promotion of new low risk products to consumers. From 2015, restrictions on the age of sale (18 years) and advertising were introduced.

Clive Bates, observing what happened, commented.

> …E cigarettes were taking off, not just in the UK, I mean France and other parts of Europe as well and e cigarette users were enormously alarmed, understandably, about the idea that they'd become a medicine and that would mean they wouldn't be able to get hold of products they liked. There was a massive campaign…Linda McAvan (Labour MEP for Yorkshire and Humber)…was the lead on getting the TPD agreed and sorted, which is what led to a compromise position where e cigarettes could still be regulated as licensed medicines, if you put in an application, but if they're

> not, then they are caught as consumer products and under the TPD there's only limited advertising and limits on the size of tanks, and the size of refills, and they need to be child safe etc.…It was all done very last minute so it was not the most carefully thought through legislation and it has some problems.…it was a compromise, because member states really didn't like e-cigarettes and that's where the ad ban comes from.…and then there was this enormous pressure from e cigarette users and other member states who wanted to make sure they stayed on the market. (Bates, 2018)

The role of vaper activists was an important new dynamic and this fed back into the research community focussed on harm reduction. An e-cigarette summit organised by a vaper, Amanda Strange, began to meet in 2013 and this brought together academics and vapers. Bates commented on the impact this and the TPD change of stance had.

> They have got a much stronger connection to the people, who are the object of study and object of public health activity and they I think between them executed a very, this sort of graceful change of position back to, backed up by data, backed up by the statements that were coming out of the smoking toolkit, that the accumulation of studies, toxicology exposure studies and so on and also driven by their personal experience of meeting people. So the empathy and humility side of this played a really important role in my view, I don't think it was they all sat down in a room and had a meeting and decided that they got the policy wrong. (Bates, 2018)

The harm reduction alliance/network recognised that medicinal licensing was not going to be an immediate way forward. A tobacco company had put in a product but this did not make it through to licensing before it became obsolete. Consumer regulation was the way forward for the foreseeable future. E-Cigarette harm reduction moved back into the British political and regulatory apparatus, where a new organisation became important.

4 Public Health England and the Evidence

The new organisation was Public Health England (PHE), set up in 2013. The origins of PHE were in the Lansley, Conservative Health minister, reforms of the health service, which had involved the devolution of public health out of the National Health Service and into local government. The national agency set up at this time brought together a number of quangos,

(semi-public bodies funded by government) primarily the National Treatment Agency, which had dealt with drugs and alcohol and the Health Protection Agency, which had the brief of dealing with infectious disease, terrorist threats, chemical spills and so on. It had played a leading role during the swine flu outbreak of 2009–2010. The new agency brought together drugs, alcohol and tobacco; a single tobacco post was transferred from the Department of Health as there was no tobacco agency to amalgamate. A temporary post was advertised for tobacco control and Martin Dockrell, who had been policy officer at ASH, moved over into the new job.

Dockrell had a background in drugs harm reduction and also in sexual health/HIV/AIDS harm reduction and this had informed his work at ASH.

He commented.

> I arrived, harm reduction was the coming thing in tobacco control and the fact that I had history not once, but twice, first in injecting drug use and then in sexual health with harm reduction, I think we discussed this in my interview and I said that one of the things I wanted to achieve in my time at ASH is to avoid the kind of fratricidal bloodletting that we saw in the other, you know deeply personalised arguments between colleagues that we saw in harm reduction for drug use and then even worse in harm reduction in sexual health. I thought we could do better this time, we know how bad it could be, so let's plan to make it a lot less bad and that guided our thinking at ASH in the way we ran a whole string of consensus, I was going to say events, but more processes. (Dockrell, 2019)

He had been involved in the same sequence of events between 2000 and 2010 which had smoothed the path for nicotine and then for the regulation of e-cigarettes.

> …when the Royal College of Physicians produced their harm reduction, I think it was 2007 report on tobacco harm reduction, again we organised some consensus building work around that. So I think that's why, that's partly, so we had this whole series of reports and meetings, most of them private, where we would try to avoid that kind of public acrimony. And certainly we did avoid that public acrimony among everybody who took part in those processes and it was only really people who weren't part of those processes, who've, in the UK anyway, who've been, where the

> relationship has been a source of acrimony. So I think we probably avoided the worst of it, or at least when you look at the way the debate is conducted in the US and Australia, it's much worse. (Dockrell, 2019)

His objective at PHE was to align the new agency's position with what was described as the "English consensus" on harm reduction and nicotine.

> I arranged high level meetings between PHE leaders and some of the kind of top leaders in tobacco control and that was how we got that position. I've got to say I was pushing at an open door. Before I arrived, everything was being commissioned by PHE, on e-cigarettes, one of them from John Britton and one from the team at Stirling, which had been led by Gerard Hastings, much less, much more cautious about e-cigarettes. But about that time Gerard retired and Linda Bauld took over and Linda is much more in that kind of, in the harm reduction tradition. So it turned out that both evidence reviews that were commissioned were pretty positive and not commissioned by me and then PHE was right from the top very supportive in driving the direction. (Dockrell, 2019)

Public Health England produced a series of reports and evidence updates beginning in 2014/2015 and continuing a regular basis after that. In the UK Tobacco Control Plan of 2017 it was charged with providing these evidence updates up to 2022. The evidence updates were produced by a team led by Ann McNeill and were clearly distinct from the US approach. US researchers noted a difference in emphasis in the UK. In the UK the focus was on current smokers and how to help them. In the US the evidence focus was on the "innocent victim," children and bystanders. PHE was also crucially the catalyst for a coalition of supportive organisations in the UK. In 2015 its statement "E-cigarettes: an emerging public health consensus" was supported by a wide range of public health bodies: ASH; the Association of Directors of Public Health; British Lung Foundation; Cancer Research UK; Faculty of Public Health; Royal College of Physicians; Royal Society for Public Health; the UK Centre for Tobacco and Alcohol Studies; and the UK Health Forum (Public Health England, 2015). Early on it stated that vaping was 95% less harmful than smoking, and this statistic was often used against it in the following years. The figure came from a paper by a group of experts led by Dr. David Nutt, who had been chair of the government's drug advisory body, the Advisory Council on the Misuse of Drugs (ACMD), but who had been forced to resign when he controversially compared

the risks of horse riding (Equacy) with the risks of taking Ecstasy-the latter came out better. Nutt was forthright in his opposition to attacks by Professor Stan Glantz of the University of California San Francisco, an anti-tobacco veteran. Nutt was quoted by the *Guardian* health journalist Sarah Boseley,

> Does he actually think that tobacco is not much more harmful than vaping or the likelihood of lung cancer? The paper 'comes up with an answer he doesn't want. That's why he thinks its bad science'. (Boseley, 2020)

Ann McNeill, who led on the PHE evidence reviews, felt that they had been unfairly attacked for the 95% figure. A 5% risk of harm was not unsubstantial and the statement had been twisted as if PHE had said vaping was completely safe (Boseley, 2020).

The British Medical Association, which had earlier been unwilling to associate itself with harm reduction, came out in support in 2017 (BMA, 2017).

Further evidence review came in the same year, when the House of Commons Science and Technology committee examined the evidence again, including the evidence on these devices for smoking cessation, the suitability of regulations guiding their use and the financial implications of a growing market on business and the NHS. Its report supported e-cigarettes and other devices as a form of tobacco harm reduction. The committee concluded that

'Some aspects of the regulatory system for e-cigarettes appear to be holding back their use as a stop smoking measure' and recommended that regulations be liberalised (Science and Technology Committee, 2017).

5 Public Health Opposition

The publication of the PHE reports and official sanction for e-cigarettes brought some public health researchers into overt opposition. Martin McKee, Professor of European Public Health at LSHTM and Simon Capewell, Professor of Clinical Epidemiology at Liverpool University, were prominent among them. They attacked the 95% figure and the implication that e-cigarettes were safe in a series of articles, editorials and letters in the Lancet and the British Medical Journal (McKee & Capewell, 2015a, 2015b). They were joined by the President of the Faculty of Public Health, John Ashton (2014). A heated debate broke

out online with vaper activists weighing in against these leading public health figures. In September 2014, John Ashton apologised for language he had used on line in the debate with vapers and took several months leave of absence from his office while the incident was investigated. The public health researchers highlighted the potential adverse effects of the chemicals in e-liquids and the risk that they might serve as a gateway to cigarette smoking in young people. They favoured limitation of access to e-cigarettes as approved medical devices.

These opponents framed their attack within the long standing public health position on tobacco, formed in the 1970s and discussed above. The aim was elimination and deep opposition to the tobacco industry. Anything which threatened that position was of great concern. A seminar held on the new approach elicited the following response, remembered by Arnott

> the sort of attitude you get from traditional tobacco control people was summed up by someone…who had been in the area for a long time and said, when I hear John Britton speak it all makes sense, but it just doesn't feel right. And that's the issue you have is that it's not about evidence, it's about emotion. (Arnott, 2018)

This wariness about e-cigarettes was something which permeated the mainstream public health community. The Chief Medical Officer had come into conflict with the "nudge" unit about the issue; and in 2019 Dame Sally Davies, then CMO, expressed her continuing concerns to the Science and Technology Committee.

> E-Cigarettes are clearly much safer than tobacco smoking, and they have become a much-liked way of stopping smoking. If they help people to stop, they are so much safer so I would like them to use them. I would encourage the NHS smoking cessation services to work with that.' Nevertheless, she continued, "I have concerns because we do not know their long-term side-effects. Therefore, not only do I reserve my position on this, but I would like us to be careful. It took us 50 years, as I said earlier, to discover the harm of tobacco. Being much safer does not mean it is safe. I just don't want us to set an example to children of them being smoked or used publicly…….. I don't want that pollution and I don't want it put over as a cool lifestyle, because it's an addictive product. Why introduce and have openly available a new addictive product? (Science and Technology Committee, 2019)

This public health approach was in sharp contrast to the network supporting harm reduction. The Royal College of Physicians 2016 Report *Nicotine without smoke: tobacco harm reduction* gave its take on policy.

> A risk averse, precautionary approach to e- cigarette regulation can be proposed as a means of minimising the risk of avoidable harm e.g. exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.
>
> However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult (Royal College of Physicians, 2016).

So whereas in the 1970s anti-tobacco activism had been the main thread within the public health field, by the time e-cigarettes came on the scene, the role of nicotine in harm reduction had assumed greater importance. Whereas the researchers of the 1970s had been located in the addictions arena, far from the public health mainstream, by the turn of the century, their role and significance within public health and also within policy, had become more significant and central. Public health researchers had engaged little with nicotine products whereas addiction scientists had.

6 Getting the Balance

By 2018–2019, it seemed as though this balance had been reached. Data from the Office of National Statistics survey (ONS) showed that UK adult smoking prevalence had fallen from 20% in 2011 to 14.7% in 2018. There were 7.2 million smokers in that year. Meanwhile vaping prevalence reached 6.3% in 2018, a rise from 3.7% in 2014 and from very low levels in 2011. There were 3.2 million vapers in the UK in 2018.

Clive Bates commented,

> Vaping has become a large scale phenomenon relative to smoking and appears to be having significant downward pressure on smoking rates. In England, we are witnessing tobacco harm reduction in action and starting to benefit from a public health win. (Bates, 2017)

However, events soon occurred which helped to undermine this optimistic assessment.

6.1 The EVALI Epidemic

In September 2019, an outbreak of serious lung disease in the US made headlines round the world. By October of that year, 1604 cases had been reported to the Centres for Disease Control (CDC) in the US, including 34 deaths. The group of people involved was very specific. This was an outbreak largely among young men: 70% of patients were male with an average age of 24. Almost half were under 21. Several US states banned the use of flavourings in e-cigarettes and called for urgent action. By December 2019, it had become increasingly clear that e-cigarettes based on THC and vitamin E acetate were the likely cause of the US outbreak of lung injuries. Vitamin E was used as a thickening agent for cannabis vaping and was toxic to the lung. Remarkably, however, that new information did not reduce confusion about the source of the injuries in a US context in which the youth vaping rate was increasing. The evidence that the acute lung injuries were related to contaminated THC products was lost in media reporting that lumped together very different types of products under the heading of e-cigarettes (vaping nicotine with flavours, vaping nicotine without flavours, and vaping THC and CBD cartridges), all of which were sold in some legal retail outlets and on the black market.

In the UK, the traditional public health attack on e-cigarettes intensified. A *Lancet* editorial "E cigarettes; time to realign our approach?" in October urged the linking of e-cigarettes and cigarettes in terms of harm.

> As concerns mount about the safety of e-cigarettes, several countries and national bodies have tightened regulations. India plans to ban e-cigarettes. Several US states have moved to ban flavoured e-cigarettes. The European Respiratory Society has aligned its recommendations on e-cigarettes with those on cigarettes, both encapsulated in one word: don't. They also announced that the same membership restrictions will apply for those with conflicts of interest related to e-cigarettes as for cigarettes. Public Health England, however continues to endorse e-cigarettes as safer than cigarettes. (Lancet, 2019)

This statement caused fury in the pro e-cigarette community and concern in PHE. It pointed out in a statement issued in October that the US epidemic was not linked to long-term use of regulated nicotine vaping products. If it was there would be a different demographic profile, more typical of long-term vapers. E-cigarettes in the UK were, crucially, more tightly regulated in the UK by the MHRA than they were in the US.

The main chemicals under suspicion, THC and Vitamin E acetate, were not permitted in UK e-cigarettes. Across European countries covered by the European Tobacco Products Directive, the regulatory system was similar and no US style vaping cases had been reported to the EMCDDA (the European Monitoring Centre) by its early warning system network. Commentators in the UK pointed that the MHRA's Yellow Card system by which health professionals and members of the public could report suspected adverse reactions to medicines, had received 73 individual adverse reaction reports between May 2016 and October 2019, with only 3 reports of lung infections, none of them fatal (PHE, 2019). As Professor Alan Boobis, chair of the government committee on Toxicity in Food, Consumer Products and the Environment, pointed out in December 2019, "the U.S experience was due to their regulatory and behavioural climate" (Boobis, 2019). It was also, as Tom Sheldon from the Science Media Centre pointed out in December 2020, the result of "lazy reporting" (Sheldon, 2020). Some UK newspapers continued to publish stories implying that nicotine based e-cigarettes were at fault. The Daily Mail for example reported, "Shocking scans show how vaping e-cigarettes left a 19 year old's lungs filled with solidified oil that looked like hardened bacon grease and left him unable to breathe on his own" (Daily Mail, 2019). However, the damage was done in terms of public confidence in the UK if not in terms of policy. At the end of 2020, the ASH survey of smoking and e-cigarettes found there were 3.2 million vapers, a figure which had reduced by 12 and a half % since 2019. The survey found that perceptions of the harm of e-cigarettes were getting worse. One in three people surveyed thought e-cigarettes were more or as harmful as cigarettes (ASH, 2020). Vaping was plateauing in the UK but there was no youth epidemic. However, the loss of consumer confidence did bring a potential change in focus. Children became more important as a group in society to be protected.

The epidemic that never was in the UK presaged a more hostile external environment on the part of international agencies and also the revival of some long standing forms of regulation in the UK.

6.2 Changing Places 2019–2022

Review of the evidence on e-cigarettes in England continued to provide judicious but overall favourable conclusions, by comparison with the harms of cigarette smoking. In July 2020, a statement from the

Committee on Toxicity in Food, Consumer Products and the Environment chaired by Professor Alan Boobis, summarised the conclusions of a review which had begun in February 2016. The committee concluded that e-cigarettes were not without risk but that the risk posed to users was substantially less than that posed by cigarettes. The committee could not quantify by how much. It pointed out that there were many data gaps, including long-term effects in users. Flavourings, which had been demonised in the US outbreak, were in fact widely used in food as well and had been for many years. The main difference from heating was the possibility of local effects in the lung (COT, 2020).

The external environment became more hostile. The attitude of the World Health Organisation (WHO) was an important factor. In October 2019, the WHO Study Group on Tobacco Product Regulation (TobReg) published its seventh report, on the scientific basis of tobacco product regulation. This concluded that states should consider a nicotine reduction policy coordinated with policies that allowed access to nicotine replacement therapies and other products, and as approved by relevant authorities and with appropriate safeguards. The report was intended to inform the work of the tobacco programme in the WHO Department for Prevention of Non-communicable Diseases, and also for the development of guidelines for the implementation of articles 9 and 10 of the WHO Framework Convention (FCTC), which deal with the testing and measuring of the contents of tobacco products and with the disclosure of the results to government and to the public. This report was not entirely hostile to harm reduction. But the attitude of the agency shifted to outright hostility. In a report published in July 2021, the head of WHO branded e-cigarettes as harmful and warned that their use should be better regulated to protect children and teenagers. Such products, the report said, were often marketed to young people using an array of different flavours which could "hook children on nicotine." The report was greeted with incredulity by UK researchers, some of whom pointed to funding of some of the organisation's work by the powerful Bloomberg Foundation, which had taken a leading anti-tobacco role in the US. But there was also concern that the WHO had failed to understand the difference between tobacco addiction, which killed millions each year and that to nicotine, which did not (Osborne, 2021). However, the profile of the concept of addiction overall was raised.

Britain's departure from the EU at the end of 2019 also saw a situation in flux. The EU was in the process of reviewing its Tobacco Products

Directive, a complex process which might produce an interim result by the end of 2022. Work within the Commission was informed by the SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) report published in 2020. The position of the Commission seemed to be anti-harm reduction. But the attitude of the Council and Parliament could be different. Commentators pointed out how the interventions of users, anti-vaping activists, had made a crucial difference in 2013–2014.

Brexit saw the TPD requirements initially enshrined in UK law and there was a review of the regulations. The use of e-cigarettes by young people grew during the COVID-19 lock down period. Young people were using disposable e-cigarettes often as an alternative to smoking tobacco. The debates shifted to how regulations could be tightened on youth use. The age of sale limit was 18 years, but with no restrictions on where sales were made. Deborah Arnott argued that better compliance was needed on sales-underage sales in specialist stores and also on promotion through online ads which were seen by young people, although illegal (Arnott, 2020). She argued that plain packaging was needed, which differentiated nicotine products from combustible cigarettes. There was also a regulatory gap for new products such as nicotine pouches. Regulation was needed to cover all products, not just e-cigarettes.

Medicines licensing also came back onto the agenda in the wake of Brexit. The MHRA had set up a working party on this some years previously. BAT had put in a product for licensing some years before but the process had taken six years, by which time the product was obsolete and never came to market. In October 2021, the MHRA produced a report which made headline news. It supported the medicinal licensing of e-cigarette products (MHRA, 2021). This development was reported as if it represented a major change. But as one expert pointed out, "This is very problematic still-there has to be consistency of giving a dose. But the dose is selected by the user and not supplied by the product. You could license JUUL but it's not straightforward…NICE could issue recommendations and it could be prescribed on the NHS." There was much to debate. No product had been submitted for such approval, although the MHRA was providing information for companies who were considering this step (MHRA, 2022). E-cigarettes had been successful as consumer products would being prescribable affect this image? Deborah Arnott pointed out in 2021 that e-cigarettes were suffering from a major image problem with potential new users, who often thought they were as, if not more, harmful than cigarettes. Licensing for cessation would add value. The products

would be available in both locations—the consumer market and through the GP, although the licensed medicine and the consumer product would need to be differentiated. Advertising would expand to include TV and print, whereas under the EU TPD it had been limited to ads at the point of sale. She pointed to the big growth of the nicotine market which had taken place at the turn of the century when both types of nicotine products became available, over the counter, and prescription based (Arnott, 2021). E-cigarettes were already available in hospitals. Mary Yates, a nurse consultant at the South London and Maudsley Foundation Trust, greeted the news positively.

> I'm a big fan of e-cigarettes and I've been supporting people to use e-cigarettes since 2012 here in South London and Maudsley. Since March 2020, we've been giving free starter packs to all our adult smokers and refills for the duration of their hospital stay. I would love to be able to extend that even further to all the smokers in community mental health services. So that's my next plan, and if the rules around e-cigarettes change, then we will definitely be able to do that. (Yates, 2022)

The arrival of COVID-19 also brought further complexity. There was some debate about smoking, e-cigarettes and the impact on the severity of COVID-19 infection. Smokers, so it seemed suffered less from COVID-19 infection but were at greater risk of in hospital disease severity. The evidence on e-cigarettes was more indecisive-nicotine could have a role in damping down the hyper-immune response stimulated by the disease. This line of research was unresolved. More important was the policy impact of the pandemic on PHE. The agency's role in combatting the epidemic was criticised and, as in previous health crises, the government sought to deflect criticism by organisational change. A widespread review of the public health system and its response saw PHE divided into two new agencies. The Health Security Agency was to focus on infectious disease while a new Office for Health Improvement and Disparities, which included tobacco control, was subsumed into the Department of Health and Social Care under the leadership of the Chief Medical Officer, Chris Whitty. COVID-19 had also brought the issue of disparities in health to the fore, with the clear evidence of how the disease had impacted more severely among poor people and racial minorities.

The e-cigarette issue was being presented in the context of overall tobacco control as part of "making smoking obsolete" (O'Connor,

2021). It was firmly tied into the issue of health inequalities. In February 2022, the Health Minister at that time, the Conservative Sajid Javid, called for a "vaping revolution." In June 2022, a report commissioned by the government into smoking and carried out by Dr. Javed Khan, *Making Smoking Obsolete*, called for the promotion of e-cigarettes as a substitute for smoking with accurate information to health professionals (Khan Report, 2022). A final evidence review on e-cigarettes was published in the autumn of 2022. This looked at the relative risk of vaping versus smoking and also at perceptions of risk. Vaping, it concluded, provided only a small fraction of the risks of smoking. But it was not risk free, in particular for people who had never smoked. The way ahead was, according to Ann McNeill, one of the authors of the review, to achieve a balance between these two groups—expanding use to users through subsidised programmes and licensed e-cigarettes available through the NHS, but at the same time ensuring use did not expand among non-smokers in particular young people. Enforcement of the age of sale laws was a key strategy there (McNeill, 2022). A dizzy period of political change within the Conservative government saw four Health secretaries in post in 2021–2022, with briefings during the brief tenure of Therese Coffey in the post, that anti-smoking plans would be dropped. However, at the time of writing, policy had resumed a relatively even keel.

7 Conclusion: What Lay Behind the British Approach?

An editorial in Nature in 2019 predicted that "policies on e-cigarettes will be built on evidence and collaboration" (Nature, 2019). But the contemporary history of e-cigarette policy in the UK confirms that a reliance on the power of evidence is too narrow a focus. Far more important have been a number of wider contextual and specifically national factors in recent history through which the debate on evidence has been filtered. This final section will briefly survey them.

7.1 The pre-History of Nicotine and Stop Smoking Services

The pre-history of "safer smoking" from the 1950s to the 1970s has been cited by some commentators as a reason for doubting the value of e-cigarettes (Elias & Ling, 2018). In the US, this history has been weaponised by anti-tobacco forces as a means of discrediting the current

British approach. The failure to establish safer cigarettes, doubt about their value and the role of the tobacco industry certainly formed the attitude of a generation of public health researchers and activists. But there was also a significant, and different, pre-history outlined above. This was the pre-history of the use of nicotine in cessation treatment and in a well-established network of stop smoking services. Specialised NHS smoking cessation services were established early on in the 1970s and 1980s and developed expertise in helping heavy smokers to quit. In 1999, comprehensive services were set up with major financial commitment as part of the Labour government's tobacco control strategy. Those who worked in the services have in some cases played a major role in the e-cigarette debate and this has influenced the focus on helping the existing smoker either to quit or to adopt a less harmful habit. As discussed above, this focus on nicotine had developed well before the advent of e-cigarettes to encompass a harm reduction agenda, into which e-cigarettes fitted, albeit initially as a consumer product rather than a medical one. The concern in the UK has historically been for the smoker as the result of this extensive network.

7.2 The Role of Regulatory Agencies and Health Institutions

In this agenda, the role of regulatory agencies and institutions was of key importance. The MHRA had an existing role in nicotine regulation. PHE was a new agency at arm's length from government, but crucially also brought together for the first time tobacco control with drugs and alcohol which had been within the National Treatment Agency. Its head, Kevin Fenton, was fully conversant with the substances across the board, in contrast to the public heath tobacco control field which tended to focus on that one issue. Tobacco, drugs and alcohol had not been natural bedmates previously. PHE's distance from the traditional focus of public health tobacco was important. And Britain's membership of the EU also led to significant change in regulation. By contrast with the US situation where there was either consumer availability or prohibition, and with few controls on advertising, Britain had a complex but effective system of regulatory agencies which had slowly but surely embraced the harm reduction utility of nicotine products prior to e-cigarettes arrival on the scene.

7.3 Networks

Networks of researchers have been of crucial importance. An influential tobacco policy network was established in London at the Institute of Psychiatry in the 1970s, which adopted a more positive view of tobacco harm reduction using nicotine. Led by Michael Russell, the psychologists he trained have been influential actors in UK policy—Ann McNeill, Robert West, Martin Jarvis and Peter Hajek. Their views later received support from the RCP and from a leading tobacco control expert, John Britton, a respiratory physician who influenced the policy advice given to David Cameron by the "nudge unit." The RCP Tobacco Advisory Group publications were important and were reminiscent of the leading role of that body in the initial fight against smoking from the 1960s.

7.4 Activism and Networks

These networks have also been accompanied and supported by a crucial coalition of public health and medical organisations underpinned by the work of ASH led by Deborah Arnott. ASH's change of position on nicotine, dating back to the 1990s, was a precursor to Arnott's effective coalition building and deft sensitivity to the avenues forward on policy. One commentator spoke of Deborah "spinning 18 plates in the air."

It helped too that Martin Dockrell in PHE had been policy officer at ASH prior to his transfer to PHE. The tobacco field was a relatively small one.

Activism was also important at the European level where vaper activists played an important role in developing the UK's policy in Europe. Pro smoking groups in the past in the UK (such as FOREST) had been primarily tobacco industry funded but the vaping activists who formed the New Nicotine Alliance avoided affiliating with or receiving any funding from the tobacco industry. Their role was also to bring "users" into a relationship with researchers and policy makers much as had happened in the drugs field from the 1980s (Mold & Berridge, 2010). The role of industry in this field was different to that of smoking. Thirlway has shown how the size of the independent vape industry has been underestimated; the Totally Wicked company had a turnover of £50 million a year. The traditional tobacco industry had bought other companies and was developing its own products but with no consistent strategy. Their products dominated in the convenience sector but had limited sale in the independent sector (Thirlway, 2020).

7.5 Time Passes; Drugs Harm Reduction and Other Influences

This concluding section has emphasised the importance of the pre-history of issues and events and this was also effective in a number of other ways. Harm reduction in the drugs field and the cross-over of personnel influenced the tobacco and e-cigarette debate in the UK more than in other countries. The concept was "in the air" by the 1990s and the cross-over of personnel such as Dockrell to PHE and the amalgamations which formed that agency brought the concept into tobacco from another direction-from drugs and HIV/AIDS—in addition to the Russell nicotine connection.

Time was passing too for the 1970s public health position on tobacco. A generation of tobacco researcher/activists was passing. One researcher commented how the position of leading agencies changed as their leaders retired. Cancer Research UK had new leadership, as did the Tobacco Control Centre at Stirling where Linda Bauld took over from Gerald Hastings. Public health researchers were no longer so focussed on tobacco or their concern was about overseas use and the role of the industry rather than in the UK.

The UK had been presented as an "outlier" in e-cigarette policy and regulation. But those in that field discerned signs of movement in other countries which had been hostile. In the summer of 2021, fifteen past presidents of the Society for Research on Nicotine and Tobacco reviewed the evidence on e-cigarettes and smoking in the *American Journal of Public Health*. Their conclusion was that the exclusive focus on youth vaping in the US had detracted from the overall goal of smoking cessation (Dockrell & Newton, 2021). The UK was presented as a pioneer rather than an outlier. Whether that position would be maintained and recognised remains to be seen.

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CHAPTER 3

The Development of E-cigarette Policy in Australia: The Policy, How It Came About and How It Is Justified

Kylie Morphett, Wayne Hall, and Coral Gartner

Abstract Australia has banned the sale of nicotine-containing e-cigarettes as consumer goods. Australian policy allows their use on prescription, but it has been very difficult for Australian smokers to legally access them for smoking cessation. Regulatory changes introduced in October 2021 may

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allow smokers' easier access to these products via a medical prescription, but Australian policy still differs markedly from that of other high-income English-speaking countries where e-cigarettes can be legally purchased as consumer goods (e.g. UK, US, Canada and New Zealand). This chapter discusses the history of Australian regulatory approaches to e-cigarettes. It begins by describing how Australian tobacco control policies influenced policy on e-cigarettes and then outlines the rationale that regulators and health organisations have used for the policy. We then discuss the factors that played a crucial role in producing an e-cigarette policy in Australia which is so starkly different from that in UK, Australia's original colonial power and a major model for other Australian public health policies.

Keywords E-cigarette sales bans · Approved therapeutic goods · Tobacco harm reduction · Precautionary approach · Gateway effects

1 E-cigarette Regulations in Australia

It is not legal to sell e-cigarettes that contain nicotine as consumer products in Australia because nicotine (except in the form of cigarettes) was classified within the federal Poisons Standard in 2008. The Therapeutic Goods Administration (TGA), Australia's national poisons and medicines regulatory agency, classifies substances into various schedules of the Poisons Standard, but state and territory governments enforce this standard via their own legislation. The Poisons Standard classified nicotine as a "dangerous poison" (Schedule 7). This prevents consumer access, unless an exemption applies (Australian Therapeutic Goods Association, 2018). The only such exemptions are for "tobacco prepared and packed for smoking" and preparations intended "for human therapeutic use" (Australian Therapeutic Goods Association, 2018). The latter are classified as "prescription only medicines" (Schedule 4) except for nicotine replacement therapy, such as nicotine patch, gum and lozenges. The TGA could approve an e-cigarette containing nicotine as a therapeutic good, if evidence was available from clinical trials of its effectiveness and safety (Bullen et al., 2013; Hajek et al., 2019; Walker et al., 2020), but no company has applied to do so and no e-cigarette has been approved for medical use.

Before 2012, nicotine replacement therapy products delivered by inhalation were classified as Schedule 2 medicines which allowed their over-the-counter sale in pharmacies. In response to concerns about e-cigarette use by youth, nicotine by inhalation was deleted from Schedule 2 (Gartner & Hall, 2015). One approved nicotine inhaler was exempted on the grounds that its site of absorption was oromucosal cavity rather than the lungs. After this change, a medical prescription was required to use nicotine e-cigarettes for smoking cessation. In October 2021, a scheduling change applied the Schedule 4 classification to all nicotine products for human use. This removed nicotine-containing e-cigarettes from Schedule 7 "Dangerous Poison" classification, but it still meant that smokers required a medical prescription to access them. This regulatory change also allows pharmacies to sell nicotine vaping products if they meet a product standard (TGO 110), and if a customer has a medical prescription. No other retailers are permitted to sell e-cigarettes that contain nicotine.

1.1 Policy Variations Between States

Because Australia is a Federation of six states and two territories, the regulation of e-cigarettes is a patchwork of federal and state/territory laws that regulate drugs and poisons, therapeutic goods and tobacco use and sales. These laws, and their interpretation, have differed between jurisdictions, creating confusion for consumers (Gartner & Bromberg, 2019; Saw et al., 2019).

In most Australian jurisdictions, it is legal to sell nicotine-free e-cigarettes and refill liquids that do not contain nicotine as consumer products subject to consumer law on product safety, packaging and marketing. In most cases, similar restrictions apply as to the sale and use of tobacco cigarettes under state tobacco control laws (Douglas et al., 2015). The exception is Western Australia where it is illegal to sell any type of e-cigarette under a law which prohibits the sale of any product that "resembles" a tobacco product (Gartner & Bromberg, 2019).

These complex regulations meant that many smokers were confused about the legality of using e-cigarettes. Inconsistent advice from state health departments showed that state regulators were also confused about the law and regulations (Gartner & Bromberg, 2019; Saw et al., 2019). The TGA and medical groups strongly discouraged the public from legally accessing nicotine e-cigarettes as an unapproved therapeutic good (Erku

et al., 2020; Therapeutic Goods Association, 2014). This made it difficult for smokers to find medical practitioners who were willing to prescribe nicotine e-cigarettes.

Australian policy has severely limited smokers' access to nicotine-containing e-cigarettes. Despite this, in 2019, approximately 39% of Australian smokers had tried an e-cigarette (Australian Institute of Health and Welfare, 2020). The International Tobacco Control Policy Evaluation (ITC) Project reported that only 43% of Australians using e-cigarettes used nicotine liquid, compared with 73% in the UK (Yong et al., 2015). The TGA reported that by 2020 it had only approved 15 prescriptions for nicotine (from 12 doctors) (Select Senate Committee on Tobacco Harm Reduction, 2020). It is likely therefore that most Australian smokers who have used e-cigarettes have illegally imported them or purchased them on the local illicit market.

1.2 Governmental Reviews of Australian E-cigarette Policy

Australia's very restrictive e-cigarette policy was developed with very little public input in 2008. State and federal officials formulated the policy on the advice of tobacco control advocates and health and medical organisations (Gartner & Bromberg, 2019). The Commonwealth Health Department commissioned reviews of the policy in 2012 and 2014, but public submissions were not invited and neither report was published (Gartner & Bromberg, 2019). The first review in 2012 was a commissioned regulatory impact assessment of e-cigarettes and smokeless tobacco products (Australian Intergovernmental Committee on Drugs, 2012). The second in 2016 was an assessment of "Options to minimize the risks associated with the marketing and use of electronic nicotine delivery systems in Australia." This included a closed consultation process and it was conducted by a consortium that included several members who publicly advocated for increased restrictions on e-cigarettes during the consultation period (Barnes, 2016).

2 Justifications of Australia's E-cigarette Policy 2008–2021

Detailed justifications for Australia's e-cigarette policy have been provided in response to attempts by critics of the policy to liberalise access. These have included applications to the TGA to reconsider its classification of

nicotine to allow easier access for smokers who wished to use e-cigarettes for quitting or as a smoking substitute. Later, vaper agitation and disquiet among backbench parliamentarians led to inquiries in state and federal parliaments that examined e-cigarette regulation.

2.1 Applications to Reschedule Nicotine

In 2008, an e-cigarette retailer applied to create a new exemption from Schedule 7 for nicotine "in electronic cigarettes prepared and packed as an alternative to traditional smoking." The application was rejected by the TGA on the grounds that e-cigarettes would widen the appeal of nicotine products, provide rapid delivery of nicotine, and contained potentially harmful chemicals such as acetaldehyde (National Drugs and Poisons Scheduling Committee, 2008).

In 2017, a consumer organisation, the New Nicotine Alliance Australia (NNAA), modelled on a consumer group of the same name in the UK, asked the TGA to exempt e-cigarettes from Schedule 7. By this time, e-cigarette use had increased worldwide and there was an international debate about their regulation. The TGA received 71 submissions: 54 from consumers and e-cigarette suppliers who supported the proposed rescheduling and 17 from health organisations that all opposed it (National Drugs and Poisons Scheduling Committee, 2017). Consumers described their success in using vaping to quit smoking after many unsuccessful attempts and the health benefits they experienced from using e-cigarettes (National Drugs and Poisons Scheduling Committee, 2017). A small group of researchers supported the rescheduling, including two of the authors of this chapter (CG and WH).

Submissions in favour of a more liberal policy argued that e-cigarettes were less harmful than smoking cigarettes and were effective quitting aids. They pointed out that the sales ban on e-cigarettes had created a black market for imported nicotine of unknown quality and forced smokers to choose between breaking the law by using e-cigarettes and continuing to smoke combustible cigarettes (National Drugs and Poisons Scheduling Committee, 2017). The 17 submissions that opposed the rescheduling of nicotine liquid came from Government Health Departments, health NGOs, peak medical bodies and a university public health academic (National Drugs and Poisons Scheduling Committee, 2017). These submissions argued that: e-cigarettes were not effective quit aids and promoted dual use of e-cigarettes and combustible cigarettes instead

of quitting; allowing e-cigarettes with nicotine would increase the number of persons addicted to nicotine and renormalise smoking, and second-hand e-cigarette vapour exposure was harmful (National Drugs and Poisons Scheduling Committee, 2017).

The TGA rejected the NNAA application on the grounds that there were risks that young people would use e-cigarettes and go on to smoke cigarettes. They also pointed to the risks of nicotine poisoning, the lack of evidence about the safety of long-term use of e-cigarettes and the health risks of nicotine dependence. It stated that "government policy supports the cessation of smoking rather than harm reduction" (National Drugs and Poisons Scheduling Committee, 2017).

2.2 Parliamentary Inquiries into E-cigarettes 2014–2018

Several state and federal government inquiries examined e-cigarette regulation and some invited public submissions. In 2014, the Australian Capital Territory conducted a public consultation that received 242 submissions, the majority from community members who wanted easier access to e-cigarettes. ACT Health stated that they were "committed to ensuring that any potential harms to the community associated with electronic cigarettes are minimised, while retaining access to the devices for smokers who choose to use them to help quit smoking" (ACT Health, 2015). A South Australian State Parliamentary Inquiry in 2015 received 142 submissions, with more than 70% from vapers advocating for easier access to e-cigarettes (South Australian Parliament, 2016). The report recommended that the state government "appeal to Federal Government for more stringent enforcement of regulations regarding nicotine importation, sale and possession to prevent its recreational use across Australia" (South Australian Parliament, 2016).

A libertarian Senator, David Leyonhjelm, made several unsuccessful attempts to reduce restrictions on e-cigarettes. He introduced a private members bill (Commonwealth of Australia, 2017) and chaired two Senate Committees (Senate Economics References Committee on Personal Choice and Community Impacts, 2016; Senate Red Tape Committee, 2017). In general, Australian politicians who advocate easier access to e-cigarettes have been free market advocates from the right-wing of the Liberal Party or other minor parties (Pauline Hanson's One Nation Party) and independents (Gartner & Bromberg, 2019). The centre-left Labor Party and the Greens both support the existing sales ban.

In 2017, a Committee of the House of Representatives commissioned a comprehensive *Parliamentary Inquiry into the use and marketing of electronic cigarettes (E-cigarettes) and personal vaporisers in Australia*. It was asked to report on: (1) the use and marketing of e-cigarettes and personal vaporisers to assist people to quit smoking; (2) the health impacts of the use of e-cigarettes and personal vaporisers; (3) international approaches to legislating and regulating the use of e-cigarettes and personal vaporisers; and (4) the appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia.

The inquiry collected evidence, invited public submissions and conducted public hearings in 2017. It received 336 written submissions, 259 from individuals and 77 from organisations, and over 1700 form letters from individuals (House of Representatives Standing Committee on Health, 2018). Most (97%) of the submissions in favour of making e-cigarettes more accessible came from e-cigarette users (House of Representatives Standing Committee on Health, 2018). A small number of vaping advocacy groups made submissions in support of greater accessibility to e-cigarettes. These included the now defunct NNAA. Another was the Australian Taxpayers Alliance, a libertarian organisation opposed to "nanny state" policies. There were also submissions from the tobacco industry, individual e-cigarettes retailers, and organisations representing e-cigarette retailers. There were very few submissions from independent manufacturers of vaping products. All submissions from the commercial or retail sector and the tobacco industry supported reduced restrictions. They argued that these products are a safer option than smoking for people who find it difficult to quit tobacco use, and that a highly restricted market would lead to black market sales and reduce income to businesses.

All State and Federal Health Department submissions supported the existing restrictions on the sale of e-cigarettes and non-government health bodies overwhelmingly opposed any relaxation of the restrictions (Erku et al., 2019). These included: the Australian Cancer Council, the Australian Medical Association, the National Heart Foundation, the Royal Australasian College of Physicians, the Thoracic Society of Australia and New Zealand, and the Australia and New Zealand Public Health Association. The only peak health body that supported greater access to e-cigarettes was the Royal Australian and New Zealand College of Psychiatrists.

The most common argument used to justify the sales ban on nicotine e-cigarettes was the claim that there was no evidence that e-cigarettes are

safe or effective in helping smokers to quit (House of Representatives Standing Committee on Health, 2018). Peak health bodies and government health departments argued that there was insufficient evidence on the long-term safety of e-cigarettes so the precautionary principle required a ban on their sale (Morphett et al., 2021). The Commonwealth Department of Health defined the precautionary approach as warranting:

> …action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy. The precautionary approach also takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia. (Australian Government Department of Health, 2018)

The Commonwealth Department of Health suggested that "conclusive evidence" about safety was required to justify a shift in policy, but it did not specify what sort of evidence would comprise "conclusive evidence."

The majority report of the House of Representative inquiry accepted this framing of the evidence:

> As the E-cigarette is a device that has only recently come into widespread use, there is limited, and often conflicting research available in relation to the impact of E-cigarettes on smoking rates and the health implications of long term E-cigarette use. (House of Representatives Standing Committee on Health, 2018)

The majority report also represented the precautionary principle and a harm reduction approach as being in opposition to each other:

> Participants advocating for a continuation of current policy towards E-cigarettes tended to emphasise the precautionary principle, while participants advocating for greater availability of E-cigarettes tended to emphasise harm reduction principles. (House of Representatives Standing Committee on Health, 2018)

Peak health bodies and government health departments argued that because there was insufficient evidence on the long-term safety of e-cigarettes, the precautionary principle required a ban on their sale (Morphett et al., 2021). The Thoracic Society of Australia and New Zealand (TSANZ) and the Lung Foundation Australia defined the precautionary principle as follows:

> If there is a suspected risk of harm and the scientific information is lacking, such that there is an absence of scientific consensus, then the burden of proof that it is not harmful falls on those wanting to progress the issue. (Thoracic Society of Australia and New Zealand and Lung Foundation Australia, 2017)

In 2018, the Committee's majority report supported a continuation of the e-cigarette sales ban (House of Representatives Standing Committee on Health, 2018). It recommended that the National Health and Medical Research Council (NHMRC) conduct a review of evidence on the safety and efficacy of e-cigarettes. It also recommended that the Department of Health develop a national approach to regulation, including "if necessary, restricting colourings and flavourings used in electronic cigarettes" (House of Representatives Standing Committee on Health, 2018).

A dissenting minority report by three members of the Liberal Party recommended that nicotine in e-cigarettes be made exempt from Schedule 7 of the Poisons Standard so that they could be regulated as consumer products like in the European Union and include restrictions on e-cigarette colourings and flavourings (House of Representatives Standing Committee on Health, 2018). The dissenting report downplayed the claims about the health risks of nicotine and argued that the primary concern was with the health effects of additives, colourings and flavourings (House of Representatives Standing Committee on Health, 2018). They also shared the concern of the NHMRC (National Health and Medical Research Council, 2017) that flavourings and colourings could appeal to young people and be toxic when inhaled. These were also among the reasons used by the committee majority to justify sales restrictions on e-cigarettes (House of Representatives Standing Committee on Health, 2018).

2.3 A 2021 Proposal to Tighten E-cigarette Regulation

In June 2020, the Federal Health Minister, Greg Hunt, announced that he would ban the personal importation of nicotine and only allow e-cigarettes with nicotine to be obtained on prescription. Nicotine would only be able to be imported with an authorisation from the Office of Drug Control (Sutton, 2020). The proposal was prompted by several developments that had alarmed the Australian public health community.

The first was a very large increase in the use of e-cigarettes by adolescents and young adults in the US between 2015 and 2019 (National Institute on Drug Abuse, 2020). The second was an outbreak in 2019 of 2558 serious lung injuries (including 60 deaths as on 7 January 2020) (Werner et al., 2020). These injuries were given the name E-cigarette and Vaping-associated Lung Injury (EVALI) because most of the cases reported using e-cigarettes (Hall et al., 2021). Australian State and Federal Chief Health Officers were quick to invoke the EVALI outbreak in the US to justify Australia's precautionary prohibition on the sale of nicotine e-cigarettes (Gartner et al., 2020a; Hall et al., 2021). A leading Australian tobacco control advocate described EVALI as a "canary in the coalmine" for nicotine e-cigarettes (Knott, 2019). Because most EVALI cases reported using e-cigarettes, CDC investigators initially focused on nicotine e-cigarettes as the cause of the outbreak (Hall et al., 2021). Investigations indicated that cannabis oils adulterated with vitamin E were the most likely cause of the outbreak (Centers for Disease Control and Prevention, 2020). Despite the CDC and FDA conclusions on the cause, a 2022 statement by the Chief Executive Officer of the NHMRC still identifies e-cigarettes as cause of EVALI.

The third factor that contributed to the Minister's decision was that e-cigarette use had increased among Australian adolescents and young adults around the same time as the US "youth e-cigarette epidemic" (King et al., 2020) and EVALI outbreak. A 2019 national household survey found a substantial increase in e-cigarettes use between 2016 and 2019 among young adults (Australian Institute of Health and Welfare, 2020). The fact that the largest increase occurred among young adults who were already cigarette smokers was overshadowed by claims that e-cigarette use had greatly increased among the minority of adolescents who had not previously smoked cigarettes.

2.4 Senate Inquiry into Tobacco Harm Reduction 2020

Because of objections from backbench coalition members of parliament, the implementation of the Minister's proposed new regulations was delayed until after the report of a Senate Select Committee on Tobacco Harm Reduction in October 2020 (that had been established in to examine criticisms of the proposed policy). The Select Committee received over 900 public and name withheld submissions, over 30 confidential submissions and 8324 form letters. The contents of the submissions largely reprised the evidence that had been presented to the 2018 House of Representatives Inquiry. The majority of medical and public health groups strongly supported Australia's "precautionary approach," arguing that: there was an absence of evidence that e-cigarettes were safe and effective, and that allowing Australian smokers to have ready access to e-cigarettes would promote uptake among Australian youth and expose smokers to the unknown long-term harms of e-cigarette use. In another echo of the House of Representatives inquiry, the Chair and a committee member (both from the centre-right governing party) dissented from the majority report because they claimed that its findings did not accurately reflect the evidence that had been presented.

The majority report accepted the findings of evidence reviews on the effectiveness of e-cigarettes for cessation and gateway effects commissioned by the Health Minister (Banks, 2020). The TGA spokesperson defended the proposal to tighten rules on importation of nicotine e-cigarettes by increasing penalties for importing nicotine without a prescription up to $222,000. The Committee's findings were framed as if the policy choice was between having no regulation of e-cigarettes and adopting a precautionary approach. The committee majority unsurprisingly supported continuing policies that restricted access to e-cigarettes.

3 The 2021 Rescheduling of Nicotine

At the Health Minister's request, the Commonwealth Department of Health developed a streamlined process to allow smokers to access nicotine e-cigarettes using the TGA's Special Access Scheme (SAS) or Authorised Prescribers (AP) programme. These programmes are intended to allow patients to have access to unapproved therapeutic goods on prescription. In the case of e-cigarettes, the programmes allow medical practitioners to apply for approval from the TGA to prescribe and arrange

the supply of NVPs to Australian smokers who want to quit smoking and who have unsuccessfully used an approved cessation medicine (Therapeutic Goods Administration, 2021a). A prescription can be written by any medical practitioner for a named patient and, in the case of prescribers approved by the TGA, to a broad class of patients (e.g. tobacco smokers who want to quit and have failed to do so using approved methods) (Gartner et al., 2020b).

The regulation allows nicotine-containing e-cigarettes to be sold in Australian pharmacies, if they meet a product standard (TGO 110) that sets minimum quality, and packaging and labelling requirements, and imposes some restrictions on the content of these products (maximum nicotine content, prohibited ingredients) (Therapeutic Goods Administration, 2021b). Heat not burn and smokeless tobacco products were excluded from the TGO 110 standard after the TGA rejected an application from Philip Morris to allow the sale of a heat not burn tobacco product in August 2020 (Therapeutic Goods Administration, 2020). If they are purchasing an e-cigarette in Australia, patients with a prescription can only obtain the specific product listed on the prescription from a pharmacist. E-cigarettes can also be imported for personal use if the individual importing the nicotine product holds a prescription from any Australian medical practitioner. Some TGO 110 requirements, such as ingredient requirements, also apply to imported products. The TGA recommends that the imported product is shipped with a copy of the prescription enclosed so that customs can confirm the item has been legally imported.

In principle, the proposed TGA processes will increase Australian smokers' access to nicotine e-cigarettes. In practice, their impact may be more limited because medical and public health spokespersons discourage patients from using them and doctors from prescribing them. The Australian Medical Association (AMA), for example, supports GPs prescribing "nicotine solutions to patients where appropriate" (Australian Medical Association, 2020), but a prominent former AMA president has said that he would never prescribe nicotine e-cigarettes for his patients because they "actually get young people into smoking, rather than helping them get off it" and the current president has argued that doctors should focus on getting smokers "off nicotine completely" (McCauley, 2020). Pharmacy professional bodies' support for dispensing unapproved nicotine e-cigarettes is unclear (Haggan, 2020; Pharmaceutical Society of Australia, 2020; Retail Pharmacy, 2020). It is also uncertain how many manufacturers or importers will supply nicotine e-cigarettes that can be

dispensed and it remains to be seen how many Australian vapers will use this pathway to access them.

The TGA has cautiously supported the use of nicotine e-cigarettes for patients who have unsuccessfully tried to cease smoking using approved cessation aids such as NRT and pharmaceutical drugs. Its website now encourages medical practitioners, pharmacists and consumers to use the approved pathways and provides advice on how to do so. It also provides a list of medical practitioners who are authorised to prescribe nicotine e-cigarettes, who have consented to being publicly listed and who are prepared to prescribe via telehealth consultations.

4 Explaining How Australia's E-cigarette Policy Came About

As noted above, Australia's policy was initially formulated by federal and state health regulators acting on the advice of tobacco control and public health advocates who favoured policies to reduce demand for tobacco, such as increased tobacco taxes, and who were opposed to tobacco harm reduction approaches. This was in large part because of the past failure of "light" and "low-tar" cigarettes to reduce harm, while convincing smokers that they were smoking less harmful products (King et al., 2003). The failure of "low-tar" cigarettes produced an understandable mistrust of tobacco harm reduction as Simon Chapman, a leading tobacco control advocate in Australia, has written:

> … most in the public health community have bitter memories of being hoodwinked by the industry. We were kept in the dark about its internal knowledge of compensatory smoking that made a mockery of machine-measured yields …. This has engendered immense mistrust of any next generation harm reduction claims. (Chapman, 2007)

4.1 Key Public Health Policy Advisors

After the election of a federal Labour government in 2007, the new Health Minister, the Hon. Nicola Roxon, established a National Preventative Health Taskforce in April 2008. Tobacco policy was given priority and she explained that she was determined to toughen up tobacco control policy motivated by her father dying from a smoking-related oesophageal cancer. She appointed a Tobacco Working Group chaired by

Mike Daube, former director of Action on Smoking and Health (ASH) in the UK, a former Director General of the Health Department in Western Australia, a past president of the Public Health Association of Australia and Professor of Health Policy at Curtin University. The working group's report (National Preventative Health Taskforce, 2009) recommended that e-cigarettes should only be marketed as smoking cessation aids, and then only if they were listed on the Australian Register of Therapeutic Goods (National Preventative Health Taskforce, 2009):

> If e-cigarettes are marketed as an aid in withdrawal from smoking they will be considered a therapeutic good, and would have to be listed on the Australian Register of Therapeutic Goods before they could be imported and retailed in Australia. It seems unlikely that they would meet standards for safety and efficacy. If, on the other hand, e-cigarettes are marketed exclusively as recreational devices, they may not meet the definition of therapeutic use. The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) currently categorises all nicotine products that are not tobacco products or are used for NRT as falling under Schedule 7, which covers Dangerous Poisons. Therefore, at present, such products (not being clearly a tobacco product or NRT) would probably not satisfy the stated exceptions, and could not be retailed under state and territory legislation. (National Preventative Health Taskforce, 2009)

Nicola Roxon supported this approach, describing e-cigarettes as an "insidious, manipulative attempt to hook people on smoking" (Cauchi, 2009). In 2011, Nicola Roxon announced a campaign to introduce tobacco plain packaging in Australia, describing this "as the next great step we could take in limiting the glamour and appeal of tobacco" (Australian Council on Smoking and Health, 2017). Plain packaging legislation came into force on 12 December 2011.

4.2 Tobacco Harm Reduction: Advocates and Opponents

Advocates of policies that would increase smokers' access to e-cigarettes justified it as a harm reduction approach to tobacco. They included researchers (such as two authors, Coral Gartner and Wayne Hall), e-cigarette advocacy groups and clinicians. A general practitioner and founder of the Australian Tobacco Harm Reduction Association, Dr. Colin Mendelsohn, argued that e-cigarettes were "an ideal tobacco harm reduction product," because they provided nicotine without most of the

harmful constituents of tobacco smoke and involved the hand-to-mouth action that smokers are accustomed to (Mendelsohn, 2017). The Royal Australian and New Zealand College of Psychiatrists also emphasised the value of e-cigarettes in tobacco harm reduction for persons with serious mental illness (Royal Australian and New Zealand College of Psychiatrists, 2017).

Nigel Gray, an Australian tobacco control pioneer, had earlier advocated for the regulation of cigarettes to reduce harm to smokers. He proposed a comprehensive nicotine policy that would combine the progressive reduction in the nicotine content of combustible cigarettes with increasing smokers' access to clean forms of nicotine, such as pharmaceutical preparations (Gray et al., 2005). After e-cigarettes were introduced and taken up by smokers in the US, he recognised their potential value as cleaner nicotine products (Gray, 2014). Professor Ron Borland, a leading tobacco control researcher at Cancer Council Victoria from 1986 to 2019, has also been a proponent of tobacco harm reduction policies within a comprehensive tobacco control strategy (Borland, 2016).

The overwhelming majority of Australian healthcare and public health organisations, however, have opposed tobacco harm reduction policies. Michael Moore, CEO of the Public Health Association of Australia, argued that Australia had very successfully reduced the prevalence of smoking so there was no need for tobacco harm reduction (Public Hearing of the Parliamentary Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, 5 October 2017). Opponents of e-cigarettes also argued that their introduction would reverse the gains Australia had made in tobacco control over the last few decades and increase the population harms arising from the use of nicotine (Studdert, 2017).

Increasing hostility to the concept of tobacco harm reduction was reflected in changes made in successive Australian National Tobacco Strategies. These form sub-strategies of the National Drug Strategy (NDS) that adopts a harm minimisation approach to alcohol, tobacco and illicit drugs in which the "three pillars" of demand reduction, supply reduction and harm reduction are "equally important" and "applied together in a balanced way" (Ministerial Council on Drug Strategy, 2010).

Tobacco harm reduction was a prominent part of the National Tobacco Strategy of 2004–2009. Among its four primary objectives was "where

feasible, to reduce harm associated with continuing use of, and dependence on, tobacco and nicotine" (Ministerial Council on Drug Strategy, 2004). An associated outcome indicator was "a reduction in the exposure of remaining users of tobacco (or tobacco substitutes) to dangerous smoke constituents" … "by replacing some or all tobacco products with medicinal nicotine or other nicotine products" (Ministerial Council on Drug Strategy, 2004). The strategy noted the lack of a comprehensive plan to regulate nicotine products with the statement that "we have no mechanism at all for regulating some classes of products" (Ministerial Council on Drug Strategy, 2004).

The strategy noted that "The absence of measures that reduce harm from continuing smoking results in greatest harm among socially disadvantaged smokers" (Ministerial Council on Drug Strategy, 2004). A document was developed: "More efficiently regulating tobacco: Ideas and resources" by an unnamed consultant "with advice from the former National Expert Advisory Committee on Tobacco and support by the Intergovernmental Committee on Drugs" (Unknown Author, 2004). It provided options to regulate tobacco and nicotine products to "reduce overall population harm." These included:

1. "Forcing the pace of innovation towards less harmful and, if feasible (and if deemed desirable), less addictive tobacco products.
2. Controlling the price and the accessibility of tobacco products and products that would replace tobacco products with inherent harmfulness.
3. Creating incentives to market tobacco products that would replace tobacco products in ways that minimise overall population harm" (Unknown Author, 2004).

These suggestions were not implemented and a proposed report commissioned by the Victorian Department of Health to investigate nicotine and tobacco product regulation (Ministerial Council on Drug Strategy, 2004) was never released.

In the 2010–2015 National Drug Strategy, by contrast, the only tobacco harm reduction strategy mentioned was smoke-free policies to reduce harms to non-smokers in workplaces and public spaces. The National Tobacco Strategy 2012–2018 contained no strategies to reduce harm to smokers other than cessation. E-cigarettes were only mentioned

in recommendation 6.7 to: "Consider further regulation of the contents, product disclosure and supply of tobacco products and alternative nicotine delivery systems" (Intergovernmental Committee on Drugs, 2012) in order to "determine whether there is a need to increase restrictions on their availability and use" (Intergovernmental Committee on Drugs, 2012).

4.3 Selective Citation of Evidence on the Risks and Benefits of E-cigarettes

Critics argue that policy makers and supporters of Australia's ban on the sale of e-cigarettes as consumer products used have justified it by selectively using the evidence on the effectiveness and safety of e-cigarettes. These appraisals have discounted evidence from clinical trials that e-cigarettes assist smokers to quit and dismissed observational evidence that smoking has declined as e-cigarettes use has increased. They have also amplified equivocal evidence that e-cigarettes cause harm to smokers and exaggerated the strength of the observational evidence that e-cigarettes served as a gateway to cigarette smoking in adolescents.

4.4 Protecting Young People from the Gateway Effect

A major justification for an e-cigarette sales ban has been that e-cigarettes could addict a new generation of young people to nicotine and serve as a gateway to cigarette smoking (National Heart Foundation, 2017). The review commissioned by the Department of Health concluded that there was "strong" evidence for a gateway effect in longitudinal studies (Banks, 2021), and the TGA cited this conclusion to justify its classification of e-cigarettes. Advocates of e-cigarettes argued that these studies failed to take account of the shared liability to addiction and pointed to the UK and the US where rates of smoking had declined among young people as the use of e-cigarettes increased (House of Representatives Standing Committee on Health, 2018). Some of those who invoked the gateway effect to support Australia's sales ban implied that policy makers had to choose between (1) banning the sale of e-cigarettes and (2) allowing e-cigarettes to be sold without regulations or restrictions on supply, advertising or age of purchase.

> There are plenty of drugs that we know do harm. I take one, but it's medically administered. That's okay in that group of people, but to sell it to children who are unable to give consent and are unable to understand the issues at hand, that's just unconscionable. (Professor Thompson, Thoracic Society of Australia and New Zealand, Public Hearing for the 2018 Parliamentary Inquiry)

Alternative policy options were neglected, such as restrictions on where e-cigarettes were sold and used, were overlooked, as was the inconsistency in imposing lesser restrictions on the sale of cigarettes than those proposed for e-cigarettes.

4.5 The Adverse Health Effects of Nicotine

Nicotine replacement therapy has long been considered safe when used for smoking cessation or as long-term substitute for smoking by organisations that have strongly opposed the use of e-cigarettes (e.g. Quit Victoria, 2018). However, Australian governments and health organisations have increasingly emphasised the potential harms of nicotine, arguing that it causes acute toxicity and poisoning in children, for example, (Queensland Government, 2018), that it is an "addictive and potentially toxic substance" (Cancer Council Australia, 2016) and may be a cancer promoter (Chapman, 2016). The Commonwealth Department of Health has argued that nicotine was addictive, posed "significant health risks including adverse cardiovascular, respiratory, and reproductive effects" and was "associated with DNA damage and other pathways of carcinogenesis" (Commonwealth Government Department of Health, 2017). In its 2017 decision on rescheduling, the TGA also claimed that nicotine adversely affects the brain development of young people and foetuses, potentially causing learning and anxiety disorders (Therapeutic Goods Association, 2017).

4.6 The Role of the Tobacco Industry

The decisive fact for many in the Australian tobacco control community is that the tobacco industry has invested in e-cigarette companies and campaigned for a relaxation of the e-cigarette sales ban. They argued that the tobacco industry would use e-cigarettes to reduce quitting among smokers and promote youth smoking. The industry was also accused of

using tobacco harm reduction to re-engage with public health authorities and ensure that tobacco policies better served their interests. For example, Maurice Swanson from the Australian Council on Smoking and Health stated of the tobacco industry that:

> Their objective…is to provide a range of nicotine delivery devices, from traditional cigarettes to e-cigarettes through to heated tobacco products, and their reason for doing so is that they know that in many Western countries the prevalence of smoking is falling and they need to maintain profitability. If they can dress up their alternative nicotine delivery products as being safer—that's what they're promoting—then they can maintain both their share value and their profitability. (Select Senate Committee on Tobacco Harm Reduction, 2020)

Advocates for tobacco harm reduction were sometimes depicted as witting or unwitting allies of the tobacco industry (Slessor, 2018). Media articles also reported on advocates' receipt of funding from commercial sources, particularly e-cigarette retailers (Chenoweth, 2021; Han, 2018; Workman & Hutcheon, 2021).

Witnesses who gave evidence to the Senate Committee inquiry in favour of more liberal e-cigarette policies were required to make multiple sworn statements that they had not received any funding directly or indirectly from the tobacco or e-cigarette industries.

4.7 The Misuse of the Precautionary Principle

The most popular arguments advanced against allowing Australian smokers to have greater access to nicotine e-cigarettes were that there was insufficient evidence that e-cigarettes are safe or effective in helping smokers to quit, and that they posed an unacceptable risk to youth (House of Representatives Standing Committee on Health, 2018). Peak health bodies and government health departments also argued that given the lack of evidence on the long-term safety of e-cigarettes, the precautionary principle required a ban on their sale until evidence showed that they were safe (Morphett et al., 2021). The Commonwealth Department of Health defined the precautionary approach as warranting:

> …action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed

> to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy. The precautionary approach also takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia. (Australian Government Department of Health, 2018)

The Commonwealth Department of Health indicated that "conclusive evidence" of safety would justify a shift in policy, but it did not specify what would comprise "conclusive evidence" of safety.

The Australian Medical Association implied that evidence of zero risk would be required:

> **CHAIR:** What would be the threshold? … The claims around less harm have ranged up to 95 per cent less harm. What is the threshold that becomes an acceptable point? If 95 per cent was accurate, would you say, 'That's a good basis, then, for legalising it'?
>
> **CHAIR:** So You Would Have to Be Convinced that It Did no Harm at All?
>
> **Dr Bartone:** I'm not Going to Be Tied to a Number Other Than 100 Per Cent Because—
>
> **Dr Bartone:** Yes, before I would personally look at that. (Public Hearing of the Parliamentary Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, 5 October 2017)

Most guidelines on the use of the precautionary principle reject the strong form that requires a product to be 100% safe because zero risk is impossible to achieve (Commission of the European Communities, 2000; Morphett et al., 2021; Weir et al., 2010). These guidelines usually recommend that regulations should be proportional to the risk the product poses (Commission of the European Communities, 2000; Weir et al., 2010). Two of the authors of this chapter (Wayne Hall and Coral Gartner) have argued that zero risk is not appropriate in a regulatory context when consumers are freely able to use a widely-available product that is an established cause of very serious health harms (House of Representatives Standing Committee on Health, 2018).

5 Conclusion

Drugs and poisons regulations in Australia have made it difficult to access nicotine-containing e-cigarettes since 2012. Moves to increase smokers' access to e-cigarettes have been resisted by regulatory authorities and the public health field. This has been despite the relaxation of similar restrictions in Canada and New Zealand and evidence that using e-cigarettes is less harmful than smoking tobacco (Byrne et al., 2018; Health, 2017; McNeill et al., 2018; U.S. National Academies of Sciences Engineering and Medicine, 2018). Influential public health organisations in Australia, and all relevant government agencies, maintain that nicotine-containing e-cigarettes should only be available on prescription.

Australian e-cigarette policy comprises a complex and confusing array of state and federal laws that have been difficult for smokers to navigate (Saw et al., 2019). The regulatory challenges raised by novel nicotine products have been acknowledged in parliamentary reports and the National Tobacco Strategy 2004–2009 (Ministerial Council on Drug Strategy, 2004), but over the past decade recommendations to develop a comprehensive regulatory regime for all tobacco and nicotine products have been ignored.

The main reasons for the strong resistance to changes in e-cigarette policy in Australia are as follows:

Firstly, public officials and politicians believe that tobacco harm reduction approaches are unnecessary because demand reduction strategies (e.g. taxation, smoke-free polices and media campaigns) have successfully reduced smoking prevalence to date. They also believe that tougher demand reduction policies will further reduce smoking prevalence.

Secondly, harm reduction strategies have been framed as presenting an unacceptable risk in comparison with "tried and true" demand reduction strategies, namely because e-cigarettes may allegedly deter smokers from quitting and recruit non-smokers to nicotine dependence and cigarette smoking.

Thirdly, there is also a lack of enthusiasm for nicotine replacement in smoking cessation because of the belief among leading public health advocates that cold turkey is the best way for smokers to quit. The result is that the majority of Australian tobacco control advocates support the sales ban on nicotine-containing e-cigarettes because they believe that Australian policy should give priority to preventing smoking uptake among young people over any benefits to adults who smoke.

The history of tobacco control in Australia has been strongly influenced by key individuals and professional networks. Tobacco control has been dominated by public health professionals whose successful advocacy for demand reduction policies has substantially reduced overall smoking prevalence. These policies have been less successful in reducing social disparities in smoking prevalence (Intergovernmental Committee on Drugs, 2012), and health inequalities have not been featured strongly in policy documents or discussions about e-cigarettes.

Major health organisations and government health departments at Commonwealth and state level have justified the rejection of e-cigarettes as a harm reduction strategy by invoking a strong interpretation of a precautionary approach. According to this approach, e-cigarettes should be shown to be completely safe before they can be legally sold to consumers. This use of the principle does not compare the safety of e-cigarettes with that of smoked tobacco but instead compares their safety to that of not using nicotine. This approach is inconsistent with guidelines on the use of the precautionary principle in public policy (Morphett et al., 2021).

The fact that the tobacco industry is now involved in the e-cigarette market has been a major reason that many in the tobacco control community oppose the sale of e-cigarettes in Australia. As one reporter observed, "The shadow of Big Tobacco has darkened the e-cigarette landscape" (Powell, 2018). Concern about tobacco industry motives is understandable, given their history of manipulation and their continued interest in selling dangerous and addictive tobacco products to consumers. Nonetheless, suspicion of the tobacco industry has produced a policy that perversely protects cigarettes by restricting smokers' access to lower risk e-cigarettes and low nitrosamine smokeless tobacco products while cigarettes remain freely accessible as consumer products in supermarkets and convenience stores.

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CHAPTER 4

E-Cigarettes and the Burdens of History: Children, Bystanders and the American War on Nicotine

Ronald Bayer and Amy L. Fairchild

Abstract Although e-cigarettes arrived on the American market in 2006, they remained unregulated at the federal level until 2022, when the Food and Drug Administration issued an order that JUUL, which once commanded some 75 per cent of the vaping market be removed from the American market. The period between introduction of e-cigarettes and FDA regulation was marked by fierce debate as states and cities sought to fill the regulatory void. Proponents of e-cigarettes embraced a harm

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reduction perspective, seeing in the new products a safer albeit not safe alternative to combustible cigarettes. Yet virtually the entire American public health establishment asserted that e-cigarettes threatened the 40-year effort to bring smoking to an end. In the battles over evidence and ethics, adolescents and non-vaping bystanders, as opposed to smokers, emerged as focus of concern.

Keywords Harm reduction · Precaution · Prohibition · Evidence · Adolescents · Bystanders · Addiction

On 23 June 2022, the US Food and Drug Administration (FDA) announced that after a thorough review of the application by JUUL—the most widely used vaping product from November 2017 to April 2022—it had determined to issue a Marketing Denial Order (MDO). The company was ordered to stop selling its products in the US market, and retailers had to stop selling them. In announcing its decision, the FDA declared that JUUL's application "Lacked sufficient evidence regarding the toxicological profile (of its) products to demonstrate (the sale and use) of its products would be appropriate for the protection of the public health" (FDA news release, FDA Denies Authorisation to Market JUUL Products, June 23, 2022).

The ruling made clear that JUUL bore the burden of proof for establishing the safety of its products. Tthe comments of FDA Commissioner Robert M. Califf underscored the degree to which youth vaping defined the US policy debate over e-cigarettes. JUUL was one of the products that, he noted, accounted "for most of the U.S. market" and "played a disproportionate role in the rise in youth vaping." At the same time, the agency underscored that "To date the FDA has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUUL pods." In a clear reflection of the impact of the precautionary principle, the FDA made clear that the absence of evidence regarding harm was not sufficient to overcome the concerns raised in its review. Against the backdrop of public furore about allegations of JUUL having blatantly marketing to youth, the FDA came to rest on the position that despite the massive evidence that JUUL had submitted, it had provided "insufficient evidence to assess the potential toxicological risks"

from using those products (FDA news release, FDA Denies Authorisation To Market JUUL Products, 23 June 2022).

For those who had pressed for years for a ban on e-cigarettes, the FDA ruling represented a triumphal moment for public health. Matt Myers, President of the prominent Campaign for Tobacco-Free Kids declared, "This would be the most significant action the FDA has taken to date to end the youth e-cigarette epidemic and stop tobacco companies from using these nicotine-loaded products to addict another generation of kids" (FDA Orders JUUL e-cigarettes Off the Market, *Politico*).

To those whose commercial interests were imperilled, the FDA determination was disastrous. The product was popular not only among youth—the product has had disproportionately higher youth rates compared to other brands—but also adult smokers (Wang et al., 2020). The president of the American Vapour Manufacturers Association denounced the decision as the "latest sorry example of the agency's campaign of regulatory arson against nicotine vaping products that millions of Americans rely on as an alternative to cigarettes" (FDA Orders JUUL e-cigarettes Off the Market, *Politico*). But there were others, not driven by narrow economic interests, who were also profoundly distressed. There had been for years a cadre of public health researchers who saw in e-cigarettes an opportunity for harm reduction, an opportunity to dramatically limit the toll exacted by tobacco cigarette smoking. Kenneth Warner, the former Dean of the University of Michigan School of Public Health and founding member and former President of the Society for Research on Nicotine and Tobacco (SRNT), who for years had sought to underscore the need for careful analysis that balanced the risks and potential benefits of e-cigarettes, saw the future as bleak unless there was a reversal of the FDA's June 23 determination. E-cigarettes would begin to disappear, "a black market for such products would emerge, fewer people would vape, more would smoke, more would die" (Kenneth Warner, interview 20 July 2022).

Yet within, a month both advocates and proponents were thrown into confusion.

On 24 June, the day after the FDA denial, the D.C. Circuit Court issued and administrative stay of the order in response to an emergency motion from JUUL. This stopped the MDO from going into effect until JUUL could file an emergency brief, which the court would consider along with the FDA response (Scribner, 2020). In their emergency brief filed 27 June, JUUL Labs, Inc. (JLI) claimed that the FDA

review of their evidence had been insufficiently thorough and that the agency had capitulated to "unprecedented, inappropriate" "political pressure" from congressional representatives that "tainted the entire agency process." Although the FDA had approved other e-cigarettes, JUUL was the 1000-pound gorilla in the room when it came to share of the US e-cigarette market. The FDA denial was, in the eyes of the company, "manifestly erroneous." JLI argued, "As it has with other PMTAs, FDA should have evaluated the totality of JLI's evidence, which conclusively established that the public-health benefits of JUUL products significantly outweigh any potential risks" (JUUL Labs, Inc., v U.S, Food and Drug Administration, 27 July 2022).

On 5 July 2022, the FDA announced a temporary stay of its own MDO, explaining, "There are scientific issues unique to the JUUL application that warrant additional review." Although the agency stressed that the stay should not be misinterpreted as FDA authorisation, under the deeming rule all e-cigarette products were technically on the market illegally until they received formal marketing authorisation. Until the matter is resolved, then, business as usual will continue for JUUL (FDA news release, FDA Denies Authorisation to Market JUUL Products, 23 June 2022, 5 July 2022 update note).

Yet for JUUL, business as usual would have to be very different. On 6 September 2022, the company tentatively settled a suit brought by some three dozen states over its sales and marketing practices, which relied on launch events, social media campaigns that had a sizeable proportion of followers 17 or younger, youthful spokespersons, and what the Attorney General of Connecticut described as "porous" age verification processes (Jewett, 2022). Without conceding fault, the company was poised to pay a $438.5 million settlement. Nonetheless, the company had already begun to emphasise that its target market was adult smokers and had curtailed its advertising and removed key flavoured products (Beachum & McGinley, 2022).

With hundreds more cases against the company awaiting conclusion or pending (Larson et al., 2022), the FDA review reopened, and rates of youth vaping dramatically down among both high school and middle school students from a zenith in 2019 (CDC, 2022), the 15-year controversy involving science, politics, and the ethics of public health continues to hang in the balance.

1 First Encounters

E-cigarettes arrived on the American market in 2006. Two years later, in October 2008, the FDA detained a number of shipments of electronic cigarettes at the Los Angeles International Airport, claiming that they were in violation of the Food, Drug, and Cosmetic Act. The FDA believed the products were intended to be used as drugs—defined as something that affects the structure or function of the body—since they contained nicotine and could treat or mitigate addiction to combustible tobacco.

Importers and manufacturers, predictably, had a different view. By strategically avoiding claims about the therapeutic effects of e-cigarettes—as a treatment for nicotine withdrawal during smoking cessation, for example—they argued that their products could not be regulated by the FDA as combination drugs/delivery devices but should instead be regulated as tobacco products. Two e-cigarette manufacturers sued the FDA to end the detention of their products. Both a District Court and the US Court of Appeals, District of Columbia Circuit, in *Sottera, Inc. v. FDA,* sided with the e-cigarette manufacturers and importers (Sottera, 2010). The FDA could not regulate tobacco products as drugs or drug delivery devices unless the products were marketed with claims about their therapeutic effects.

In April 2011, in the aftermath of the D.C. Circuit's opinion in *Sottera*, the FDA released a letter to stakeholders stating that "the government has decided not to seek further review of this decision, and the FDA will comply" (Letter to Stakeholders, 2011). Three years later, with U.S. sales of e-cigarettes rising meteorically, reaching $1.5 billion, the FDA continued to contemplate its options (Wahba, 2014). The agency's inaction raised several questions, including what the FDA had the authority to do (the Family Smoking Prevention and Tobacco Control Act of 2009 had given the agency authority to regulate tobacco, but the act was not updated to extend authority to e-cigarettes until 2016), what it *should* do, and when it would act. They were operating in a grey area when it came to e-cigarettes.

In October 2013, the FDA submitted a draft Notice of Proposed Rulemaking to the Office of Management and Budget's Office of Information and Regulatory Affairs in the White House. The FDA announced its intention to bring e-cigarettes and a variety of other products under its regulatory authority by "deeming" them tobacco products under the

Tobacco Control Act (Husten & Deyton, 2013). The content of the proposed rules, including product manufacturing standards such as appropriate ingredients, provisions for testing, and limits on advertising, sales, and distribution, had yet to be determined. The absence of adequate data on the possible harms of e-cigarettes to users and to bystanders exposed to the vapour they emitted, as well as on the question of whether e-cigarettes were more likely to create new combustible tobacco smokers or ease current smokers away from their habit, made it extremely difficult for the FDA to base its regulations on epidemiological or medical evidence (the deeming rule would not go into effect until August 2016).

In the face of uncertainty, US anti-tobacco advocates took a precautionary stance, arguing that accepting lesser harms was akin to being wilfully duped by the industry and serving as little more than "naïve" pawns in a grand scheme to take back lost ground in the long battle over smoking (Chapman & Wakefield, 2013). Given the long history of tobacco industry deception regarding what it knew about the harms of smoking, such advocates asserted there was no room for compromise when it came to a product in which Big Tobacco had any financial interest. As the FDA moved cautiously, municipalities in the US were responding to the new challenge from e-cigarettes.

In 2011, Boston, Massachusetts health officials voted to treat e-cigarettes like tobacco products, banning their use in the workplace and restricting their sale to adults (BPHC, 2011). Boston would go on to ban all combustible cigarette smoking, including the use of e-cigarettes, in outdoor parks, squares, and cemeteries (Rousseau, 2014). New York City was the second major city to ban e-cigarettes in all of the places tobacco smoking was banned, including parks and beaches (Gay et al., 2013; Robertson, 2013). While the measure was not passed unanimously, it passed without significant controversy. Los Angeles unanimously passed an e-cigarette ban in March 2014 (Whitcomb & Gorman, 2014; Zahniser, 2014). Like New York, Los Angeles also banned smoking and vaping in parks and certain beaches.

Chicago, Illinois also banned e-cigarette vaping in public, but with some degree of controversy. On a first attempt in November 2013, the proposed ban received a chilly reception from city aldermen, who said their constituents were using e-cigarettes to wean themselves off of combustible tobacco products (Yellen, 2014). A second attempt in January 2014, aided by the advocacy of Mayor Rahm Emanuel, succeeded in prohibiting the use of e-cigarettes in bars, restaurants, and most other

indoor public places in the city (AP, 2014; Byrne, 2014). In 2018, San Francisco passed a new ban on sales of menthol cigarettes and flavoured e-cigarette liquids, which was deemed to be the strictest municipal restriction on e-cigarettes sales in the nation (Hoffman, 2018b). By 2018, 12 states, including California, Massachusetts, New Jersey and New York, and the District of Columbia had laws prohibiting the use of e-cigarettes in otherwise smoke-free settings.

2 Harm Reduction Confronts Precautionary Thinking

In the context of tobacco, harm reduction—if not always by that name—surfaced in the mid-1990s. In 1996, the FDA approved Nicorette gum, which was nicotine-based, for sale over-the-counter. The next year it approved two forms of the nicotine patch, which delivered nicotine through the skin (Hughes et al., 1999). Over-the-counter availability of nicotine replacement therapies (NRTs) forced the medical, public health, and research communities to investigate the likelihood and consequences of long-term nicotine use (Fairchild & Colgrove, 2004).

In 2000, a Public Health Service panel, drawing on widely respected researchers across an impressive array of leading schools, institutions, and agencies, dramatically reframed tobacco dependence as "a chronic condition that warrants repeated treatment until long-term or permanent abstinence is achieved" (TCPGT Tobacco, 2000). The panel equated tobacco dependence with "high blood pressure, high cholesterol or diabetes." Drawing an analogy to psychiatric patients, its chair explained that good practice sometimes requires "keeping them on medication for the rest of their lives because I know it saves their lives. We have the exact same circumstances here" (Barker, 2000). In framing the guidelines in this fashion, the panel offered long-term treatment using nicotine replacement as a companion to cessation (*Clinical practice guideline*, 2008; Fiore et al., 2000). This did not amount to a formal endorsement of tobacco harm reduction. It did, however, solidify the acceptance of NRT and established a treatment mindset with cigarette smoking abstinence as the goal.

One year later, the Institute of Medicine (IOM), a private, nonprofit institution renowned for its scientific advice, released a report opening the door for endorsement of such products as a feasible component of a harm reduction strategy (Bondurant et al., 2001). The FDA, concerned

about the safety and efficacy of emerging nicotine-laced and tobacco-based products, had commissioned the report from the IOM, which had on more than one occasion endorsed the concept of harm reduction in the case of needle exchange to prevent HIV transmission (Normand et al., 1995; Trussell et al., 2001). The 2001 IOM committee on smoking and harm reduction released its report after a year-long process of reviewing evidence on tobacco control and harm reduction. Key to the panel's conclusion that harm reduction was "feasible and justifiable" was the observation that "approximately 10–15 per cent of the adults in the United States are expected to be regular users of tobacco in 2010, and they will continue to suffer the increased incidence of harmful and lethal consequences. Among this group are many who cannot or will not stop using tobacco, and it is to this group that effective programs and products of harm reduction should be directed" (Bondurant et al., 2001). This perspective was inevitably met by challenges that ranged from scepticism to utter rejection, in important ways recapitulating the history of responses to the evidence of the efficacy of needle exchange.

Underscoring the persistence of profound disagreement over tobacco harm reduction, on the heels of the IOM report the National Cancer Institute (NCI) issued its own analysis: *Risks Associated With Smoking Cigarettes With Low Machine-Measured Yields of Tar and Nicotine* (NCI, 2001). It fuelled enthusiasm for a cessation-only approach. The NCI was decidedly hostile to less harmful tobacco products like smokeless tobacco (e-cigarettes were not yet on the scene) and raised provocative questions about the place of harm reduction within tobacco control. The NCI described its monograph as a complement to the IOM report, but its emphasis fell more heavily on discrediting low-tar cigarettes, once touted as safer, and underscoring the duplicity of the tobacco industry (Burns & Benowitz, 2001). The NCI report thus confirmed for many that the only reasonable objective remained total cessation: "If you are concerned about your health, quitting is your only choice" (American Lung Association, 2001; Davis, 2001).

3 E-Cigarettes Take the Stage

In 2009, the World Health Organization warned that e-cigarettes threatened bans on public smoking, which were key to tobacco control. In the US, long-time anti-tobacco champion Stanton Glantz, a prominent tobacco researcher at the University of California, and his colleagues

raised similar concerns: "Given the substantial research demonstrating the effect of viewing smoking in the movies on adolescent smoking initiation, the addictive nature of nicotine and the lack of regulatory assurance of their quality or safety, it is important to keep Electronic Nicotine-Delivery Systems (ENDS), and other similar products, from being sensationalized through the use of celebrity promotion or product placement in movies or other entertainment media" (Fairchild & Bayer, 2016a, 2016b).

Glantz and others—a geographically dispersed group of researchers, many of whom had studied with him or looked to him for leadership—were alarmed by a flood of e-cigarette advertisements (Fairchild & Bayer, 2016a, 2016b). "Smelling like an ashtray is not the ideal aphrodisiac," scolded talk-show host Jenny McCarthy, as she enjoyed her BlueCig. Actor Stephen Dorff, another Blu spokesperson and former smoker, added, "I'm tired of feeling guilty every time I want to light up." He implied that public health messages were paternalistic: "We're all adults here. It's time to take our freedom back. Come on guys, rise from the ashes." On Super Bowl Sunday 2013, an NJOY e-cigarette ad seen by 10 million viewers declared, "Finally, smokers have a real alternative. Cigarettes, you've met your match" (Fairchild et al., 2014). That the e-cigarette promotions also sought to stigmatise combustible cigarettes was of little consequence to those who saw in them a grim assault to the television promotion ban on tobacco advertising established nearly five decades earlier.

Although youth use of tobacco, understood as underaged use and typically meant to mean use in middle or high school but also inclusive of use by even younger children, continued its steady decline, dread was compounded by data from the Centres for Disease Control and Prevention: twice as many young people experimented with e-cigarettes in 2012 as in 2011 (Fairchild et al., 2014). The driving concern, at that time, was that e-cigarettes would prove to be a "gateway" or "bridge" product, leading to an increase in underage smoking. Invoking images of terrorism, two tobacco-control advocates claimed, "smoking bans and clean air advocacy are being hijacked" (Fairchild et al., 2014). Seeing in e-cigarettes a Trojan horse that would unleash a new epidemic of tobacco consumption, in September 2013, 40 US attorneys general, the chief legal officials in the states, called on the FDA to act swiftly to regulate e-cigarettes as tobacco products.

This group of alarmed scientists struck a decidedly precautionary stance, echoing the sentiments of the Wingspread Statement of 1998, one

of the foundational documents in the history of precautionary thinking focused on preventing environmental threats. "When an activity raises threats of harm to human health or the environment," the Wingspread environmentalists agreed, "precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" (*Visionary Science*, n.d.).

By 2015, it appeared clear that a precautionary perspective informed the outlook of the Centres for Disease Control and Prevention (CDC). In October of that year the CDC hosted a public health grand rounds expert panel on e-cigarettes, during which speakers discussed background information and strategies for addressing the emergence of these devices. All five of the speakers, including CDC director Tom Frieden and Campaign for Tobacco-Free Kids president Matthew Meyers, focused on the health concerns associated with e-cigarette use. The Campaign for Tobacco-Free Kids, an advocacy organisation that was among the most vocal proponents of ever-more restrictive tobacco policy, was critically important because while other non-governmental organizations (NGOs) had emerged as sharply opposed to e-cigarettes (such as Action on Smoking & Health, known as ASH), Meyers's organisation was the most influential and focused exclusively on youth. None acknowledged the potential role of e-cigarettes in reducing the tobacco burden on marginalised populations or in reducing health disparities (*E-cigarettes*, 2015). Overwhelming concern for the threat to youth and non-smokers set the parameters for the precautionary approach for US policymakers.

Challenging those whose precautionary perspective suggested a need for strict regulation, if not explicit outright prohibition, were vaping organisations, e-cigarette industry retailers, and a small but vocal group of academic experts on tobacco policy, whose disciplines included economics, epidemiology, psychology, and medicine. Most important at this juncture was the American Legacy Foundation.

4 The Contours of Opposition

The American Legacy Foundation, which in time would be renamed Legacy and then Truth Initiative, was a non-profit public health organization created by funds made available by the Master Tobacco Settlement, a civil litigation settlement with major tobacco companies. Organisationally, it would provide an ongoing commitment to policies that would counter the still powerful tobacco industry. The position that it would take on the

emerging debate over e-cigarettes was signalled in a keynote address by its founding chief executive officer, Cheryl Healton. In 2008, she sought to locate that controversy in the context of public health challenges other than those posed by tobacco. "I think we really need to consider making that product more accessible to individuals so that they may choose to use that product in lieu of smoking" (Healton, 2008). Healton's Board of Director's included individuals who would emerge as strong proponents of harm reduction. Among them were Thomas Miller, the Iowa Attorney General who had led the effort to secure creation of the foundation as part of the Master Settlement Agreement, and Kenneth Warner, a Professor of Economics and former Dean of the School of Public Health at the University of Michigan, who had initially expressed scepticism over e-cigarettes. Healton also created an autonomous but affiliated research group, the Schroeder Institute, staffed by social scientists who would become among the most prominent proponents for making e-cigarettes available to those who smoked combustible tobacco cigarettes.

But the deck was hardly stacked in favour of e-cigarettes. Initially, the Schroeder Institute was hostile to the prospect of e-cigarettes as harm reduction. In a 2010 editorial in *AJPH*, Schroeder Director David Abrams wrote, "ENDS should be removed from the market and permitted back only if and when it has been demonstrated that they are safe, that their benefits outweigh their harms to overall public health, and that a comprehensive regulatory structure has been established under the appropriate FDA division. … Until then, health and safety claims based on assumptions are unacceptable" (Cobb et al., 2010).

As the evidence evolved, the institute cautiously opened itself to the harm reduction potential of e-cigarettes. By 2014, Abrams called the products "a disruptive technology that might give-cigarettes a run for their money" (Abrams, 2014a). A year later Abrams expounded on this perspective in *JAMA*. "Applying overly burdensome, expensive regulatory hurdles to e-cigarettes could stifle innovations and favor the market domination of tobacco companies." For Abrams the central question was whether e-cigarettes should be aggressively supported by tobacco control advocates. He described this as "an extraordinary opportunity to end the-cigarette century well before the 100th anniversary of the Surgeon General's report on smoking and health in 2064" (Abrams, 2014b).

But it was a moment in which political controversy was mounting. Those who advocated for tobacco harm reduction found themselves under enormous political pressure. Over the years in the course of our

formal research, the individuals we interviewed in both academic and government positions reported experiencing a variety of tactics that had become part of the anti-tobacco playbook to silence them or bring them around to the emerging public health anti-e-cigarette consensus (Pertschuk, 2001). Some were accused of taking funds from big tobacco. Pressure was put on supervisors to "muzzle," fire, or deny tenure to individuals. Others did not need a direct threat, but it was clear to them that their jobs depended on aligning with anti-vaping messages coming from major NGOs and the CDC (Fairchild & Bayer, 2016a, 2016b).

At the centre of the heated controversy that had begun to inform the debate over e-cigarettes, Abrams wrote, "Policy making relies on science not dogma…It is not nicotine per se that kills people.... If nicotine can be decoupled from deadly tobacco smoke, adults and youth can be saved—The public health standard need not be weighed to favor youth prevention" (Abrams, 2014a).

It was thus no surprise, in 2015, that the foundation, now renamed the Truth Initiative, published an extensive review of the literature that made clear the grounds for the role of e-cigarettes in harm reduction. The "Truth About: Electronic Nicotine Delivery Systems" sought to debunk what it deemed as unfounded assertions about the risks posed by e-cigarettes. A striking feature of the analysis was the extent to which it relied on the work of Public Health England, which had published the evidence base for UK e-cigarette policy. Truth's report concluded, "If prudently regulated we believe ENDS hold promise as one means to move smokers to a less harmful product and reduce the devastating death and disease burden caused by combustible tobacco products" (*The Truth about*, 2015).

Cheryl Healton left the Truth Initiative in 2014. But her impact lingered for some time. In a 2015 letter to the acting commissioner of the FDA, the Truth Initiative reiterated its belief that "the overarching goal of …regulation must be to protect the public health. By maximizing ENDS benefits and minimizing ENDS potential harms…" (Udall et al., 2015).

In time, however, new leadership at the Truth Initiative did a dramatic about-face on e-cigarettes. A determination to focus exclusively on the potential risks to children was central to the radical shift. Reflecting the new orientation, the organization took all earlier public facing messages that embraced the role of e-cigarettes for harm reduction from its website. Asked to explain the new stance CEO Robin Koval stated, "We have

an epidemic of young people vaping. We know from an emerging body of science that these products are far from harmless" (Gunther, 2021). By 2018, the Schroeder Institute was absorbed into the Truth Initiative, losing its quasi-independent status. It is two most prominent scientists, who had been strong proponents of the role e-cigarettes in confronting the toll of smoking combustible-cigarettes, resigned.

With the radical turn on the part of Truth Initiative, there remained no strong institutional voice on e-cigarette policy that was firmly grounded in a commitment to harm reduction for current adult cigarette smokers. That voice was to be filled by what amounted to an ad hoc group periodically called together by Thomas Miller. Of note, a number of those who joined the group were formerly leaders in the no longer independent Schroeder Institute at the Truth Initiative.

Miller's position as an advocate for the role of e-cigarette in combatting the toll of tobacco cigarettes was well-known. A public address he delivered in 2016 was titled, "E-cigarettes—A Harm Reduction Tool to Save Millions of Lives." As he laid out his case, he underscored how poorly understood the evidence-based was. "What troubles me and bothers me a lot," he concluded, "is that the American public does not realize that e-cigarettes are dramatically less harmful. The misconceptions are amazing and extremely troublesome. … People are going to die because they are misinformed" (Miller, 2016). It was that commitment to sharing unvarnished evidence that was to inform Miller's ongoing efforts to address the public health challenge of e-cigarettes.

The FDA officially deemed c-cigarettes tobacco products on 8 August 2016 (FDA, n.d.). On 14 June 2017, in a letter addressed to recently appointed FDA commissioner Scott Gottlieb, Miller brought together a group of co-signers who laid out what was essential to a policy approach that would be committed, in deed as well as word, to harm reduction. Children had to be protected from nicotine addiction while adult smokers had to have access to e-cigarettes that protected them from the harms of combustible tobacco cigarettes. Further, the group urged, "It was necessary to have in place a regulatory framework for less harmful products." While acknowledging that Gottlieb had spoken favourably about harm reduction, the letter asserted, "At this time we do not believe that the current regulatory framework for the low-risk nicotine products such as e-cigarettes and smokeless tobacco is appropriate or will deliver the substantial public health benefits we hope and expect FDAs oversight will bring" (Miller et al., 2017). The letter went on to lay out a broad set

of policy proposals that would be familiar to those who had followed the arguments that had made clear by the early American Legacy Foundation stance and the publications of the research scientists at the Schroeder Institute.

5 Protecting Children: Harm Reduction Under Fire

Two weeks after the FDA's deeming rule, on 28 June 2017, Scott Gottlieb announced a "new comprehensive plan for tobacco and nicotine regulation" under the Tobacco Control Act (TCA) (Gottlieb, 2017). Companies that hoped to market new e-cigarettes were required to submit to the FDA a pre-market tobacco product application, known as a PMTA. E-cigarettes that were already on the market when they were deemed tobacco products in 2016 also had to meet this requirement. To allow for both scientific deliberation and product innovation, the FDA initially set a deadline of August 2018 for those products to submit a PMTA (Lindbloom, 2020). In 2019, it extended that deadline to August 2022. At the heart of the change was what the agency described as "a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible-cigarettes" (FDA, 2017). Combusted tobacco was the most dangerous, followed by regular smokeless tobacco, low-nitrosamine smokeless tobacco, e-cigarettes, and, finally, nicotine replacement therapy. The FDA's statement, followed by a strong rationale in the *New England Journal of Medicine* in September, 2017, recognised harm reduction as an appropriate public health strategy for curbing the tremendous morbidity and mortality toll of combustible tobacco (Gottlieb & Zeller, 2017).

Just months after its potentially game-changing summer statements, the FDA published a blog that suggested to many that it might, after all, hew to a more restrictive definition of harm reduction, harking back to its original position in which it tried but failed to treat them as therapeutic devices. On 29 November 2017, the agency announced the creation of a Nicotine Steering Committee charged with "re-evaluating and modernizing FDA's approach to development and regulation of nicotine replacement therapy products that help smokers quit." Alarming to some e-cigarette advocates was a new medical orientation: "FDA also sees compelling opportunities to explore additional opportunities

for the development of new and improved products that could be sold as new drugs, typically as over-the-counter pharmaceuticals" (Gottlieb, 2017). For advocates of harm reduction, there had to be non-medical (e.g., recreational) alternatives for smokers who either wanted to quit or who wanted to enjoy nicotine without the terrible risks of combustible tobacco smoking.

The FDA's more cautious course would come to rest on an evidence review that it commissioned from the prestigious National Academies of Science, Engineering and Medicine (NASEM, 2018). NASEM's official charge was to analyse the research literature, identify the need for research to fill evidentiary gaps, and make judgments about the short- and long-term health effects of e-cigarettes.

The NASEM report affirmed the mounting evidence that e-cigarettes were substantially safer than combustible products: "There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes" (NASEM, 2018). But the report sounded an alarm when it came to the risks to children and bystanders, two of the weight-bearing pillars of the US approach to tobacco control.

NASEM concluded that since e-cigarettes contained and emitted potentially toxic substances, "using e-cigarettes in indoor environment may involuntarily expose non-users to nicotine and particulates, but at lower levels compared with exposure to secondhand smoke from combustible tobacco cigarettes." On the heels of the NASEM report, the CDC stated in information for consumers, "E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful substances, including nicotine, heavy metals like lead, volatile organic compounds, and cancer-causing agents" (NASEM, 2018).

When it came to children, the report advised, "There is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes among youth and young adults." While the report did note contradictory data, it determined that observational or ecological evidence could not provide a conclusive refutation of the risk to children. Only randomised clinical trials could meet that bar. And conclusive proof, for NASEM, was the standard when it came to vulnerable populations like children (NASEM, 2018).

Most important was how the head of FDA's Tobacco Division, Mitch Zeller, read the evidence in light of the NASEM Report. "For kids

who initiate on e-cigarettes, there is a great chance of intensive use of cigarettes. As the regulator," he said, "we've got to factor that in" (Kaplan, 2018). How that evidence should be factored in was clear to Shannon Lea Watkins, a member of Stanton Glantz's research team, which had long warned of threats posed by e-cigarettes. "It comes down to this tradeoff between definitely hurting kids and maybe helping some adults," she said. "To me the tradeoff sounds quite clear" (Anapol, 2018).

How different the "trade off" might be understood was made clear by an analysis conducted by Kenneth Warner and his colleague Lynn Kozlowski. Citing evidence from large, cross-national studies, they argued that adoption of e-cigarettes as a harm reduction tactic "might come at the cost of additional new smokers among the younger generation. While unpleasant to contemplate, this cost must be compared to the far more immediate benefit in terms of health consequences that would be realized by adults quitting smoking" (Kozlowski & Warner, 2017).

With children at the centre of debate, harm reduction became a politically unpalatable approach. Said FDA Commissioner Gottlieb, "Innovations that could present an alternative to smoking—particularly as it relates to e-cigarettes—cannot, and will not, come at the expense of addicting a generation of children to nicotine through these same delivery devices" (Gottlieb, 2018).

In September 2018, the FDA launched a $60 million campaign targeted at adolescents who had used or might be tempted to use e-cigarettes. Employing graphic imagery, the campaign depicted hideous worm-like creatures crawling under the skin and into the lungs and brains of otherwise blemish-free teenagers. The ads sounded an urgent warning: "There is an epidemic spreading" and "vaping can put dangerous chemicals into your lungs." The Agency's "Don't Get Hacked" campaign suggested that nicotine triggered a kind of wild-eyed mania or personality hacking, in which nicotine transforms teens into emotionless robots that lack the autonomy or charm of a chatbot. The imagery and language evoked the 1920s and 1930s, when narcotic crusaders framed drugs as "parasites" and addicts as little more that "The Living Dead" (Speaker, 2001).

Beyond the risk that e-cigarettes posed as a gateway to tobacco cigarettes, another danger informed the FDA's posture. Increasingly, the argument became that nicotine, in and of itself, posed a threat to the developing brain of adolescents. This was all the more remarkable since decades of research on tobacco had never suggested such a threat. Indeed,

the Surgeon General's 1988 Report on Nicotine centred on the harms of addiction and the potential nature of the impact of nicotine on organ systems without mentioning the brain (Kandel, et al., 1994). But the 1988 Joe Camel controversy, centered on R.J. Reynold's adoption of a cartoon character in its marketing, had sparked interest in nicotine's impact on the brain (Fairchild & Colgrove, 2004). Both the Surgeon General and the director the CDC came to express alarm about the threat of nicotine exposure to the adolescent brain.

It is against this backdrop that JUUL—an inexpensive, trim, high tech device that looked like a long, elegant thumb drive—entered the market in 2015 without the legacy of having previously manufactured combustible products. Sales of JUUL kits increased 680 per cent and sales of refills increased 710 per cent between 2017 and 2018, according to RBC Capital Markets. JUUL quickly took command of the e-cigarette market. On 6 October 2018, Wells Fargo Securities attributed 74.5 per cent of e-cigarette market unit shares to JUUL (Craver, 2018).

JUUL, which in the US had a much higher nicotine content than in the UK, improved nicotine delivery to users, meaning that they got more nicotine, faster, than with other vaping products. Most products on the market used propylene glycol and glycerine as the solvents that allow the delivery of nicotine (*Public Health Statement*, 1997). Distinguishing JUUL was its use of nicotine salts, a mix of a nicotine base combined with a weak organic acid (NASEM, 2018). Nicotine salts allowed for absorption of nicotine in a fashion similar to combustible products. One 2018 study suggested that the nicotine hit from JUUL was also less harsh on the throat, which might produce a more pleasant experience for both seasoned cigarette smokers and people who had never smoked or vaped (Nguyen, 2018).

All of the features that made it appealing to adults also made "JUULing" a youth phenomenon. It was, in addition, easy to hide because it was small and produced little vapour. A Truth Initiative study found that, in a national sample of 1012 people aged 15–17, seven per cent reported ever having used a JUUL. Twenty-one per cent of this age group also recognised a photograph of a JUUL. Recognition (34 per cent) and past 30-day use (11 per cent) were higher among those in the sample who were more affluent. Adolescents who were just experimenting might not realise that JUUL delivered nicotine as efficiently as a combustible product, potentially increasing their risk of addiction (Willet et al., 2018).

In May 2018, the former chair of the American Academy of Pediatrics Tobacco Consortium weighed in on the side of peril. Dr. Jonathan Winickoff described JUUL in *The New Yorker*, a culturally sophisticated and politically liberal weekly with a generally affluent readership, as nothing short of "bioterrorism." He declared JUUL "a massive public-health disaster" (Tolentino, 2018). Once again resisting the tide, Iowa Attorney GeneralTom Miller, continued to see promise in JUUL and other products that delivered nicotine electronically. Miller continued to argue that public health had an obligation to inform the public that e-cigarettes were substantially safer than combustible products. While Miller said that JUUL gave "cause for concern" when it came to kids, "it had not reached panic or epidemic stages" (Miller, 2018a).

6 The Pressure for Regulation Mounts

Deep concern about the malevolent intentions of e-cigarette proponents was fuelled when JUUL established an important financial relationship with Altria, the makers of Marlboro. "The union," the *New York Times* reported, "would create an alliance between one of public health's greatest villains and the start-up that would upend it. Particularly, alarming was Altria's plan to invest "$12.8 billion for a 35 percent stake in JUUL, at a $38 billion valuation" (Richtel & Kaplan, 2018).

A review of newspaper articles, op-eds, and editorials from the *New York Time*s, and *Los Angeles Times* makes clear that from 2010 onward, pessimistic pieces on e-cigarettes had come to over-shadow descriptive new accounts. Optimistic stances were all but eclipsed.

Nothing more tellingly underscored the prevailing tone of profound hostility to e-cigarettes, than the decision on the part of the *New York Times* to publish on its front page an investigative report detailing the horrific experience of an adolescent who quickly became addicted to nicotine through e-cigarettes, and his subsequent struggle to break free of the overpowering drive of his dependence. In what may have been an act of balancing, the *Times* published a less emotionally compelling account of a person who had successfully used e-cigarettes to free herself from tobacco. In mid-December 2018, the day that US Surgeon General Jerome Adams tweeted that he was "officially declaring e-cigarette use among youth an epidemic." The *Times* returned to the theme of e-cigarettes use as a crisis, again in a front-page story (Vurthy, 2018). "Addicted to Nicotine, Teenagers Have No Clear Path to Quitting" was an account of parents,

teachers and clinicians all paralysed as they observed teenagers falling prey to a brain and health threatening drug (Hoffman, 2018a).

Not just in the popular media were e-cigarettes characterised as a grave threat. In January 2019, the *New England Journal of Medicine* published the results of a major randomised clinical trial on efficacy of e-cigarettes. It concluded that e-cigarettes were more effective for smoking cessation than nicotine replacement therapy (NRT). After one year, 18.0 per cent of the e-cigarette group was "tobacco abstinent" compared to only 9.9 per cent of the nicotine replacement group (Hajek et al., 2019a). For e-cigarette users who were not tobacco abstinent, the problem of dual use remained. The journal's senior editors published a formal commentary alongside the results of the clinical trial. They repeated the grim NASEM conclusions without ambiguity, "There is substantial evidence that e-cigarette used by youth increases the risk of smoking combustible tobacco cigarettes" (Hoffman, 2019).

Under these circumstances, the FDA history of delaying the PMTA process struck the mainstream public health community as inexcusable, leading many to conclude that it was necessary to challenge the agency in federal court. On 27 March 2018, after the PMTA deadline had been extended to 2022, major US NGOs including the American Cancer Society, Cancer Action Network, the American Heart Association, the America Lung Association, The Campaign for Tobacco-Free Kids, and the Truth Initiative filed a lawsuit in the Maryland Federal District Court claiming that the FDA had, in effect, violated its legal responsibility. "The FDA had effectively arrogated to itself…statutory forbearance that Congress had nowhere derogated to the agency" (*Complaint*, 2018). If it was following the law, in other words, the agency had no right to keep delaying.

One year later, on 15 May 2019, the court handed down a stinging decision. "Instead of addressing public health concerns associated with tobacco the August 2017 Guidance exacerbates the situation by stating in essence, that manufacturers can continue to advertise and sell products that are addictive and that target a youth market." The Guidance "was clearly contrary to the Tobacco Control Act's purpose" (*Memorandum Opinion*, 2019). The FDA, the court concluded, had "exceeded the authority granted to it by Congress" (*Memorandum of Opinion and Order*, 2019).

Two months later in a Memorandum of Opinion the Court imposed a 10-month deadline for PMTA submission and a one-year deadline for

FDA approval. The 2022 deadline was unacceptable to the court. Yet, the onset of the COVID-19 epidemic set the stage for yet another move to extend the court's deadline. On 30 March 2020, the FDA filed a request for a 120-day extension, a request the court agreed to. Hence, the new deadline was 9 September 2021.

In the midst of these legal manoeuvres, the FDA took a modest step. In November 2018, it declared that many flavoured e-cigarettes could be sold only in shops that had age-restricted entry or that set aside products in areas that were not accessible to those under age 18. Flavours like "gummy bear" or "bubble gum" had long drawn caustic critique from those who had fought so hard to combat efforts to make vaping appealing to youth. The FDA had thus not, as many had initially hoped, banned all flavours and all advertising. Rather, it took the approach of requiring exacting age verification controls on all sales, both in stores and online.

In a forceful op-ed in the *Washington Post* in response to the new FDA regulations, Tom Miller again weighed in. Sceptical of numbers that suggested plague-like youth uptake and hyperbolic concerns that nicotine could be injurious to adolescents he wrote, "To overreact and limit access to harm reducing tools means that adults die.… The FDA should be the last institution to strip the harm reduction potential of these products. The FDA should never act in a way to cause tens of thousands of Americans, perhaps hundreds of thousands, to die" (Miller, 2018b).

These events occurred against the backdrop of dramatic amplification of the already heated controversy. In August 2019, the CDC reported the emergence of a striking number of cases of life-threatening vaping-related pulmonary illnesses. A growing concern about the rising number of young vapers—15 per cent of cases were younger than age 18, and 37 per cent were ages 18 to 24—exposed to the risks of nicotine addiction had taken a dramatic turn with hospitalisations and fatalities from this condition (CDC, 2020). Confounding policy makers' response to the new threat was uncertainty about what had caused the sudden outbreak of acute lung injuries.

News reports captured the emerging sense of alarm. On August 15, the *New York Times* published an update with the headline, "Dozens of Young People Hospitalized for Breathing and Lung Problems After Vaping" (Kaplan, 2019). Two weeks later, against the backdrop of 193 cases nationwide, the *Times* announced, "First Death in a Spate of Vaping Sicknesses Reported by Health Officials" (Richtel & Kaplan, 2019).

Over time, public health messages became ever starker. Following a death in Los Angeles, the county's public health director stated, "Today we are issuing a warning to all residents 'Stop vaping now'" (Christodoulou, 2019). In so doing, he echoed the position of the American Medical Association, which called vaping an "urgent public health epidemic" (Berg, 2018). To spur the adoption of local and state restrictions on flavoured vaping products, Bloomberg Philanthropies announced the funding of $160 million campaign over the next three years. Matt Myers stated that his organisation had mobilised to "transform what is going on" in "the battle over e-cigarettes" (McGinley, 2019).

Primed by long-standing fears that flavours attractive to adolescents were responsible for the steep acceleration in youth vaping, the new outbreak set the stage for more restrictive policy proposals. Indeed, total bans on e-cigarettes were being considered. In early September, Michigan's governor announced an immediate ban on the sale of e-cigarettes. In California, the governor made clear while announcing a $20 million vaping awareness campaign that if he had the necessary legislation he would ban e-cigarettes. On September 24, Massachusetts declared a public health emergency and imposed a four-month ban on e-cigarettes.

By December 2019, four months after the initial CDC reports, both the CDC and the FDA confirmed that vitamin E acetate, a tetrahydrocannabinol (THC) product additive, was the likely cause of the US outbreak of lung injuries. Strikingly, although neither nicotine or flavoured vaping liquids were implicated and both CDC and FDA warnings focused on THC and products purchased off the streets, that new information did not reduce confusion about the source of the injuries in a context in which the youth vaping rate was increasing. Massachusetts, San Francisco, Ohio, and New York made immediate moves to ban either vaping products or flavours. The American Medical Association (AMA) called for a total ban on all vaping products. By 14 January 2020, there had been 2,668 cases and 60 deaths (CDC, 16 January 2020).

Political controversy continued unabated in 2020 as the FDA's efforts were characterised as half-measures that failed to address the threat of e-cigarettes. In January, the FDA made its most substantial move against the sales of flavoured e-cigarettes. Although no e-cigarettes had yet received FDA authorisation through the PMTA process, the agency retained enforcement discretion and opted to "prioritizing enforcement" against flavoured products. Only tobacco-or menthol-flavoured e-cigarettes could

continue to be sold. Further, it targeted manufacturers that targeted minors or failed to prevent access by minors to its products. In its press release, the agency stressed, "By not prioritizing enforcement against other flavoured ENDS products (e.g., tobacco and menthol flavours) in the same way as flavoured cartridge-based ENDS products, the FDA has attempted to balance the public health concerns related to youth use of ENDS products with consideration regarding addicted adult cigarette smokers who may try to use ENDS products to transition away from combustible tobacco products." In other words, although it did not shut the door on flavours other than menthol or tobacco, it drew a line in the sand when it came to kids: flavours like mint and fruit could no longer be marked without agency authorisation. It also determined to target enforcement against e-cigarettes, regardless of flavour, that had not submitted a premarket application (*FDA finalizes*, 2020).

This move drew sharp rebukes from those who believed the agency had retreated from what many took as a pledge by President Donald Trump to "sweep the market" of all flavours except tobacco (McGinley, 2020). Harold Wimmer, President and Chief Executive of the American Lung Association said the plan could "only compromise the health of our nation's children" (Dasey, 2020). For Robin Koval of the Truth Initiative, this was nothing more than a Band-Aid when major surgery was called for (Dasey, 2020). Significantly, the ongoing hostility to e-cigarettes by Democratic law makers became ever more present. Patty Murray, the ranking member of the Health Education, Labor and Pensions Committee of the US Senate, attacked the FDA Commissioner as "having placed politics ahead of science, data and public health." She like other Democrats saw this retreat on the part of the FDA as emblematic of the politics of the Trump Administration. After all, she said the President had said that vaping was a big industry and "we want to protect the industry" (Dasey, 2020).

Thirty Democratic Senators, in a letter to the Commissioner to the FDA, wrote that the "Newly announced e-cigarette flavour policy represent[ed] an alarming reversal from what the administration promised." The policy, they said, was "weak and unlikely to have a meaningful impact on e-cigarettes use by youth" (Weixel, 2020). A month later Democrats in the House of Representatives passed a bill that would forbid the sale of flavoured cigarettes and e-cigarette liquids (Sheryl, 2020). The vote was 213 for banning and 195 against, and largely along party lines. "All

but 5 Republicans voted against the bill. For them the measure represented overreach by a big government, liberal elites, telling adults what they can do." A striking feature of this vote was the fact that some African American Democrats viewed the bill and its ban on menthol as "a targeted attack" rather than as a "value neutral health car policy decision" (DeBonis, 2020).

At the same time, the FDA's effort was attacked by the vaping industry as a grave threat (DeBonis, 2020). Evidence suggested that vaping flavours with or without nicotine might appeal to youth, but flavours also appealed to adult smokers and might help them switch. Some evidence suggested that the vast majority of smokers who successfully switched completely from smoking combustible products to vaping did so—often after weeks, months, or even years of dual use—by transitioning from tobacco-flavoured or menthol-flavoured liquids, to other flavours and often to lower nicotine concentrations, or even to no nicotine in order to reduce the triggers that reminded them of their prior combustible smoking product (Abrams et al., 2018; Hajek et al., 2019b; McNeill et al., 2018; Russell et al., 2018).

In the next months, prior to the court-imposed deadline of 2021, the FDA followed through with its targeted approach. In April 2020, the FDA issued 10 warning letters to those who sold and produced or imported unauthorised nicotine delivery systems that were targeted to or were likely to promote use by youths. The director of the FDA's Centre for Tobacco Products said of these warnings, "the public should really be outraged by these products." He went on to say, "If you're marketing or selling these products to youth, the FDA will not tolerate it" (*FDA Warns*, 2020). In July, the FDA again issued warning letters notifying 10 companies to remove their flavoured products from the market since they lacked premarket authorisation (*FDA Warns*, 2020).

The COVID-19 epidemic provided yet another occasion for pressure to mount for more aggressive regulation. A study published in the *Journal of Adolescent Health* suggested a dramatic increase in the risk of disease among those who vaped. The study leader stated, "In young people many believe their age protects them but the data shows that this isn't true" (Digitale, 2020). This provoked a Democratic controlled subcommittee of the House of Representatives to send a letter to the FDA calling upon the agency to "temporarily clear the market of all e-cigarettes for the duration of the coronavirus crisis" (Howard, 2020).

The long-anticipated 9 September 2021 FDA regulations that would confront the challenges posed by larger companies involved in the production and sale of e-cigarettes was, as we have noted, met with an announcement that there would be yet another delay. While it had rejected the applications of 940,000 flavoured e-cigarette products, one careful observer noted, "they hadn't made any of the tough decisions…I expected a little bit more" (Richtel, 2021). The American Heart Association, which had long called upon the FDA to reject the application of JUUL, expressed its disappointment noting that large companies involved in the vaping industry "had targeted our nation's teens for years and contributed to the epidemic of tobacco use among youth" (Phend, 2021).

In August 2021, the depths of the division over policy was thrown into bold relief. The *American Journal of Public Health* published yet another appeal to consider the potential contribution that e-cigarettes could make to the goal of reducing morbidity and mortality associated with smoking tobacco cigarettes. "Balancing Consideration of the Risks and Benefits of E-Cigarettes" was co-authored by 15 past presidents of the SRNT, an international organisation with approximately 1000 members. Of the past presidents since the organisation's founding in 1994, only seven had chosen not to join the effort that had commenced several months before the article's publication (Balfour et al., 2021).

There was little that was new given the long-standing effort of harm reduction proponents to press for a careful understanding of the evidence. What mattered most was an appeal to reason: "our objective is to encourage more balanced consideration of vaping within public health and in the media and policy circles." Given the conclusion that e-cigarettes could contribute to smoking cessation it was essential that smokers "should be well informed about the relative risks of vaping and smoking and vaping's potential to help quit smoking." Acknowledging the need to carefully monitor the challenge of youth vaping, the authors lamented that "as public health groups, the media, policy makers and the general public focus[ed] on youth vaping, vaping's potential to help adults quit smoking too often gets lost. That may come at a significant public health cost." A final element of this appeal centred on the fact that a disproportionate number of African Americans, those with lower education, individuals with mental illness, and LGBTQ individuals smoked cigarettes. It was they who became ill in greater numbers; it was they

who died from tobacco-related illness at higher rates. In short, this was a challenge to social justice (Balfour et al., 2021).

A contemporaneous statement by the Truth Initiative could not have been more different. Most strikingly in their September 2021 statement was the determination to embrace a very narrow interpretation of what harm reduction truly necessitated. Truth acknowledged the contribution of needle exchange to preventing the spread of HIV infection among drug users. But it went on to state, "We forcefully reject…the notion that [harm reduction] requires the further development of a huge commercial market in addictive nicotine products focused on youth and young adults. Instead, we argue that a genuine harm reduction approach requires a measured and careful deployment of nicotine alternatives that are tightly focused on helping smokers who otherwise would not quit smoking cigarettes…[We] reject the notion that unregulated or lightly regulated commercial markets in nicotine alternatives are equivalent to harm reduction" (*Truth Initiative Statement*, 2021). It was against this background that the FDA appeared, surprisingly, to side with those who had argued that e-cigarettes could indeed make an important contribution to the public health effort to reduce the toll exacted by smoking tobacco. On 12 October 2021, the FDA issued a long-awaited decision on e-cigarettes, permitting the sale of two nicotine flavoured cartridges manufactured by R.J. Reynolds corporation. In making the announcement, the FDA stated that the "potential benefit to smokers who switch completely or significantly reduce their cigarette use, would outweigh the risk to youth provided that [the company] follows post marketing requirements aimed at reducing youth exposure and access to [these] products." In taking these steps, the agency noted that it had ordered the removal of more than 1,000,000 products "that lacked sufficient evidence that the benefit to adult smokers who used the flavored products would overcome the public health concern posed by the well documented and considerable appeal of the products to youth" (*FDA Permits*, 2021).

Left to a future moment was the question of menthol. On 29 April 2021, the FDA had made clear its intention to ban menthol in combustible cigarettes (*FDA Commits*, 2021). Menthol has long been the single most dangerous tobacco chemical flavour when it comes to both adult and youth smoking. Despite two FDA-derived reports that recommended a ban on menthol in combustible products, one internal and one externally commissioned, there has been policy paralysis in the face of appalling evidence: 52 per cent of all adolescents initiate smoking

with menthol. But among African American youth, that figure is over 90 per cent (Villanti et al., 2017). The menthol burden on African American communities reflects a history of deliberate marketing. After the 1950s, as the evidence on the harms of smoking began to mount, industry shifted from marketing menthol away from women to Black Americans. Industry engaged in what historian Keith Wailoo calls "corporate race work" to target the urban market in Black communities. For marketers, "human crises (drug use, economic distress, fears of cancer, poverty) were opportunities" (Wailoo, 2021, p. 12). Although smoking rates dropped for all racial groups in the US, targeted marketing created disparities in consumption (and, as a result, death and disease) that have narrowed since the middle of the last century but not yet closed for Black men. In a context in which behaviours like smoking were increasingly viewed not as having structural causes but as being the result of bad choices, such disparities had consequences for stigma and discrimination in social and economic life as well as in access to care (MMWR, 2011).

Even though there is currently a renewed push to ban menthol in combustible products, it continues to remain unclear whether the FDA would extend such a ban to e-cigarettes. But in approving only tobacco-flavoured e-cigarette products in October 2021, it seemed more certain that e-cigarette flavours would be a thing of the past, shaped in large measure by the historical contours of debate over tobacco and youth in this US.

The decision on the part of the FDA was remarkable in that it had determined that the evidence supported a harm reduction approach to the human toll of smoking combustible tobacco products. In so doing, it hewed to a position that put it at odds with a well-financed campaign on the part of virtually the entire public health establishment in the US. At the same time, the agency rejected the claims on the part of e-cigarette proponents that a range of flavours other than tobacco could enhance the appeal of e-cigarettes to adult smokers.

It was not surprising that the FDA drew the ire of long-time antagonists to e-cigarettes who saw in them yet another ploy on the part of the tobacco industry. The national assistant vice president for advocacy of the American Lung Association stated bluntly "This throws young people under the bus. The industry has been waiting for the next big thing and they found it with e-cigarettes" (Richtel & Kaplan, 2021). A Democratic Congressional representative echoed the position that had characterised the party's deep hostility to the tobacco industry e-cigarettes, stating,

"The FDA has turned its back on the public health by approving high nicotine e-cigarettes" (Washington Post 10/2021), and accusing the agency of "ignoring the data" (Pietsch, 2021).

The decision was also castigated by e-cigarette proponents, who had asserted that a range of flavours made e-cigarettes more appealing to smokers seeking options that helped them transition away from combustible cigarettes.

It thus came as a surprise to many that, not ten months later, the FDA issued is Denial of Marketing Order to JUUL, noted at the start of this chapter.

7 Conclusion

On 23 June 2022, the FDA issued its ruling against the marketing of JUUL vaping products. For proponents of harm reduction, this seemed nothing short of a defeat, despite the willingness of the FDA to approve some e-cigarettes. It is thus important at this juncture to acknowledge the issues at hand have not finally been put to rest.

A huge, and apparently unbridgeable, gulf continues to separate the Truth Initiative, other major NGOs, and the core of the public health community from those who warned that overly restrictive measures would subvert the fundamental goals of public health by denying harm reduction as a viable approach for smokers. It would be naïve to imagine that evidence alone will resolve this debate with its deep historical roots. Fear of addiction, even benign addiction, remains a central concern for American policy makers. Youth, too, remain centre stage. Understanding and reckoning with these powerful frames will continue to shape the prospects for both those opposed and committed to tobacco harm reduction.

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CHAPTER 5

Conclusion: Why Did the UK, US and Australia Have Different E-cigarette Policies?

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Abstract We sought to understand why three countries with similar political systems and similar anti-smoking policy histories developed such very different policies towards e-cigarettes. All appealed to a value-free concept of "evidence" in making use of precautionary and harm reduction principles to deal with the remaining uncertainties in the evidence. Yet policy processes were mediated by important contextual factors. These

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included: the nature and role of the state in each country; the political parties in power at the time e-cigarettes were first introduced; the role played by existing regulatory institutions in dealing with e-cigarettes; longer-term changes in ways of thinking about tobacco smoking within public health; the specific pre-history of tobacco control policy, nicotine and smoking cessation services; the organisation of professional and activist networks that were in favour of and against e-cigarettes; the uses of fear to discourage e-cigarette use; and the influence (or lack thereof) of harm reduction ideas from drug or AIDS policy on tobacco control policy. The object of policy also differed between countries from protecting the smoker to protecting children and young people.

Keywords Evidence · Precautionary principle · E-cigarettes · Nicotine · Policy · Activism · Public health · Fear

The UK, Australia and the US are three nations that share a liberal democratic tradition and each of which adopted similar approaches to reducing the public health toll of cigarette smoking after 1962. By the twenty-first century, all had achieved dramatic reductions in smoking prevalence among adults by introducing a range of tobacco control policies that included increased cigarette taxes, restrictions on tobacco promotion,

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smoke-free policies and public education campaigns to encourage smokers to quit and to discourage non-smokers from taking up smoking.

In the early 2000s, all confronted a new common challenge in deciding how to respond to the marketing of e-cigarettes in the first decades of the new century. Each country pursued a different path towards the regulation of these new products; all did so in the name of public health. In this final chapter, we synthesise our accounts as to why our three countries developed very different policies on e-cigarettes over the last decade. Discussion on the subject has often focused on seemingly value-free concept of "the evidence" and the appeal to "the precautionary principle" and tobacco harm reduction. Our analyses emphasise how these concepts are rooted in and mediated by social and policy contexts.

Our conclusions reveal the important role played by country-specific factors. These include: the nature of the state and the "pre-history" of policies towards tobacco and nicotine in each country, as well as the broader political context. Against that backdrop, also key were leading ideas about tobacco control within regulatory institutions and the role of policy and activist networks in each country. Changes within public health, particularly after World War II, also helped to shape differences, as did the impact of ideas from the field of drugs and HIV. The approach to drugs and HIV heavily influenced the political viability of harm reduction approaches, which had implications for tobacco control and e-cigarettes. Also important were differences in the acceptability of fear-based campaigns and what counted as evidence and populations of concern. Who was the object of policy was also important—whether it was the smoker who had to be protected and encouraged to stop smoking or whether it was young people who had to be protected. Let us consider each of these factors in turn.

1 The Nature of the State

England is a highly centralised state in which relatively little power is delegated to local government. The centralisation of policy making in England means that when the central government decided on a policy towards e-cigarettes it became the policy of the whole country. There were initiatives at the local level, but in most cases these were pioneering uses of e-cigarettes in smoking cessation services before this policy was endorsed centrally.

Australia and the US, by contrast, are federal states in which policy making is divided between federal and state governments. States may have their own policies or adopt variations of federal policy. In Australia, federal and state governments agreed to ban the sale of e-cigarettes containing nicotine by using poisons regulations. Some state governments banned the sale of all e-cigarettes, including those that did not contain nicotine. A National Tobacco Strategy has attempted to harmonise state policies.

In the US, most public health policy is a matter of state and sometimes municipal decision making. In the absence of federal policy on e-cigarettes for more than a decade, some cities and states imposed stringent regulation involving limitations on where and to whom e-cigarettes might be sold. San Francisco, for example, was ahead of the federal government striking a precautionary posture when it came to regulating e-cigarettes. Within the federal government, there were disagreements in approach between key bureaucracies with responsibility for the regulating e-cigarettes, the CDC and the FDA. It was only in 2021 that the federal government assumed a leading role shaping policy that would provide a policy framework that would override state and local policies that might have been less restrictive. So the degree of centralisation of state power was a key factor in policy making.

2 The Political Context

Governments from the late 1990s in the UK, both Labour and Conservative/Liberal Democrat, generally welcomed the use of nicotine products and later e-cigarettes. The Labour government expanded stop smoking services to address social inequalities in smoking prevalence, and the use of NRT was a key feature of these services. The Conservative-Liberal Democrat coalition government continued this support. It also expanded the approach to include e-cigarettes in line with its preference for a light, "hands off" approach to regulation.

In the US, there was virtually no political support for making e-cigarettes available as harm reduction devices. Indeed, at a federal level, the Democratic Party and, especially, its most liberal constituents saw e-cigarettes as a threatening ploy by the tobacco industry to undermine tobacco control. In the period marked by federal restraint, restrictive measures were adopted by state and local governments where Democrats were in power. Only marginal libertarian voices with no political sway

expressed an openness to e-cigarettes as part of the more generalised opposition to a "nanny" regulatory state.

In Australia, e-cigarette policy was formulated under a centre-left Labour government that was more sympathetic than its Liberal-National Party predecessor to tough tobacco control policies. Policy was made by a Health Minister who wanted to end tobacco smoking. She was advised by tobacco control advocates who had secured earlier bans on tobacco advertising and the sale of smokeless tobacco products. Smoking was increasingly concentrated in low-income groups, but reducing social inequality in smoking prevalence was much less of a policy focus in Australia apart from public subsidies for NRT and smoking cessation medicines. There was little history of the use of NRT for harm reduction in quit smoking services.

3 The Role of Regulatory Institutions

Regulatory institutions have played a key role in the three countries. In England, the MHRA as the licensing organisation was already heavily involved in the harm reduction agenda. NICE guidelines did not advocate the use of e-cigarettes immediately but later took on board the harm reduction case. Public Health England played a particular important role. As an "arm's length" government body, it was not part of the Department of Health or the "empire" of the Chief Medical Officer. Its tobacco function was free standing and in strong relationship to the drugs and alcohol field, for which the agency was given responsibility when founded in 2013. The new organisation facilitated linkages between policies across tobacco and other substances. In that sense, it mirrored the linkages within the Addiction Research Unit where Michael Russell had carried out his work.

The regional regulatory level was also important. The role of the European Union and Britain's membership was important, as was the consumer response to e-cigarettes in policy processes. This contrasted with the role of WHO's influence on policy. There was a long history of UK/WHO liaison and of policies flowing from national to international levels and vice versa. That did not happen in the case of e-cigarettes in the UK where the EU role was far more influential.

In the US, as noted, there was no unanimity of approach at the federal level. The FDA was more open to tobacco harm reduction than the CDC, which was set against harm reduction in the case of e-cigarettes. This was

illustrated by the CDC's haste in identifying nicotine e-cigarettes as a cause of an outbreak of lung injuries—EVALI that its own investigations later showed were the result of contaminated illicit cannabis vaporisers. Yet there was also a long history of delay in formulating e-cigarette policy at the FDA, which allowed the precautionary position time to take hold and harden.

In Australia, the regulation of nicotine went down the poisons route under the leadership of the federal TGA agency that regulates poisons and medicines. State health departments agreed with this approach and used their own poisons regulations to enforce the policy. Regulators took a hostile stance towards e-cigarettes and used their poisons regulations to effectively ban the sales of e-cigarettes with nicotine unless they had been approved for medical use.

4 Changes Within Public Health Thinking

Our discussion has described changes in public health ideology and focus which have taken place since the nineteenth century. The most notable ones were the post-World War II emphasis on the role of lifestyle and risk in noncommunicable diseases symbolised by the smoking issue. This and the anti-industry/stop smoking "turn" of the 1970s dominated a whole generation of public health researchers and activism. This was the case in all three countries a notable area of similarity between them.

The UK and US pioneered in making anti-tobacco a key public health issue and their approach—restrictions on public smoking, limiting advertising and taxation—had become the standard one across many issues in that field. In the UK, however, by the second decade of the twenty-first century, the anti-tobacco movement, although important as a public health cause, was no longer as dominant as it had been. Those who expressed mistrust of tobacco harm reduction were not specialists known for their tobacco work, but public health generalists, who commented on many public health issues. The nicotine researchers on the other hand were specialists in that field who had spent many years researching the topic. They had moved from the niche of "addiction scientists" into the public health arena. Public health as a practice was also changing in some areas in the UK, with medication and drugs as standard preventive tactics-statins for heart disease, methadone for opioid addiction, nicotine for smoking cessation and harm reduction. It was notable how the mainstream public health approach was still institutionalised in the position

of the Chief Medical Officer (CMO) within government. The CMO, for example, was opposed to the Nudge Unit's encouragement of e-cigarettes uptake under the coalition government. A subsequent CMO, Professor Sally Davies, expressed concerns about e-cigarettes in evidence to the Science and Technology committee of the House of Commons.

In the US, although the public health field had increasingly emphasised "personal responsibility" for health in the 1970s, smoking continued to be framed in terms of industry manipulation. Individuals could not be held accountable for smoking when the tobacco industry lied about the risks of smoking and the power of nicotine addiction. Indeed, the industry had deliberately manipulated nicotine content to better hook smokers. That framing along with the threat to "innocent" bystanders helped to justify strong government action to drive, first, smoking and, later, vaping, into the shadows.

Yet the personal responsibility framing was interpreted as "personal choice" in many parts of the nation, particularly those where Republicans dominated. In these states, there were areas where smoking in public places was not banned and high cigarette taxes had been pre-empted. In both liberal and conservative strongholds, for those who continued to smoke and wanted to quit, it was a clinical model and not a harm reduction approach that came to dominate. Treatment—lifelong, if necessary—was the path to cessation. And complete cessation was the only acceptable outcome.

In Australia, the public health advocate Simon Chapman had been an outsider for most of the 1980s and 1990s as a critic of government inaction and an advocate for tougher tobacco control policies. He became a policy insider by the middle 2000s and along with Michael Daube, shaped policies towards e-cigarettes under the new Federal Health Minister Roxon. Their advocacy of an e-cigarette sales ban was strongly supported by the cancer councils and receptive officials in the federal and state health bureaucracies. There was no countervailing, well-organised professional group that agitated for tobacco harm reduction. Those who were sympathetic to the use of e-cigarettes for cessation (including two of the authors Coral Gartner and Wayne Hall) found themselves with few allies in the tobacco control field. As was also true in the US, attempts were made to silence dissenters in the interests of the field presenting a "united front" to government.

So traditional public health, with its views formed in the 1970s, was strong and institutionalised in all three countries. But its influence in the UK was reduced for various reasons including the position occupied by researchers sympathetic to nicotine harm reduction.

5 The Pre-history of Nicotine Regulation for Cessation and Harm Reduction

There has been much discussion in the public health and anti-smoking fields about the "safer smoking" debacle of the 1970s. The tobacco industry introduced filtered and low-tar cigarettes to reassure smokers that the risks of smoking had been reduced. Initially, this was done with the support of governments, NGOs and public health bodies. The release of internal tobacco industry documents in the 1990s revealed that the companies were aware from their own research that low-tar and filtered cigarettes did not reduce smokers' tar exposure. Even before this in the UK, the issue of compensatory smoking had derailed the safer smoking agenda by the end of the 1970s.

The low-tar cigarette experience engendered strong hostility on the part of the public health field in Australia and the US, provoking scepticism about the feasibility of tobacco harm reduction. In the US, considerable interest in and support for safer cigarettes that dated from the mid-1960s crumbled in the early 1980s when several factors converged: evidence that tobacco companies were targeting children, lawsuits forcing the publication of internal tobacco industry documents that revealed the extent of industry deception, the conceptualisation of nicotine addiction as a disease that required treatment and acceptance and later widespread availability of nicotine replacement therapies.

In Australia, the search for safer cigarette was supported by government in the 1960s and 1970s with the aim of growing domestic tobacco production. Tobacco control advocates such as the Cancer Councils later followed the lead of peers in the UK and US as evidence on compensatory smoking emerged. The failure of safer cigarettes to reduce harm was used as justification for Australia's precautionary ban on the sale of e-cigarettes. The low-tar cigarette experience was also invoked in recent debates about e-cigarettes, with a sales ban often advocated as the best way of avoiding a replication of this earlier history. This was the case to some degree in all three countries.

In the UK, there was a more important harm reduction pre-history. This was the role assigned to nicotine as a therapy and substitute for smoking, long before e-cigarettes came on the scene. Here, there were distinct differences between the three countries. In the UK, there had been support for nicotine as a cessation tactic since the 1970s and this grew in importance during the 1980s and 1990s. Research on nicotine had expanded and, at the policy level, nicotine replacement therapy became embedded within NHS stop smoking services, which had expanded under the Labour government elected in 1997. In the first decade of the twenty-first century, the utility of nicotine therapies had expanded even further with a harm reduction objective. Nicotine was no longer seen as a short-term therapy for smoking cessation but as a potential long-term substance to replace cigarettes and thereby reduce tobacco-related harm. Allied to this was a very different attitude to nicotine addiction. It was seen as acceptable outcome in terms of the balance of risk in relation to tobacco smoking.

The US is a nation that has a long history of hostilities to public health policies perceived to be paternalistic. Youth, however, have always warranted special protections. Concern about the potential danger to youth has dominated US policy conversations about e-cigarettes. In this context, researchers began to suggest that nicotine posed a threat to the adolescent brain. Laboratory studies based on mice proved powerful and politically persuasive. The "brain disease" concept of addiction across the substances also had strong appeal in the US.

In Australia, leading tobacco control figures had long been sceptical of need for NRT, arguing that cold turkey was the most common and successful method of quitting. The policy emphasis was accordingly given to encouraging smokers to make quit attempts and providing behavioural counselling and support via telephone helplines. NRT was available for sale over the counter after the late 1990s, but there was no public subsidy for its use until 2006, when cancer councils persuaded the government to give it a public subsidy to address the social inequalities in smoking prevalence. The fear that NRT would produce an addiction was not a reason given for opposing NRT, but the fear that e-cigarettes would addict non-smoking adolescents become a common justification for a sales ban on e-cigarettes in Australia. This was increasingly reinforced using claims originally made in the US that nicotine exposure damaged adolescents' brains.

So the role of nicotine and attitudes towards addiction showed considerable variation across the three countries even before e-cigarettes arrived. Neither the US nor Australia had the range of stop smoking services nor the health service support for nicotine as a therapy. This meant that the main focus of UK policy was the smoker, not so much the case in the two other countries.

6 Professional Networks in Favour and Against

Professional networks have played a key role in producing a positive response to e-cigarettes in the UK. These have a long history deriving from the network of researchers who first came into the field to work with Michael Russell at the Addiction Research Unit at the Institute of Psychiatry in the 1970s. This group was located in a psychiatric institution and favoured the use of nicotine for what later became called harm reduction. It was not part of the public health mainstream in the 1970s and 1980s. But it remained a cohesive group whose members moved into positions of influence in health institutions from the 1990s onward. Ann McNeill, for example, had worked with Russell and chaired the PHE evidence reviews of e-cigarettes. There were also allied networks, such as the Tobacco Advisory Group of the Royal College of Physicians with John Britton at the helm. This group had moved to support a harm reduction position for nicotine before e-cigarettes came on the scene. The prestige of the RCP and its stop smoking history dating back to the late 1950s gave the Tobacco Advisory Group's views particular weight.

In the US, by contrast, the most prominent networks were anti-e-cigarette and concerned about the adverse impact of nicotine on adolescent brains. At one juncture, the Legacy Foundation—a significant, well-funded organisation—was open to the promise of e-cigarettes, but a change in leadership produced a remarkable about-face. Renamed the Truth Initiative, it took on a leading vocal role in opposing e-cigarettes, which it portrayed as a special threat to adolescents and young adults. Those who took the contrarian pro-harm reduction view comprised a loose network of prominent researchers led by a state attorney general who had played a leadership role in the massive, successful state lawsuit against the tobacco industry. Networks of individuals, research centres and NGOs that opposed e-cigarettes all emerged as powerful evidence brokers. They took the stance that e-cigarettes were dangerous—harmful in and of themselves, even to smokers and especially so to youth.

Other groups in the broader public health community accepted their evidence, partly through trust but partly because there were reputational consequences for dissenters.

The Australian network of tobacco control advocates and state cancer councils was unanimous in supporting Australia's e-cigarette sales ban. Their advocacy had successfully driven smoking prevalence down by persuading governments to adopt public health policies that reduced demand for cigarettes, viz. increased taxes; advertising bans; graphic health warnings; smoke-free policies; and a ban on the sale of smokeless tobacco. Their major policy preference when e-cigarettes appeared was to introduce plain cigarette packaging. They did not see any need for THR policies and were worried that allowing the sale of e-cigarettes would be used to promote smoking and reduce quitting. Given these policy preferences, an e-cigarette sales ban was seen as the best approach to avoid e-cigarettes entering the legal market in Australia.

The minority of Australian health professionals who supported the use of e-cigarettes for cessation and harm reduction were a disparate group of researchers and clinicians. They were not part of the major tobacco policy networks and those with the highest public profile were the subject of personal attacks that alleged they were financed by the e-cigarette and therefore the tobacco industry. Younger tobacco researchers were advised against expressing public support for e-cigarettes or harm reduction to avoid funding at risk, especially that provided by the cancer councils.

So the situation around networks of research has differed sharply between the UK and the other two countries. All have had their e-cigarette supporters, but only the UK had such a well-placed and cohesive network around nicotine with a long history of support for tobacco harm reduction using nicotine. Only in the UK did these researchers have the ear of policy makers.

7 The Use of Fear Campaigns Against E-cigarettes

In both the US and Australia, public health campaigners had used fear campaigns to encourage smoking cessation. This has continued with the use of fear-based campaigns about the risks of e-cigarettes for smokers and young people. In Australia, opposition to e-cigarettes has become something of a moral crusade against youth vaping and smoking. This was demonstrated, first, by the rapidity with which the EVALI outbreak in the

US was used to brand e-cigarettes as dangerous products and, second, by the slowness to acknowledge the evidence that cannabis vaping had played the major role in the outbreak. What distinguished the fear-based campaigns against e-cigarettes from earlier efforts to reduce smoking was a willingness to claim harms—often related to behavioural and personality changes in youth who vaped—that arguably went well beyond the evidence.

Fears were raised in the UK by some tabloid newspapers at the time of EVALI. This led to a significant shift in UK public attitudes towards e-cigarettes after media reports of EVALI. However, public campaigns about e-cigarettes in the UK have not been based on fear. Indeed, public campaigns explicitly promoted e-cigarettes as a safer alternative to smoking and a tool for cessation. This may in part be because of the Science Media Centre, which has called out some of the more dubious research claims about the risks of e-cigarettes that have been promoted by the tabloid media.

8 Activism and Links with Government

The UK has had a long history in tobacco control of nominally outsider organisations working with government while publicly maintaining an "outside/activist" role. ASH was one organisation that had its anti-tobacco origins in the 1970s when it worked closely with the Labour Minister of Health David Owen to introduce tobacco control policies. ASH had changed its policy stance by the early twenty-first century to encompass harm reduction within its tobacco endgame agenda. Nicotine was seen as playing an essential role in ending tobacco smoking in British society. Deborah Arnott, ASH's chief executive, who was adept at coalition building, developed a cohesive group of prestigious institutions to support the concept of nicotine harm reduction well before e-cigarettes came on the scene. This was accomplished in parallel with her advocacy of a smoking ban in public places so that the connection between the two policy objectives was made plain.

Vaper activists were important in Europe where they worked with MEPs to secure the defeat of a move to treat e-cigarettes as medicines. In the UK, they were successful in bringing a "user" dimension to the discussion of policy and research on e-cigarettes. People who smoked had never figured in policy discussion at that level, apart from the emergent discussion of inequality and lone motherhood in the 1980s. But the

policy role of the "user" had become prominent in the illicit drugs field and the smoking field followed suit in the 2000s. There were also links with stop smoking services, which had a strong pro-user ethos. Louise Ross, formerly head of the stop smoking service in Nottingham, became a prominent figure in the New Nicotine Alliance.

In Australia, an ASH organisation had been created to lobby for the public health policies that were introduced in the 1980s and 1990s. It was phased out after all the policies that it advocated for had been implemented. The State Cancer councils took over its advocacy role. Nigel Gray and Ron Borland, two leading anti-smoking advocates, were open to the use of e-cigarettes for tobacco harm reduction, but most of their peers supported the e-cigarette sales ban.

There were no pro-vaping activists in Australia who were as well organised or as effective as those in the UK. Several small groups were established, but they did not prove sustainable with limited funding. This left pro-free market groups with connections to the tobacco industry to make the case for more liberal e-cigarette. This enabled these groups to be easily discredited and public health advocates to unfairly portray all advocates of e-cigarettes as astroturfed tobacco industry fronts.

In Australia, there was no coalition of medical and public health organisations that advocated for e-cigarettes as in the UK. All the Australian organisational equivalents of UK organisations that supported tobacco harm reduction—the state cancer councils, the heart foundation, colleges of physicians and general practitioners, and the Australian Medical Association—were hostile to the use of e-cigarettes for smoking cessation and so strongly supported a sales ban.

Vaper advocates, including some members of the LNP, attempted to allow the sales of e-cigarettes as consumer products, as happened in Canada and New Zealand. These advocates succeeded in forcing two parliamentary inquiries whose majority reports supported Australia's e-cigarette sales ban. The TGA has recently responded to the advocates' pressure for change by reclassifying nicotine in a lower poisons category that allows it to be prescribed by physicians and general practitioners under a special access scheme for unapproved pharmaceuticals. They have also taken steps to facilitate its prescription by general practitioners while still publicly opposing the sale of nicotine as a consumer good. It remains to be seen whether enough doctors will ignore the hostility to e-cigarettes within the organised medical profession and prescribe nicotine to smokers.

In the US, there was activism on the part of vapers and vape-shop owners as well as harm reduction proponents, discussed above. But the more influential NGO activists—Tobacco Free Kids, the Truth Initiative, the American Cancer Society, Bloomberg—all stressed the threat that e-cigarettes pose to youth and children and discounted the potential benefits to smokers who wanted to quit.

9 The Impact of Drugs, HIV and Harm Reduction

The concept of harm reduction had been advocated in the smoking field in all three countries before the advent of e-cigarettes, but only in the UK had harm reduction been linked with nicotine since the 1970s. The impact of harm reduction approaches to reduce HIV transmission in the illicit drugs field varied between the three countries.

In the UK, harm reduction through methadone and needle exchange was a policy response to HIV from the late 1980s and into the 1990s, before the focus shifted towards "recovery" under a Conservative government. The creation of Public Health England brought harm reduction ideas from drugs, alcohol and tobacco into an institutional relationship that influenced policy making. It brought together like-minded staff who had all been through the debates about harm reduction in the illicit drugs field in the 1980s. In most countries, tobacco policy had been a "standalone" public health topic in which policy was made independently of policies on other drugs and alcohol. Those boundaries were weakened within PHE and earlier in the network of nicotine researchers that was forged within the Addiction Research Unit in the 1970s.

In the US, harm reduction for drugs had a more contested policy history. Illicit drug policy had, for most of the past century, been framed by a prohibitionist outlook that criminalised drug use. This remained the case even when, in the 1970s, methadone maintenance became an established element of the therapeutic landscape. The HIV epidemic opened the debate about harm reduction in the drugs field. Activists, drawing upon European experience, became strong advocates for needle exchange, but their efforts met with the fierce resistance at federal and state levels for years. Ultimately, the toll of HIV-related deaths, and the strength of evidence for reducing viral transmission, opened the way for publicly funded needle exchange programmes. Those efforts gained the support of more liberal Democrats, especially. Strikingly, the public voice of proponents of needle exchange and safe injection sites did not make itself much

heard in the controversy over e-cigarettes until very recently. For example, Ethan Nadelman, who for decades had challenged US prohibitionist dug policies, has only recently become a proponent of e-cigarette harm reduction. While harm reduction was important in shaping the outlook of those who moved into the e-cigarettes field, the institutional and policy underpinning seen in the UK was absent.

In Australia, policy influence from the HR movement in the drugs field was largely absent. The illicit drug and tobacco policy arenas were very distinct and had no overlap in their key personnel. An exception was Alex Wodak, who had pioneered NSP and methadone treatment and also worked on tobacco cessation in prisons and general practice. There was support for e-cigarettes among clinicians who worked in the addictions and mental health fields because there was a high prevalence of smoking among their clients. They received no support from key networks in tobacco control. Indeed, some key figures who had supported needle exchanges and heroin prescribing argued that a HR approach to tobacco would increase rather than decrease harm. Similarly, the Australian Greens whose platform supports cannabis legalisation, heroin maintenance treatment and NSP opposes the use of e-cigarettes for THR and supports current Australian policy.

So again, it was mainly in the UK that harm reduction ideas from the drugs field were in a relationship with smoking. Traditionally, those areas were not close and specialists in one area had little to do with experts in the other. But in the UK, there was a history of collaboration dating back to the early alliance at the Addiction Research Unit in the 1970s. This was consolidated by the formation of Public Health England in 2013 which included drugs, alcohol and tobacco within one agency.

10 Who Is Policy For?

Explicit in the discussions round e-cigarettes was a difference in who was seen as the target group for who policy was framed. In the UK, initially it was the chronic smoker, a figure who tied into concerns about inequalities in health which resurfaced at the end of the 1990s. The notable decline in smoking since the 1970s had brought the "poor smoker" to greater prominence. But in Australia and in particular the US, the focus was a traditional one within policy of the "innocent victim" and children.

11 Conclusion

This book represents a first pass at explaining the origins of very different policies towards e-cigarettes in Australia, the UK and the US. We hope that it will encourage more research into policy making in these countries. We also hope that it will encourage similar case studies in additional countries. There would be particular value in similar analyses of the factors influencing e-cigarette policies in Canada and New Zealand, two countries that initially adopted much the same the medical regulation approach as Australia's approach, before allowing the sale of e-cigarettes as consumer goods under tighter regulation. Similarly, there would be value in policy case studies in other high- and middle-income countries that have adopted e-cigarette sales bans, such as Brazil, Malaysia and Singapore.

Expanding the cross-national comparative frame is important because what we can take from this study of three countries who were early leaders in global debates is that interpretation of "the evidence" on the effectiveness and safety of e-cigarette was refracted through pre-existing policy commitments produced by a host of contextual and historical factors highlighted above. British research and evidence focused on the beneficial impacts that e-cigarettes had on smokers who wanted to stop smoking. US research, by contrast, highlighted the threat to the "innocent victim" and children, traditional tropes within the tobacco field. Australian policy makers were very much more influenced by research from the US on the adverse effects on youth than by British research on its benefits for smoking cessation. This was a departure from the previous Australian response to evidence on the harms of cigarette smoking that looked primarily to the UK. The invocation of the precautionary principle to justify an Australian sales ban was strongly mediated by the historical and contextual issues we have outlined.

Some commentators have drawn attention to the inconsistency in the hostility shown to harm reduction using e-cigarettes in the US and Australia, when both countries are in the process of liberalising access to cannabis which is still primarily smoked and vaped. There has also been a debate in the public health field as to whether England's policy is an "outlier" in a world where hostility to e-cigarettes is the norm, or whether it is blazing a pioneering path towards a more rational policy that other countries will eventually follow. Optimists of the latter persuasion

have pointed to policy movements in this direction in the US and more recently in Canada and New Zealand.

What emerges strongly in this comparison of the three countries is the importance of pre-history in relation to nicotine and its usage for cessation and harm reduction. This experience needs to be understood within the context of state decision making and the durable "policy communities" that form around particular issues, such as nicotine and e-cigarettes, and exert considerable influence in concert with powerful interests within government.

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