IMPERIAL TOBACCO GROUP PLC AND IMPERIAL TOBACCO UK:

JOINT SUBMISSION TO THE DEPARTMENT OF HEALTH CONSULTATION ON THE FUTURE OF TOBACCO CONTROL, SEPTEMBER 2008

Imperial Tobacco

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JOINT SUBMISSION TO THE DEPARTMENT OF HEALTH CONSULTATION ON THE FUTURE OF TOBACCO CONTROL, SEPTEMBER 2008

INTRODUCTION

Imperial Tobacco welcomes this opportunity to contribute to the Department of Health Consultation on the Future of Tobacco Control. This submission is made jointly on behalf of both Imperial Tobacco Group PLC and Imperial Tobacco UK.

Imperial Tobacco Group PLC ("Imperial Tobacco" or "ITG") is the world's fourth largest international tobacco company and the second largest European tobacco company. Imperial Tobacco Group PLC manufactures and sells a comprehensive range of cigarettes, fine-cut (roll-your-own) tobaccos, cigars, rolling papers and tubes. ITG has sales in over 160 countries worldwide and is world leader in the premium cigar, fine-cut (roll-your-own) tobacco and rolling papers sectors. ITG is headquartered in Bristol in the UK.

Imperial Tobacco UK (ITUK) is the Bristol-based trading operation of ITG which distributes Imperial Tobacco's products to the UK market, of which it is market leader holding approximately 46% market share. Its leading UK brands include Lambert & Butler, Richmond, Embassy and Regal cigarettes; Golden Virginia and Drum fine-cut (roll-your-own) tobacco; Rizla rolling papers; Classic cigars and St Bruno pipe tobacco. It also distributes tobacco products on behalf of Philip Morris Ltd.

Tobacco is a significant contributor to the UK economy, delivering around £9bn annually to the UK Exchequer through excise duties and making further significant contributions through corporate taxation, employment taxes and other revenues.

BACKGROUND TO THE CONSULTATION

The Department of Health Cancer Reform Strategy 2007 announced the Government's intention to consult on the next steps on tobacco control and the further regulation of tobacco products. It planned to consult with stakeholders *"on measures to reduce the significant harm to health caused by smoking for those who are addicted to nicotine and not able to quit".*

In May 2008 the Department of Health published *"Consultation on the future of tobacco control"* with a deadline for responses of 8 September 2008. This was positioned as *"the first step in developing a new national tobacco control strategy"* and covers four main areas described as:

- reducing smoking rates and health inequalities caused by smoking;
- protecting children and young people from smoking;
- supporting smokers to quit;
- helping those who cannot quit.

Imperial Tobacco participates in a range of UK Government consultations that are relevant to our business. We do this on the basis that our views will be considered in an objective manner and that the evidence we provide will be properly evaluated, with due regard given to the principles of good regulation to which the UK Government adheres.

This response to the Department of Health's *"Consultation on the Future of Tobacco Control"* sets out our views in detail on the range of issues discussed in the consultation document and should be regarded an expert contribution to the process.

It also appears at www.imperial-tobacco.com.

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EXECUTIVE SUMMARY

Imperial Tobacco

EXECUTIVE SUMMARY

Introduction

Imperial Tobacco rejects the assertions in the Department of Health's (DoH) consultation document *The Future of Tobacco Control* that levels of youth smoking or smoking in general would be reduced through a ban on tobacco retail displays, branded packaging, the advertisement of tobacco accessories and an increase in the minimum size of cigarette packs. In some incidences we believe that these measures could even have the opposite effect. Furthermore, we believe that the measures outlined in the document would merely serve to boost the illicit trade in tobacco, reducing the level of the legitimate trade and impacting significantly on UK public revenues whilst failing to fulfil the stated ambitions of the DoH.

PRINCIPLES OF GOOD REGULATION

1. Imperial Tobacco supports the sound, reasonable and practicable regulation of tobacco products. We recognise that it is the role of governments to provide the general public with clear and consistent messages about the health risks to smokers that are associated with their smoking. We do not challenge these messages.

2. The standards to be applied to regulatory policy with regard to risks such as those associated with tobacco have been clearly established, for example, in HM Treasury's Green Book, Appraisal and Evaluation in Central Government 2003[1] and Orange Book, Management of Risk, 2004[2]. They are elaborated in the context of tobacco regulation in the House of Lords' Select Committee on Economic Affairs' Report "Government Policy on the Management of Risk" 2006[3]. They were

[1] The Green Book, Appraisal and Evaluation in Central Government 2003, http://www.hm-treasury.gov.uk/
[2] The Orange Book, Management of Risk Principles & Concepts 2004, http://www.hm-treasury.gov.uk/
[3] House of Lords' Select Committee on Economic Affairs 5th Report of Session 2005-06 p6 sections 4, 6,8

documented in 2006 by the Better Regulation Commission in its "Five Principles of Good Regulation"[4].

3. In 2006, The Better Regulation Commission documented its "Five Principles of Good Regulation" as:

   a. Proportionality – regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.

   b. Accountability – regulators must be able to justify decisions and be subject to public scrutiny.

   c. Consistency – government rules and standards must be joined up and implemented fairly.

   d. Transparency – regulators should be open and keep regulations simple and user-friendly.

   e. Targeting – regulation should be focused on the problem and minimise side effects.

4. Imperial Tobacco believes that the consultation document does not reflect these principles on the grounds that:

   a. While the use of tobacco products by young people is an issue of public policy, the consultation document has not advanced significant credible evidence which shows that retail tobacco product displays including vending, branded tobacco packs or the sale of cigarettes in packs of fewer than twenty are directly responsible for young people starting to smoke or smoking more;

   b. The section in the UK DoH consultation document on plain packaging states that *"denormalisation"* is an objective of tobacco control policy (section 3.70). Imperial Tobacco contends that "denormalisation" is not in itself a conceptual objective that is compatible with the principles of good regulation of a legal product. It is unclear in its definition and has no clear, measurable objective. It is impossible to further define and

[4] Risk, Responsibility and Regulation – Whose risk is it anyway?, Better Regulation Commission, October 2006, http://archive.cabinetoffice.gov.uk/brc/publications/risk_report.html

validate the concept through clear and concrete evidence. It is, at best, a speculative supposition;

c. The consultation document places undue weight on some research and ignores the substantial research evidence set out in this response that points to factors which are better indications of why young people use tobacco products;

d. There is a considerable body of research which suggests that a significant number of non-smoking young people as well as existing youth and adult smokers may become "reactant" in the face of new tobacco control measures such as display bans and plain packaging. That is to say that they could act counter-intuitively to proposals and that smoking incidence could increase;

e. The UK DoH has failed to take into account the balance between regulation and personal freedoms; and

f. The Regulatory Impact Assessment underpinning the Government consultation document fails to meet standards of "analytical rigour" (as defined by the Better Regulation Executive[5]) and is based on a flawed supposition.

5. There is widespread misunderstanding of the concept of 'risk' in society which opens the way for sensationalism or coercive publicity and leads to disproportionate public policy responses. Imperial Tobacco also believes that there is over-reliance on the "precautionary principle", bolstering general risk-aversion.

6. Imperial Tobacco believes that the regulatory proposals in the consultation document make no overall contribution to the public awareness of the risks associated with smoking, which we believe are already well known. It is our view that such actions are designed to stigmatise existing adult smokers who exercise their freedom to choose to smoke and to place further significant burdens on the retail chain.

[5] The Tool to Deliver Better Regulation: Revising the Regulatory Impact Assessment – a consultation, Better Regulation Executive, 2006

7. The Government's case for 1) banning the retail display of tobacco products and the limited advertising space permitted at the point of sale; and 2) the imposition of plain, unbranded tobacco packaging is premised on three suppositions:

   a. that tobacco packaging constitutes a form of advertising for smoking;

   b. that tobacco advertising in general causes individuals to smoke; and

   c. that seeing tobacco packaging on display and point of sale advertising causes young people, occasional smokers, smokers who are attempting to quit and former smokers to smoke.

8. Imperial Tobacco does not accept the view as expressed in the consultation document that tobacco packages and displays of tobacco packages constitute tobacco advertising. This is backed up by evidence in terms of the effects (or lack of effects) on youth smoking initiation. We concur with the conclusions of the expert health panel report to Health Canada in 1995 that young people do not decide to smoke on the basis of tobacco packages, that they do not have images of brands that are connected to lifestyles, that packages do not lead to smoking and that changing the package will not *"have any major effect on the decision(s) to smoke or not to smoke".*[6]

Tobacco advertising and retail displays

9. Whether the tobacco packet is considered to be a form of advertising or not, none of the available evidence suggests a causal relationship between tobacco advertising and consumption, between tobacco advertising and smoking initiation or between restricting tobacco advertising and changes in consumption or initiation. The fact that past restrictions of tobacco advertising have not been shown to reduce smoking initiation or consumption negates the UK DoH's claim in section 3.44 of the consultation document that the *"evidence suggests that we could expect to*

[6] Goldberg ME, Liefeld J, Kindra K, Madill-Marshall J, Lefebvre J, Martohardjono N and Vredenburg H. *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products: Expert Panel Report to Health Canada, Ottawa, 1995.*

see fewer young people starting to use tobacco, and that smoking prevalence among young people could decline at a faster rate than we are currently experiencing[7]*"* should tobacco displays be restricted or tobacco packaging changed.

10. The UK DoH consultation document argues that the *"evidence about the public health benefits of prohibiting the display of tobacco products in retail environments is strong*[8]*".* This claim is also unfounded. The evidence cited by the UK DoH consultation document in support of a display ban consists of a limited review of a small number of studies. It ignores a significant number of other studies about smoking uptake, prevention and cessation.

11. We also do not find convincing the evidence cited by DoH from other jurisdictions which purports to show that tobacco product display restrictions have reduced either the consumption of tobacco products or youth smoking initiation in countries where they have actually been introduced. In fact, evidence from Canada and Iceland, for example, suggests the contrary.

12. The retail supply of tobacco to consumers is already strictly controlled. Currently, tobacco products can only be purchased in two ways: 1) face-to-face transactions with the retailer, with product stored on gantries which are always situated behind the retailer and out of reach of the customer; and 2) from vending machines (this applies to less than 1 per cent of overall market volume).

13. Maintaining the display of tobacco at the point of sale is essential for efficient retailing, given the high turnover and value of the product.

14. The display of tobacco products is important to ensure adult choice and free and fair competition. It provides consumers with the information to make a selection from the wide range of tobacco products, brands and prices that are available in retail outlets. A ban on tobacco product displays

[7] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.44
[8] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.45

would favour dominant brands and suppliers and would act as a barrier to entry for new brands and suppliers.

15. It is our view that a retail display ban would exacerbate the already significant levels of illicit trade taking place throughout the UK as the lines between legal and illegal product are blurred. Imperial Tobacco agrees with the assessment made in the consultation document that illicit trade undermines public health objectives, damages legitimate business and results in substantial revenue losses to HM Treasury, through creating a market that is uncontrolled, untaxed and unaccountable.

16. In view of the lack of credible evidence presented in the UK DoH consultation document that restricting or banning retail tobacco product displays will have any positive impact on youth smoking initiation or consumption, and mindful of the negative effects it would have on competition and illicit trade, Imperial Tobacco supports **Option One** as set out in the consultation document. However, it is our view that this should be supported with greater enforcement of current minimum age laws together with additional resources to support Trading Standards in their efforts to tackle illegal selling.

Plain Packaging

17. We believe that plain packaging for tobacco products is unnecessary, unreasonable and unjustified. It is not based on sound public policy, or on compelling evidence. Plain packaging would not address the issues that the DoH seeks to combat: it would make no overall contribution to the public awareness of the risks associated with smoking; it would not provide more information to smokers; and it would not reduce the appeal of tobacco products, especially to young people.

18. The primary risk factors for youth smoking initiation are clearly documented. Packaging of tobacco products is not one of these risk factors. The introduction of plain packaging would make no contribution to addressing youth smoking initiation.

19. The balance of the available evidence (including evidence upon which the UK DoH claims to rely) does not provide a compelling argument to suggest that the plain packaging of tobacco products would have the effect of deterring young people from smoking. In fact, certain evidence suggests the potential for the contrary.

20. Imperial Tobacco is concerned about the continued erosion and potential expropriation of our valuable intellectual property rights. We believe that we are entitled to use our packaging to enable adult consumers to distinguish our quality products from those of our competitors. Regulation that requires plain packaging will expropriate valuable corporate assets in which the Company and its shareholders have invested for more than a century and risks placing the UK government in breach of a range of legal and treaty obligations that relate to intellectual property rights, international trade and EU law. The introduction of plain packaging would set a regulatory precedent for intellectual property owners and their shareholders outside the tobacco sector.

21. Plain packaging will have a negative effect on competition. There would be little incentive for retailers to stock new brands and it would be practically impossible for a new competitor to enter the market successfully or an existing competitor to compete with others by launching a new brand.

22. Plain packs would facilitate counterfeiting and undermine the excellent work that has been done jointly by the industry and UK HMRC over a long period of time to combat illicit trade. Due to the relative ease with which the materials for a tobacco product are acquired and the cigarette itself counterfeited, one of the key components in the fight against counterfeit is the packet itself. Both overt and covert elements of the pack design are incorporated to frustrate counterfeiters' attempts to copy the pack exactly and to facilitate identification of illegal product. An obvious repercussion of the introduction of plain packaging would be to make the counterfeiter's task substantially easier.

TOBACCO ACCESSORIES, VENDING MACHINES AND MINIMUM PACK SIZES

Tobacco accessories

23. Imperial Tobacco is implacably opposed to the suggestion that there should be restrictions on the advertising and promotion of tobacco accessories (such as rolling papers, lighters, filters and matches).

24. The demand for tobacco accessories is determined by the extent of tobacco smoking and not vice versa. Non-smokers who do not use tobacco products are not encouraged to start smoking by seeing an advertisement for a brand of rolling papers or an advertisement for a cigarette lighter. Similarly, brand advertising of rolling papers has neither the purpose nor the effect of increasing the consumption of hand-rolling tobacco. There is no evidence for either supposition made in the consultation document.

25. The advertising of rolling papers or of any other tobacco-related accessory has the purpose and effect of promoting one specific brand over competitor brands to consumers who already require the product (i.e. those who already enjoy tobacco).

26. No evidence is presented to demonstrate that a ban on the advertising of rolling papers would reduce the incidence of cannabis use. This would be as illogical a step as restricting the advertisement of drinks in plastic bottles because these are known to be delivery systems for illegal drugs.

Vending machines

27. Imperial Tobacco supports reasonable solutions to reduce the illegal access by minors to cigarettes through vending machines. With this in mind, we support Option Two - restricted access mechanisms - as a proportionate measure.

28. Imperial Tobacco does not believe that minors access cigarettes from vending machines in great numbers, and the incidence appears to be declining, as demonstrated by a 2006 Government study[9].

29. The implementation of the smoking ban in public places (including licensed outlets such as pubs, bars and restaurants) has caused a major decline in vending sales. Less than 1 per cent of all tobacco sales come from vending machines. It is highly unlikely that many licensed outlets would opt to continue to sell tobacco (i.e. over the bar) in the event of a ban on vending. In such a scenario it is most likely that, if smokers are unable to purchase tobacco from a vending machine, the void would be filled by illegal sellers who move from pub to pub selling UK non duty paid cigarettes.

30. It is our view that a ban on vending would be a disproportionate response to a diminishing problem and would create other unintended unfortunate consequences.

Minimum Pack Sizes

31. Imperial Tobacco does not believe that the proposal to increase the minimum size of cigarette packets has any merit as an initiative to reduce smoking uptake by young people – or anyone else. We believe it may in fact be counterproductive as it may encourage both increased consumption and the illicit trade.

32. Many adult smokers use smaller packs to manage their daily consumption and/or their daily expenditure. Rather than stopping smoking in the event of a ban, those who would otherwise buy smaller packs would migrate instead to packets of twenty cigarettes, both legitimate and non-duty paid.

33. Since the ban on smaller packs in Ireland, overall sales volumes have increased in the market although unit pack sales have decreased. This demonstrates that, rather than encouraging smokers to quit, there has been a transfer from smaller packs to packets of twenty[10].

[9] Smoking, Drinking & Drug Use, 2006, The Information Centre for Health & Social Care.
[10] Nielsen Ireland based on 60% of retail universe

34. A ban on smaller packs may encourage the price-sensitive consumer who cannot afford to purchase a larger pack to seek a cheaper alternative. This is most likely to be derived from the black market (smuggled and counterfeit) through the many illegal selling networks which are present throughout the UK.

35. Non-duty paid volumes in Ireland have also increased markedly since the ban on smaller packs. It can be assumed that this is partly attributable to consumers seeking cheap cigarettes from the black market via street markets and other illicit channels. It is also of note that Imperial Tobacco is not aware of any instances of packs of ten cigarettes being counterfeited and no instances in the UK of such packs being smuggled.

YOUTH SMOKING

36. Evidence outlined in this submission suggests that the root causes of youth smoking have nothing to do with tobacco advertising, displays or packaging. Instead, the principal causes include factors such as rebelliousness and risk taking, family structure and relationships, socioeconomic status, school connection and educational success. As such, the determinants of youth smoking are not advertising, tobacco displays or tobacco packaging but more fundamental factors.

37. A tobacco strategy focused on advertising, displays and packaging will be disconnected from these factors and is unlikely to achieve the DoH's stated objective.

38. Imperial Tobacco does not believe we are qualified or sufficiently well informed on broader socio-economic issues and how those might be successfully influenced by Government policy. However, we are certain that further tobacco control measures as those outlined in the consultation document are not the measures which will address the Government's objectives of reducing youth smoking initiation. If the UK Government are serious about achieving those objectives they should look more closely at all the evidence and propose solutions that address its indications rather

than seeking out 'easy targets' which can be introduced at little cost to the Government but will be entirely ineffective.

39. This should be supported with greater enforcement of current minimum age laws together with additional resources to support enforcement agencies in their efforts to tackle illegal sales.

40. We would not oppose legislation which would make it an offence for an adult to purchase tobacco on behalf of a minor (proxy purchasing) should the UK Government wish to reconsider complementing existing age of sale laws. As it may be difficult to enforce proxy purchasing regulation we would encourage careful consideration to be given to the practicality of effective enforcement.

COMBATING THE ILLICIT TRADE

41. Imperial Tobacco defines the illicit trade in tobacco as the sale of tobacco products on which UK taxes and excise duties have not been levied (non UK duty paid or NUKDP); including smuggled and counterfeit products. The "grey" market consists of NUKDP tobacco products that have been imported legitimately for personal consumption.

42. We are totally opposed to the illicit trade and work closely with governments and customs and excise authorities around the world to combat such activities.

43. Smuggling benefits only the criminals involved. It creates an uncontrolled and unregulated market that is untaxed and unaccountable. The illicit trade undermines public health policy and law and order and threatens the livelihoods of tobacco retailers.

44. The UK Tobacco Manufacturers' Association estimates that 27 per cent of all cigarettes consumed in the UK are non-UK duty paid. This is very close to the HMRC estimate of 26 per cent[11]. Around 70 per cent of all large seizures of illegal cigarettes are counterfeit, as opposed to genuine product smuggled from other countries.

[11] HMRC, October 2007, Measuring Indirect Tax Losses 2007, p.11

45. The illicit trade in tobacco products is driven by the potential profits for smugglers. The source for such profit is in price differentials which are, in turn, created by tax differentials. The highest profits for smugglers are derived from counterfeit tobacco products, as these are entirely free of tax. The price differentials derived from counterfeit products in the UK make the UK a very attractive market in which smugglers and counterfeiters can operate.

46. Imperial Tobacco believes that regulation to introduce plain packaging, ban retail product displays and reduce availability by increasing the minimum pack size and banning vending with a potential consequent reduction in legal points of sale, is likely to increase the illicit trade.

47. Display bans will make distribution of illicit tobacco products easier. If legal products are hidden from view, it will be more difficult for retailers, customers and enforcement officers to distinguish between legal, duty paid products and illegal, non-duty paid products. This could lead to an increase in the market for illicit tobacco products.

48. A display ban could lead to a reduction in the number of retail outlets legitimately selling tobacco. Any reduction in the legitimate retail universe is likely to lead to an increase in illicit sales as those channels replace legitimate ones.

49. Plain packs are likely to lead to an increase in counterfeit products that are sold in the UK. Plain packs are easier for a counterfeiter to copy and the scope for design changes would be dramatically reduced, making it easier for counterfeiters to keep up to date with manufacturers' genuine products. Consumers and enforcement agencies would have much more difficulty in differentiating between genuine and counterfeit products.

50. Any ban on vending machines is likely to increase the illicit trade. In a large number of venues, tobacco products are not stocked behind the counter and are only available through vending machines. If vending machines are removed from those outlets, tobacco products would not be legitimately available and uncontrolled vendors selling illicit products would be likely to replace them.

51. Smokers use smaller packs (i.e. those containing fewer than twenty cigarettes) to manage their consumption and expenditure. If cigarettes in packs of fewer than twenty were banned, the illicit trade would be very likely to increase. Smokers who could not afford a legitimate pack of twenty would be likely to seek alternative sources of supply from the illicit market.

52. Imperial Tobacco enjoys a constructive and fruitful relationship with HMRC which has seen a reduction in the illegal tobacco market in recent years. On the back of its significant expertise and experience in combating the spread of non-duty paid tobacco globally, Imperial Tobacco makes a number of policy recommendations in this submission.

NICOTINE AND ADDICTION

53. Imperial Tobacco believes that the underlying assumptions of Parts C ("Supporting smokers to quit") and D ("Helping those who cannot quit") of the consultation document fundamentally misinterpret why people choose to smoke and the role that nicotine plays in smoking. This chapter provides a complete and balanced view of the relevant evidence.

54. Smoking is a complex behaviour and different people smoke for different reasons. Fundamentally however, people smoke cigarettes because they enjoy smoking. It brings them pleasure and they derive a variety of benefits from smoking.

55. Imperial Tobacco agrees that smoking can be characterised as addictive as the term is commonly used today. Some people may find it difficult to stop smoking, but we believe it is important for them to understand that if they choose to stop, they are able to do so. Millions of people have stopped smoking, the majority without assistance. There are, however, many people who exercise an adult choice to continue to smoke and use tobacco.

56. When pharmacologists first established standards for distinguishing addictive substances from ordinary substances that people use, smoking fell into the category of habit and not addiction. The pharmacological

definitions of addiction and habit were promulgated by the World Health Organization ("WHO") in 1957 and later used by the Advisory Committee to the US Surgeon General ("Advisory Committee"), in preparing its 1964 Report. The 1964 report concluded that smoking is a habit, not an addiction.

57. As the field of addiction, or more properly "dependence", fell under the provenance of psychiatrists and psychologists (behaviouralists) as opposed to pharmacologists, the definition of dependence expanded and became more flexible and less objective.

58. The term "addiction" was never used in the various versions of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM), and the term was replaced with "dependence" by the World Health Organisation in its International Classification of Diseases (ICD) as early as 1965. The term "addiction" was reintroduced into the public discourse on smoking primarily by the US Surgeon General in its 1988 report entitled "Nicotine Addiction". This is now widely acknowledged to have been a deliberate move to apply pejorative connotations to a smoking habit – the term "addiction" carries with it not only a sense of moral judgement, but also the convenient comparison to the abuse of illicit substances.

59. The use of the term "addiction" in connection with smoking has also become commonplace in the UK. The view that smokers are "addicted" to smoking or nicotine has fostered an environment in which the term "addiction" and related concepts, such as "dependence," "hooked," "diminished autonomy," etc. are used without qualification.

60. A view of smoking as the equivalent to "nicotine addiction" in which the smoker has no choice but to smoke is also inconsistent with the way in which society views the ability of individuals to make informed decisions. It also flies in the face of the fact that millions of people have stopped smoking. Cigarette smoking is not an "addiction" if the use of that term is intended to mean that a person is unable to stop smoking. While some

smokers might have difficulty in stopping, anyone can stop if they choose to do so.

61. If the consultation's assertion that "nicotine dependence is a major determinant of the ease of quitting" (section 2.15) is true, it would be expected that use of Nicotine Replacement Therapy ("NRT") would be highly effective in assisting smokers in stopping smoking. Contrary to this, the Tobacco Advisory Group of the Royal College of Physicians in its 2007 Report noted that NRT *"is not as efficacious as would be anticipated if tobacco dependence reflected a 'simple' addiction to nicotine."*[12] This conclusion confirms that, *"The most well-known anomaly to the nicotine addiction thesis is the modest efficacy of nicotine replacement therapy (NRT) for smoking cessation."*[13]

62. A recent meta-analysis of 111 NRT studies found that in almost 60% of those trials, NRT either had no effect or was less effective than placebo.[14] In studies claiming that NRT is effective, the actual differences between NRT and placebo are small and, in fact, a recent study found that after 48 weeks, only 10% of people using NRTs had stopped smoking, in contrast to 12% of people using placebo.[15]

63. It might also be expected that if nicotine were "addicting," nicotine administered in an NRT would be abused like heroin and other drugs of abuse. However, there is no convincing evidence to suggest that NRTs are abused. A leading commentator observed that "*evidence of nicotine replacement product abuse is essentially nonexistent."*[16]

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12 Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP; 2007. p. 54.

13 Dar R, Frenk H. Re-evaluating the nicotine delivery kinetics hypothesis. *Psychopharmacology (Berl)* 2007; 192: 1-7.

14 Stead L, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Datab Syst Rev* 2008; CD000146

15 Id.

16 Hughes JR. Part IV. Behavioural toxicity of nicotine: Dependence on and abuse of nicotine replacement medications: An update. In: Benowitz NL, editors. Nicotine Safety and Toxicity. New York: Oxford University Press; 1998. pp. 147-57.

64. The lack of efficacy of NRTs and the fact that they are not abused like usual drugs of abuse, present major challenges to the claim that cigarette smoking can be explained as an addiction to nicotine.

65. To attempt to explain an individual's lack of success in smoking cessation as the result of "addiction" lacks explanatory power. It is merely a convenient way to try to explain a behaviour ("smoking") by attributing a reason for the behaviour (*"people smoke because they are addicted"*).

66. It is more useful to analyse why people may find it difficult to stop smoking in the context of why people generally may find it difficult to alter other habits. When one considers that smoking confers many and different benefits to smokers in different times and situations, it is understandable that altering this habit and stopping smoking might be difficult for some people.

POTENTIALLY REDUCED EXPOSURE AND POTENTIALLY REDUCED RISK PRODUCTS FOR THOSE WHO CHOOSE TO SMOKE

67. Imperial Tobacco has long requested the UK Government to develop criteria by which tobacco products can be judged on the basis of their relative risks. These would serve to provide adult consumers with the means by which they can manage their own health by choosing recognisable tobacco products that may offer reduced risk. There has been little progress on this.

68. Successive UK governments appear to have been ambivalent with regard to the concept of so-called "reduced harm" or "reduced risk" tobacco products. Our experience in developing and marketing a concept called New Smoking Material in the 1970s highlighted the importance of collaboration and the establishment of common goals between the tobacco industry and the Government.

69. Specific Government aims should be made clear if there is to be progress on this issue. However, the debate is overly politicised by the emotional intervention of many single issue pressure groups which do not seem to understand the relevant science.

70. Imperial Tobacco continues to conduct research into tobacco products which may come to be regarded as potentially offering reduced risk to consumers. We have submitted data on such products to the DoH but, as yet, have received no considered expert review.

71. In the consultation document the Department of Health notes the significant effort by the tobacco industry in the research and development of Potentially Reduced Exposure Products but that the "[e]vidence on the *relative safety of these products is not conclusive*[17]".The lack of evidence on the relative risks of these products is in part due to a lack of consensus on objective criteria and predictive tests required to make such a comparative analysis.

72. If the Department of Health is serious in exercising its obligations to people who choose to continue smoking, the best way forward is to pursue a policy of constructive dialogue with Imperial Tobacco and other tobacco manufacturers with the aim of developing the objective criteria and predictive tests that are essential to make progress in this area.

ENVIRONMENTAL TOBACCO SMOKE

73. Imperial Tobacco believes that the decision to use tobacco products is a choice for adults. In as much as smokers should show courtesy to other adults, this courtesy should especially be extended to children, who are often unable to exercise a choice in their environment and surroundings in the way that adults can.

74. However, Imperial Tobacco completely rejects the notion that further restrictions on smoking in private premises or in private vehicles in isolation are in any way justified. It is our view that Government has no role in regulating the private lives of adults in the UK who have chosen to smoke.

75. Imperial Tobacco's view on Environmental Tobacco Smoke (ETS) concurs largely with the opinion expressed by the Economic Affairs Committee of

[17] Department of Health (2008). Consultation on the future of tobacco control. p.54, para.5.18.

the House of Lords in 2006 that: *"the decision to ban smoking in public places [in the UK] may represent a disproportionate response to a relatively minor health concern."*

76. Rather than encouraging smoking cessation, the smoking ban has instead had a well-documented negative impact on many other UK businesses, especially in the hospitality sector.

77. The UK Department of Health should stand aside from the emotion of vested interests and critically re-examine the impact of the existing ban, accepting that there have been negative impacts both in financial and in social terms. These areas need to be addressed in the forthcoming review of the smoking ban which is scheduled for 2010.

78. Imperial Tobacco believes that adults who choose to smoke and non-smokers who choose to accompany them should be able to do so in primarily adult venues in which they work and socialise.

79. In reassessing this balance, the Government should give consideration to the proven potential of ventilation to achieve exceptional indoor-air quality, even in venues where smoking may be permitted. To focus entirely on the elimination of smoking ignores other substances that affect indoor-air quality, and smoke free policies have removed the incentive for many owners to provide effective ventilation in their premises. We therefore believe that indoor-air standards for workplaces and hospitality venues would provide a more comprehensive and holistic approach to achieving beneficial indoor-air quality.

1. THE PRINCIPLES OF GOOD REGULATION

1. THE PRINCIPLES OF GOOD REGULATION

1.1. SUMMARY

Imperial Tobacco supports the sound, reasonable and practicable regulation of tobacco products. We recognise that it is the role of governments to provide the general public with clear and consistent messages about the health risks to smokers that are associated with their smoking. We do not challenge these messages.

The standards to be applied to regulatory policy with regard to risks such as those associated with tobacco have been clearly established; for example, in HM Treasury's Green Book, Appraisal and Evaluation in Central Government, 2003[18] and Orange Book, Management of Risk, 2004[19]. They are elaborated in the context of tobacco regulation in the House of Lords' Select Committee on Economic Affairs' Report "Government Policy on the Management of Risk" 2006[20]. They were documented in 2006 by the Better Regulation Commission in its "Five Principles of Good Regulation"[21] as:

- Proportionality;
- Accountability;
- Consistency;
- Transparency; and
- Targeting.

Imperial Tobacco believes that the consultation document does not reflect these principles on the grounds that:

- While the use of tobacco products by young people is an issue of public policy, the consultation document has not advanced significant credible evidence which shows that retail tobacco product displays

[18] The Green Book, Appraisal and Evaluation in Central Government 2003, http://www.hm-treasury.gov.uk/

[19] The Orange Book, Management of Risk Principles & Concepts 2004, http://www.hm-treasury.gov.uk/

[20] House of Lords' Select Committee on Economic Affairs 5th Report of Session 2005-06 p6 sections 4, 6, 8

[21] Risk, Responsibility and Regulation – Whose risk is it anyway? Better Regulation Commission, October 2006, http://archive.cabinetoffice.gov.uk/brc/publications/risk_report.html

(including vending), branded tobacco packs or the sale of cigarettes in packs of fewer than twenty are directly responsible for young people starting to smoke or smoking more;

- The section in the UK DoH consultation document on plain packaging states that *"denormalisation"* is an objective of tobacco control policy (section 3.70). Imperial Tobacco contends that "denormalisation" is not in itself a conceptual objective that is compatible with the principles of good regulation of a legal product. It is unclear in its definition and has no clear, measurable objective. It is impossible to further define and validate the concept through clear and concrete evidence. "Denormalisation" is, at best, a speculative supposition;
- The consultation document places undue weight on some research yet ignores the substantial research evidence (set out in this response) that points to factors which provide better indications of why young people use tobacco products;
- There is a considerable body of research which suggests that a significant number of non-smoking young people as well as existing youth and adult smokers may become "reactant" in the face of new tobacco control measures such as display bans and plain packaging. That is to say they could act counter-intuitively to proposals and that smoking incidence could increase;
- The UK DoH has failed to take into account the balance between regulation and personal freedoms; and finally,
- The Regulatory Impact Assessment underpinning the Government consultation document fails to meet standards of "analytical rigour" (as defined by the Better Regulation Executive[22]) and is based on a flawed supposition.

There is widespread misunderstanding of the concept of 'risk' in society which opens the way for sensationalism or coercive publicity and leads to disproportionate public policy responses. Imperial Tobacco also believes that

[22] The Tool to Deliver Better Regulation: Revising the Regulatory Impact Assessment – a consultation, Better Regulation Executive, 2006

there is over-reliance on the "precautionary principle"[23], bolstering general risk-aversion.

Imperial Tobacco believes that the regulatory proposals in the consultation document make no overall contribution to the public awareness of the risks associated with smoking, which we believe are already well known. It is our view that such actions are designed to stigmatise existing adult smokers who exercise their freedom to choose to smoke and to place further significant burdens on the retail chain.

1.2. INTRODUCTION

Imperial Tobacco supports the sound, reasonable and practicable regulation of tobacco products. We recognise that it is the role of governments to provide the general public with clear and consistent messages about the health risks to smokers that are associated with their smoking. We do not challenge those messages.

Good regulation is principled regulation. The core principles of sound regulatory policy have frequently been identified, including in a range of Government documents, parliamentary reports and speeches by senior advisers. For example, under the leadership of HM Treasury, the Government's Risk Programme has laid down a general framework of regulatory principles with regard to risk management. The standards to be applied to regulatory policy with regard to risks such as those associated with tobacco have been clearly established, for example, in HM Treasury's Green Book, Appraisal and Evaluation in Central Government, 2003[24] and Orange Book, Management of Risk, 2004[25]. They are elaborated in the context of tobacco regulation in the House of Lords' Select Committee on Economic Affairs' Report "Government Policy on the Management of Risk" 2006[26]. They

[23] Communication from the Commission on the Precautionary Principle (2nd February 2000) COM(2000)1

[24] The Green Book, Appraisal and Evaluation in Central Government 2003, http://www.hm-treasury.gov.uk/

[25] The Orange Book, Management of Risk Principles & Concepts 2004, http://www.hm-treasury.gov.uk/

[26] House of Lords' Select Committee on Economic Affairs 5th Report of Session 2005-06 p6 sections 4, 6,8

were documented in 2006 by the Better Regulation Commission in its "Five Principles of Good Regulation"[27]. It is therefore justified to critically review and question the degree to which the UK DoH consultation meets these recognised standards and criteria against an established framework.

The Better Regulation Commission documented its "Five Principles of Good Regulation" as:

- Proportionality – regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.
- Accountability – regulators must be able to justify decisions and be subject to public scrutiny.
- Consistency – government rules and standards must be joined up and implemented fairly.
- Transparency – regulators should be open and keep regulations simple and user-friendly.
- Targeting – regulation should be focused on the problem and minimise side effects.

In the foreword to "Risk, Responsibility and Regulation – Whose Risk is it Anyway?"[28] the Chairman of the Better Regulation Executive, Rick Haythornthwaite, called on *"our leaders to redefine our approach to risk management in a number of ways*:

> *a) emphasise the importance of resilience, self-reliance, freedom, innovation and a spirit of adventure in today's society;*
>
> *b) leave the responsibility for managing risk with those best placed to manage it and embark on state regulation only where it represents the optimum solution for managing risk;*
>
> *c) re-examine areas where the state has assumed more responsibility for people's lives than is healthy or desired; and*

[27] Risk, Responsibility and Regulation – Whose risk is it anyway?, Better Regulation Commission, October 2006, http://archive.cabinetoffice.gov.uk/brc/publications/risk_report.html
[28] Risk, Responsibility and Regulation – Whose risk is it anyway?, Better Regulation Commission, October 2006, http://archive.cabinetoffice.gov.uk/brc/publications/risk_report.html

d) separate fact from emotion and emphasise the need to balance necessary levels of protection with preserving reasonable levels of risk."

The 2006 Report of the House of Commons Science & Technology Committee[29] noted that in March 1997, the then Government Chief Scientific Adviser published Guidelines on the Use of Scientific Advice in Policy Making, *"setting out principles to be followed by government departments in using and presenting scientific advice and evidence".* The Guidelines were subsequently updated in 2000 and 2005 and *"explicitly state that they apply to social science as well as natural and physical science".*

These Guidelines aim to address *"how evidence should be sought and applied to enhance the ability of government decision makers to make better informed decisions".* The key messages include the advice that policy makers should:

- *"get a wide range of advice from the best sources, particularly when there is uncertainty;* and
- *publish the evidence and analysis and all relevant papers"*[30].

Regulatory policies that do not meet the standards outlined above cannot properly be described as proportionate and in our view should be rejected by regulators.

1.3. PUBLIC HEALTH REGULATION AND TOBACCO

Imperial Tobacco believes that government policy with regard to tobacco products must meet the same standards and principles of sound regulatory policy as those set out by the Better Regulation Commission and others (see above). However, Imperial Tobacco believes that the proposals for and discussions about potential tobacco regulation (including proposals or references in the UK DoH consultation document that relate particularly to the

[29] House of Commons Science & Technology Committee 7th Report of 2005/6 session, Scientific Advice, Risk and Evidence Based Policy Making, HMSO, 8 November 2006

[30] Chief Scientific Adviser/Office of Science and Innovation, Guidelines On Scientific Analysis In Policy Making, October 2005, para 4

display and packaging of tobacco products, as well as to cigarettes in packs of fewer than twenty, vending and advertising for tobacco accessories) that are advanced in the UK DoH consultation document fail to meet the standards of sound regulation in several key respects.

a. While the use of tobacco products by young people is an issue of public policy, the consultation document has not advanced credible evidence which shows that retail tobacco product displays including vending, branded tobacco packs, the sale of cigarettes in packs of fewer than twenty or the advertising of tobacco accessories are directly responsible for young people starting to smoke or smoking more.

While we accept that youth smoking is a public policy issue, we do not accept that retail tobacco product displays including vending, branded tobacco packs, the sale of cigarettes in packs of fewer than 20 or the advertising of tobacco accessories constitute problems requiring regulatory action. Indeed, the UK DoH consultation fails to meet the Treasury's requirement of openness and transparency in risk regulation. This is particularly obvious in two respects.

First, the consultation (while appearing to ask about options for *"reducing demand for tobacco products among young people")* effectively precludes a broader or alternative approach to this issue by focusing exclusively on its apparently preferred options, such as display bans. The Minister for Health has been interviewed in the UK media[31] stating her Department's preferences to explore these solutions. The consultation document however excludes alternative opinions on tobacco control, even those of some of its own experts, which suggest radically different approaches to *"reducing demand for tobacco products among young people"*.

Second, a lack of transparency and openness is clear in the consultation document in its apparent misinterpretation or possibly even its misrepresentation of the evidence about (for instance) display bans and plain packaging. The document not only fails to mention the contradictory evidence

[31] Today Programme, BBC Radio 4, 31/05/08 at 08:10 am

and studies (thereby apparently not undertaking a fair appraisal of the issue); it also excludes relevant studies from some of its own sources. This is evidence which calls into question the material being put forward to support the already limited options that are being considered.

b. The evidence provided in the consultation document fails to meet the minimum standards of rationality, consistency or substance. For example, the consultation document fails to provide any compelling evidence that retail display bans, plain packaging, bans on cigarettes in packs of fewer than twenty or bans on vending machines will reduce smoking initiation, reduce consumption or prevent smoking relapse.

We do not believe that the UK DoH consultation document fulfils its evidentiary responsibilities. This is apparent in a number of areas, most particularly with regard to the evidence cited with respect to tobacco advertising, tobacco displays and tobacco packaging.

For example, in its discussion of tobacco advertising and its claimed effect on smoking initiation, the UK DoH consultation document fails to include any discussion of econometric studies of tobacco advertising and consumption. This is despite the fact that this has been the primary means of analysing this issue for more than twenty-five years. Instead, it relies exclusively on advertising exposure and recall studies without acknowledging the significant methodological flaws in such studies. The UK DoH consultation document cites a study undertaken for the UK DoH by Smee et al[32] in 1992 of tobacco advertising in the UK market, which included an analysis of other studies. The consultation document does not acknowledge that the conclusions of Smee's own study do not support the UK DoH's contention that tobacco advertising leads young people to start smoking:

"There is a great deal of evidence to show that young people recognise tobacco advertisements and that those who go on to smoke are more likely to

[32] Smee C, Parsonage M, Anderson R, Duckworth S. (1992) *Effect of tobacco advertising on tobacco consumption: A discussion document reviewing the evidence.* London: Economics & Operational Research Division, Department of Health

recognise them. But awareness of advertising is at most a necessary condition for coming under its influence. It is not reliable evidence that advertising increases consumption. … Some studies have found that advertising has a statistically significant effect on consumption: others, including our own, have not."[33]

Similarly, the UK DoH consultation document refers to strong evidence about the supposed connection between smoking initiation and tobacco displays or between tobacco displays and smoker relapse. Yet in reality the document examines only two studies that look at displays and youth smoking and only one study that considers displays and smoker relapse. Moreover, each of these has significant flaws and in many instances do not reach statistical significance. To describe such evidence as "strong" is significantly over-stating the case.

The UK DoH consultation document's evidentiary burden is inadequately discharged with regard to plain packaging. The results of the studies offered in support of such proposals actually provide empirical support for not proceeding with such a policy.

The consultation fails the evidentiary responsibilities set out by the House of Lords' Select Committee on Economic Affairs[34] in that it does not cite all of the *"appropriate evidence"* nor carefully judge the quality of the evidence. As a result, it fails to fulfil what the Committee suggested is the Government's chief responsibility in advancing regulation; namely that it be *"soundly based on available evidence and not unduly influenced by transitory or exaggerated opinions … "*

It is our view that such policy proposals or discussions are designed to stigmatise and denormalise existing adult smokers who exercise their freedom to choose to smoke; and to place further significant burdens on the retail chain.

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[33] Smee C, Parsonage M, Anderson R, Duckworth S. (1992) *Effect of tobacco advertising on tobacco consumption: A discussion document reviewing the evidence.* London: Economics & Operational Research Division, Department of Health

[34] House of Lords' Select Committee on Economic Affairs 5th Report of Session 2005-06

c. Imperial Tobacco believes that the consultation document places undue weight on some research and ignores the substantial research evidence set out in this response that points to factors which are better indications of why young people use tobacco products.

Imperial Tobacco believes that the consultation document fails to provide a rational or coherent regulatory agenda that connects precisely the most reliable risk factors for smoking initiation (as outlined in Chapter 4 of this submission) and continued adult smoking with measures designed to address these factors. In other words, there is a profound disconnect between the major sources of smoking initiation suggested by the consultation document's own cited experts and the strategy proposed to prevent smoking initiation that is ultimately put forward in the document. It is difficult to understand for example how banning tobacco displays will address the problem of educational failure and poor schools, which are widely acknowledged as strong predictors of smoking uptake. In effect, the consultation, even on its own limited terms, fails rationally to connect its proposed solutions to its perceived problem.

d. There is a considerable body of research which suggests that a significant number of both non-smoking young people as well as existing youth and adult smokers may become reactant in the face of new tobacco control measures such as display bans and plain packaging; something that could result in increased rather than reduced levels of smoking incidence.

We believe that the measures advanced in the UK DoH consultation document cannot meet the requirement of a high probability of success. Indeed, the UK DoH itself concedes this by noting that the empirical evidence in favour of these measures is marginal. As we put forward in this document, it is our view that the empirical evidence is non-existent or, in some instances, suggests that the measures simply will not work.

The evidence for the likely failure of the proposed measures comes from four sources.

First, there is the lack of probity in the studies cited in support of these proposals (see Chapter 2 for a full analysis). The results of these studies, which frequently fail to reach statistical significance (or in the case of plain packaging do not offer any statistical analysis), cannot provide any optimism for success. Indeed, in the case of plain packaging the few empirical results that are reported suggest that the measure will have no impact on youth smoking.

Second, there is the fact that the proposed measures do not address the root causes of smoking initiation or youth smoking. Without such a link it is highly unlikely that they will achieve the goals.

Third, "real-world" results in jurisdictions such as Canada and Iceland have shown that measures such as display bans have not reduced smoking prevalence or enhanced quitting rates.

Finally, the literature on smoking reactance and data from several of these studies on plain packaging suggest that measures such as these will likely lead to more smoking uptake and hardened attitudes against quitting (reactance) in existing smokers. This latter fact points to the likelihood that the measures advanced in the consultation document will also fail one of the key Principles of Good Regulation in that they will generate perverse and unintended consequences. There is a very real risk, as the House of Lords' Select Committee noted, of generating *"an outcome which is actually worse than the one that would have prevailed in the absence of intervention, particularly when the policy action has unintended consequences* [35]*"*

e. Imperial Tobacco believes that the UK DoH has failed to take into account the balance between regulation and personal freedoms as identified by authorities such as the House of Lords' Economic Affairs Select Committee in its 2006 Report "Government Policy on the Management of Risk".

Imperial Tobacco believes that the consultation document fails to meet a key principle of good regulation; namely to be respectful of core democratic values

[35] House of Lords' Select Committee on Economic Affairs 5th Report of Session 2005-06

such as individual freedom. It is a particularly regrettable fact of tobacco regulation that it consistently fails to take the House of Lords' Select Committee's concerns about the *"trade-off between liberty and regulation"* sufficiently seriously. Instead, it is often thought that because such regulation is justified on the grounds of protecting young people, it inevitably trumps adult liberty. This is not, however, the case with regard to some of the key proposals advanced in the consultation. Not only is there no demonstrated connection between tobacco displays and packaging and smoking uptake, but there is no compelling evidence that banning displays or requiring plain packages would prevent youth smoking. Such regulations would therefore have no proven effect on youth smoking levels while instead acting as a significant brake on personal liberty.

The section in the UK DoH consultation document on plain packaging states that *"denormalisation"* is an objective of tobacco control policy (section 3.70). Imperial Tobacco contends that "denormalisation" is not in itself a conceptual objective that is compatible with the principles of good regulation of a legal product. It is unclear in its definition and has no clear, measurable objective. Neither is it possible to further define and validate the concept through clear and concrete evidence. It is, at best, a speculative supposition.

Government either regulates or it does not regulate. In turn, a product is legal or it is not legal. To attempt to create a grey area as an objective of public policy represents a deliberate and illegitimate attempt to demonise and discriminate against a chosen, legal activity freely enjoyed by a significant proportion of the adult population. This is contrary to the respect for core democratic values that is linked both to freedom of expression and to personal liberty.

All these suggest that the UK DoH consultation document has failed in a fundamental sense to discharge its regulatory responsibilities in, as the House of Lords' Select Committee put it, *"an informed, balanced and consistent manner."*

f. The Regulatory Impact Assessment underpinning the consultation document fails to meet standards of "analytical rigour" (as defined by the Better Regulation Executive[36]) and is based on a flawed supposition.

Imperial Tobacco believes that the DoH Regulatory Impact Assessment (RIA) has failed in its responsibility as defined by the Better Regulation Executive in 2006 when it said *"The purpose of Regulatory Impact Assessment is to place analytical rigour at the heart of policy making, ensuring that the costs and benefits are clearly set out for decision makers so that Government only regulates where the benefits clearly exceed the costs."* It is our view that the RIA offered by the UK DoH in this case is a prime example for the concern expressed by the National Audit Office in 2006 when it said: *"Too often RIAs are used to justify decisions already made rather than an ex ante appraisal of policy impacts."*

In its impact assessment of display bans, the UK DoH consultation document claims that *"it is reasonable to expect that fewer young people would start using tobacco and that smoking prevalence among young people would decline at a faster rate than otherwise[37]"* if such bans were to be introduced.

Imperial Tobacco believes that this is not the case for the following reasons:

1) The evidence relied on in the UK DoH consultation document to support claims that tobacco product displays leads to smoking initiation or increased prevalence is limited and flawed.

2) The evidence from those jurisdictions that have implemented display bans does not demonstrate an overall reduction in youth smoking initiation, general smoking prevalence or increased success in quitting.

3) The potential regulatory interventions discussed in the consultation document (including display bans and plain packaging) are entirely disconnected from the well-documented risk factors which lead to adolescent smoking initiation and continued smoking. It has not been

[36] The Tool to Deliver Better Regulation: Revising the Regulatory Impact Assessment – a consultation, Better Regulation Executive, 2006
[37] Department of Health, *Consultation on the Future of Tobacco Control*, para 34

demonstrated that their introduction would reduce smoking initiation or prevalence.

4) Evidence from a range of past and continuing regulatory interventions designed to control, reduce or to eliminate tobacco advertising shows that these interventions do not produce statistically significant results sufficient to justify further interventions which impact on adult freedoms.

5) Finally, the UK DoH impact assessment fails to take account of the fact that tobacco control policies such as display bans or plain packaging can also have significant unintended and perverse consequences. The studies cited by the UK DoH acknowledge this possibility with regard to plain packages and many studies of youth smoking, (and other risk-taking behaviours) and routinely report that strong tobacco control measures are likely to make reactant a significant number of intending or existing youth and adult smokers.

1.4. INDIVIDUAL RESPONSIBILITY

It is Imperial Tobacco's view that the decision to use tobacco products is a matter of informed adult choice.

The 2004 Wanless Report *"Securing Good Health for the Whole Population"*, asserted:

"Individuals are, and must remain, primarily responsible for decisions about their and their children's personal health and lifestyle. Individuals must be free to make their own choices about their own lifestyles. They are generally the best judges of their own health and happiness; people differ significantly in their preferences and their situations in life. But this does not remove the duties on government and many organisations in society, including businesses, to help individuals make better decisions about their health and welfare. Significant failures in how decisions are made can lead to individuals inadvertently making choices that are bad both for themselves and society. Therefore, to promote improved health outcomes and to reduce health

inequalities, the government and other bodies need to act to reduce these failures and assist individuals to make better decisions.[38]

"…for good decisions to be made both for the individual and society as a whole, it is important that:

- *The individual is fully informed about all possible options, and their consequences;*
- *The individual is forced to take all the consequences of a decision (including those that affect others) into account;*
- *The social context within which individuals make decisions is conducive to making good choices; and*
- *Opportunities exist for individuals to engage fully in the management of their health and general welfare; regardless of their background and circumstances."*[39]

In the opinion of Lord Nimmo Smith in the case of Margaret McTear vs Imperial Tobacco (2005)[40]:

"It is not difficult to find instances today of people who, rather than blaming themselves for the consequences of their own decisions, seek to negate responsibility by claiming that a condition such as obesity or addiction to a controlled drug has just happened to them, independently of their own volition, or is someone else's fault … The individualist philosophy requires that individuals must live with the legal consequences of their own informed choices."

We agree that in general matters of public health, some individuals may require support in their decision making, but this should be achieved in ways which are educative and enabling, rather than disproportionate, coercive or discriminatory. We believe that the health risks associated with smoking are already well-known, and have been so for decades.

[38] Wanless D (2004) Securing Good Health for the Whole Population HMSO section 7.3
[39] Wanless D (2004) Securing Good Health for the Whole Population HMSO section 7.5
[40] Opinion of Lord Nimmo Smith in the case of Margaret McTear v Imperial Tobacco Ltd, para 7.179, 31, May 2005

1.5. UNDERSTANDING THE CONCEPT OF RISK

One main barrier to be overcome is the generally poor understanding in society of the concept of risk. This opens the way for sensationalism or coercive publicity and leads to disproportionate public policy responses. For example, the media may report a doubling of risk as a shocking story when the risks involved may be mathematically minute (even when doubled) and unlikely to affect an individual reader.

The House of Lords' Select Committee on Economic Affairs' report *"Government Policy on the Management of Risk"* pointed out:

"Most of the things we do have uncertain outcomes and risk is necessarily an inherent feature of life … Perceptions of risk by the public clearly have a potentially important impact in a policy environment that rightly aims to be responsive to public concerns over safety … In this context, it is worth noting that excessive risk aversion in the formulation of policy, which, if it exists, has been attributed to the pressure arising from public perceptions or the media, may also stem from single interest lobbying groups or indeed from government itself …"

Sir Kenneth Calman, a former UK Chief Medical Officer, has commented:

"In understanding issues surrounding risk assessment, perception is a key aspect of understanding patient and public choice …"

"This leads to one of the major issues facing those who make decisions about public health: the relation between the science base, the knowledge available, the evidence accumulated, and the public policy which derives from them. This can be extraordinarily difficult, and the costs of taking action based on minimal evidence or simply on the basis of a proposed hypothesis can be very considerable indeed …"

"The public should have a right to as much information as is available, but people also have to recognise that this information may not be complete and that it may not be possible to provide further information on a particular issue without more work, resources and, in particular, time. Nevertheless,

individuals need to make choices, and the individual perception of risk is important."[41]

There is a significant emotional overlay placed on the dispassionate scientific calculation by consumers when certain disease end-points are potentially involved. An evaluation of risk is effectively replaced by emotionally-driven dread and real but distorted perceptions result. Such considerations lead to politicised or over-cautious judgements and to measures beyond the proportionate response warranted by the data. These in turn lead to undue or disproportionate constraints on an adult's freedom to choose.

Such emotional judgements may also lead to coercive approaches to their enforcement.

1.6. PRECAUTIONARY PRINCIPLE[42]

There are occasions when little is known about the possible effects on human health of a material and some prudence is called for before such information is available. These considerations gave rise to the "precautionary principle"[43]. This is not a legal principle. It is a principle applied increasingly widely by public health bodies and regulators, including the European Commission. Put simply, the principle (as it has come to be understood) suggests that where there is doubt about the safety of a product or an ingredient or component food stuff, consumer product, environmental emission etc then it should not be used or should be removed. It is an approach to avoid public health risks by erring on the side of caution.

However, the European Commission[44] states that measures based on the precautionary principle should be:

(i) proportionate to the chosen level of protection;

[41] Calman K C (1996) British Medical Journal 313: 799-802
[42] Communication from the Commission on the Precautionary Principle (2nd February 2000) COM(2000)1
[43] See Morris J Ed. (2000) "*Rethinking Risk and the Precautionary Principle*", Butterworth-Heinemann, Oxford
[44] Communication from the Commission on the Precautionary Principle (2nd February 2000) COM(2000)1

(ii) non-discriminatory in their application;

(iii) consistent with similar measures already taken;

(iv) based on an examination of the potential benefits and costs of action or lack of action;

(v) subject to review, in the light of new scientific data; and

(vi) capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

The precautionary principle appears however to be being used with alarming regularity to bolster general risk-aversion.

"The precautionary principle undermines legal certainty by providing bureaucrats with an excuse to change the rules of the game in an essentially arbitrary manner … Attempts to redefine the precautionary principle have done little more than restate the views of interest groups and regulators whose antipathy towards the development of new technologies was already well known."[45]

Imperial Tobacco shares the concerns of the House of Lords' Select Committee on Economic Affairs which stated in 2006:

"We are concerned that regulatory requirements concerning risk appear to rely heavily on a range of concepts – such as As Low As Reasonably Practicable (ALARP); Gross Disproportion; Societal Concerns and the Precautionary Principle – which may not be sufficiently well-defined to enable the framing of useful operational guidelines. The danger inherent in the use of such ambiguous concepts is that they may encourage excessively risk-averse responses from policy-makers."[46]

[45] Morris J Ed. (2000) "*Rethinking Risk and the Precautionary Principle*", Butterworth-Heinemann, Oxford p19

[46] UK House of Lords' Select Committee on Economic Affairs 5th Report 2006 Section 60

1.7. CONCLUSION

We believe that a proper and legitimate function of government is to safeguard the autonomy of the individual and his or her ability to be self-determining. Key to this is the ability to make informed decisions, whether or not those are "popular" with others, with an awareness of the individual's responsibility as a member of a greater society. We believe that individuals are the best judges of their own interests. It is the role of the state to protect such freedoms, not to remove them or to make such decisions on an individual's behalf. Such freedoms should be protected by the state and should, in particular, be protected from simple majority rule.

We believe that, while complex, justification for any restrictions on personal authority, on the basis that the restriction is to prevent harm to others must be based on solid, factual evidence (rather than emotive speculation). It should be treated consistently with other potential risks which are either accepted or legislated against by the law maker.

We believe that when removing any such freedom, a burden of the highest order is placed on the regulator to examine such risks from a factual point of view and to be satisfied that the risk is; a) real; b) of a quality which has led to similar restrictions for other risks and; c) incapable of being managed in another way which does not restrict personal authority. Convenience or ease of application or enforcement is not enough to justify any restriction where other options are possible. This must be a minimum expectation for any state which attaches value to the freedom of the individual.

We do not believe that introducing plain packaging for tobacco products or banning displays of tobacco products at the point of sale are necessary or proportionate. They do not seem to us to meet the principles of good regulation or to address the key determinants of youth smoking initiation. It is our view that the UK DoH has not met its responsibility to demonstrate the workability or the effectiveness of potential regulatory interventions. Such interventions would make no overall contribution to the public awareness of the health risks associated with smoking, which we believe are already well-known. It is our view that such actions are designed to stigmatise existing

adult smokers, who exercise their freedom to choose to use a legal product; and to place further significant burdens on the retail chain.

2. RETAIL DISPLAY OF TOBACCO PRODUCTS AND PLAIN TOBACCO PACKAGING

2. RETAIL DISPLAY OF TOBACCO PRODUCTS AND PLAIN TOBACCO PACKAGING

2.1. SUMMARY

The Government's case for 1) banning the retail display of tobacco products and the limited advertising space permitted at the point of sale; and 2) the imposition of plain, unbranded tobacco packaging is premised on three suppositions:

d. that tobacco packaging constitutes a form of advertising for smoking;

e. that tobacco advertising in general causes individuals to smoke; and

f. that seeing tobacco packaging on display and point of sale advertising causes young people, occasional smokers, smokers who are attempting to quit and former smokers to smoke.

Imperial Tobacco does not accept the view expressed in the consultation document that tobacco packages and displays of tobacco packages constitute tobacco advertising. This is backed up by evidence in terms of the effects (or lack of effects) on youth smoking initiation. We concur with the conclusions of the Expert Panel for Health Canada's summary of the qualitative report in 1995 that young people do not decide to smoke on the basis of tobacco packages, that they do not have images of brands that are connected to lifestyles, that packages do not lead to smoking and that changing the package will not *"have any major effect on the decision(s) to smoke or not to smoke".*[47]

[47] Goldberg ME, Liefeld J, Kindra K, Madill-Marshall J, Lefebvre J, Martohardjono N and Vredenburg H. *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products: Expert Panel Report to Health Canada, Ottawa, 1995.*

Tobacco advertising and retail displays

Whether the tobacco packet is considered to be a form of advertising or not, none of the available evidence suggests a causal relationship between tobacco advertising and consumption, between tobacco advertising and smoking initiation or between restricting tobacco advertising and changes in consumption or initiation. The fact that past restrictions of tobacco advertising have not been shown to reduce smoking initiation or consumption negates the UK DoH's claim in section 3.44 of the consultation document that the *"evidence suggests that we could expect to see fewer young people starting to use tobacco, and that smoking prevalence among young people could decline at a faster rate than we are currently experiencing*[48]*"* should tobacco displays be restricted or tobacco packaging changed.

The UK DoH consultation document argues that the *"evidence about the public health benefits of prohibiting the display of tobacco products in retail environments is strong*[49]*".* This claim is also unfounded. The evidence cited by the UK DoH consultation document in support of a display ban consists of a limited review of a small number of studies. It ignores a significant number of other studies about smoking uptake, prevention and cessation.

We also do not find convincing the evidence cited by DoH from other jurisdictions which purports to show that tobacco product display restrictions have reduced either the consumption of tobacco products or youth smoking initiation in countries where they have actually been introduced. In fact, evidence from Canada and Iceland, for example, suggests the contrary.

The retail supply of tobacco to consumers is already strictly controlled. Currently, tobacco products can only be purchased in two ways: 1) face-to-face transactions with the retailer, from gantries which are always situated behind the retailer and out of reach of the customer; and 2) from vending machines which should be placed where they cannot be accessed by minors (this applies to less than 1 percent of overall market volume).

[48] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.44
[49] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.45

Maintaining the display of tobacco at the point of sale is essential for efficient retailing, given the high turnover and value of the product.

The display of tobacco products is important to ensure adult choice and free and fair competition. It provides consumers with the information to make a selection from the wide range of tobacco products, brands and prices that are available in retail outlets. A ban on tobacco product displays would favour dominant brands and suppliers and would act as a barrier to entry for new brands and suppliers.

It is our view that a retail display ban would exacerbate the already significant levels of illicit trade taking place throughout the UK as the lines between legal and illegal product are blurred. Imperial Tobacco agrees with the assessment made in the consultation document that illicit trade undermines public health objectives, damages legitimate business and results in substantial revenue losses to HM Treasury, through creating a market that is uncontrolled, untaxed and unaccountable.

In view of the lack of credible evidence presented in the UK DoH consultation document that restricting or banning retail tobacco product displays will have any positive impact on youth smoking initiation or consumption, and mindful of the negative effects on competition and illicit trade, Imperial Tobacco supports **Option One** as set out in the consultation document. However, it is our view that this should be supported with greater enforcement of current minimum age laws together with additional resources to support Trading Standards in their efforts to tackle illegal selling.

Plain Packaging

We believe that plain packaging for tobacco products is unnecessary, unreasonable and unjustified. It is not based on sound public policy, or on compelling evidence. Plain packaging would not address the issues that the DoH seeks to combat: it would make no overall contribution to the public awareness of the risks associated with smoking; it would not provide more information to smokers; and it would not reduce the appeal of tobacco products, especially to young people.

The primary risk factors for youth smoking initiation are clearly documented. Packaging of tobacco products is not one of these risk factors. The introduction of plain packaging would make no contribution to addressing youth smoking initiation.

The balance of the available evidence (including evidence upon which the UK DoH claims to rely) does not provide a compelling argument to suggest that the plain packaging of tobacco products would have the effect of deterring young people from smoking. In fact, certain evidence suggests the potential for the contrary.

Imperial Tobacco is concerned about the continued erosion and potential expropriation of our valuable intellectual property rights. We believe that we are entitled to use our packaging to enable adult consumers to distinguish our quality products from those of our competitors. Regulation that requires plain packaging will expropriate valuable corporate assets in which the Company and its shareholders have invested for more than a century and risks placing the UK government in breach of a range of legal and treaty obligations that relate to intellectual property rights, international trade and EU law. The introduction of plain packaging would set a regulatory precedent for intellectual property owners and their shareholders outside the tobacco sector.

Plain packaging will have a negative effect on competition. There would be little incentive for retailers to stock new brands and it would be practically impossible for a new competitor to enter the market successfully or for an existing competitor to compete with others by launching a new brand.

Plain packs would facilitate counterfeiting and undermine the excellent work that has been done jointly by the industry and UK HMRC over a long period of time to combat illicit trade. Due to the relative ease with which the materials for a tobacco product are acquired and the cigarette itself counterfeited, one of the key components in the fight against counterfeit is the packet itself. Both overt and covert elements of the pack design are incorporated to frustrate counterfeiters' attempts to copy the pack exactly and to facilitate identification of illegal product. An obvious repercussion of the introduction of plain packaging would be to make the counterfeiter's task substantially easier.

2.2. THE RELATIONSHIP BETWEEN TOBACCO ADVERTISING AND TOBACCO CONSUMPTION

The case for banning the retail display of tobacco products is founded on the claim that the tobacco package is an explicit advertisement for smoking; that tobacco advertising in general and specifically tobacco packaging causes individuals to smoke; and that seeing such package-based "advertisements" displayed in retail environments causes young persons and former smokers to smoke and causes occasional smokers and quitting smokers to continue to smoke or to smoke more.

Three categories of evidence are used to support the claim that tobacco advertising both initiates and maintains smoking and prevents quitting:

(i) evidence about the nature of the tobacco market;

(ii) econometric evidence about the associations between tobacco advertising and consumption; and

(iii) studies of tobacco advertising exposure and recall and their association with smoking initiation.

Imperial Tobacco believes that none of this evidence provides compelling support for the claim that tobacco advertising leads to smoking uptake or prevents quitting. The UK DoH consultation document asserts that *"the evidence base shows that tobacco promotion encourages people to take up and continue smoking*[50]*"*. Yet the UK DoH fails to provide any supportive evidence about the nature of the UK tobacco market, or the relationship between tobacco consumption and tobacco advertising in the UK over the last 50 years. No econometric study about the association between tobacco advertising and smoking uptake and consumption supports this position. Instead, this claim about the evidence base is advanced whilst the majority of published research literature on this issue is ignored. Rather than discharging its responsibility under Government regulatory guidelines to provide a comprehensive review of the evidence, the UK DoH has instead put forward

[50] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.39

what appears to be a skewed picture of what the evidence suggests. In so doing it has misrepresented the current state of scholarship about the effects of tobacco advertising.

Imperial Tobacco does not accept that tobacco packages and displays constitute tobacco advertising. Nor does Imperial Tobacco accept that a comprehensive and impartial review of the evidence about tobacco advertising shows that such advertising causes people to become smokers, to remain smokers or to return to smoking. It is highly improbable that tobacco packaging and the display of tobacco packaging in retail settings either initiate smoking, maintain or increase smoking or lead to smoking relapse.

2.2.1. THE NATURE OF THE TOBACCO MARKET

There is substantial evidence that the tobacco market is one in which advertising (in those jurisdictions where it is still permitted) functions to redistribute customers amongst the various companies' brands rather than increasing the overall size of the market through attracting new consumers[51][52][53][54][55][56]

2.2.2. ECONOMETRIC EVIDENCE ABOUT TOBACCO ADVERTISING AND CONSUMPTION

The econometric evidence fails to provide support for the claim that tobacco advertising promotes smoking initiation and consumption or impedes cessation.

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[51] The economics of advertising; Richard Schmalensee; Contributions to Economic Analysis; No 80; Amsterdam and London: North-Holland Publishing Company; 1972, pp xiii, 312.

[52] Hamilton, J. L. (1972). Advertising, the health scare, and the cigarette advertising ban. Review of Economics and Statistics, 54: 401–11.

[53] Fujii E.T. The economics of tobacco advertising: spending, demand, and the effects of bans'. International. Journal of Advertising 22: 461–9. (1980).

[54] Friedman, J. Advertising and Oligopolistic Equilibrium; Bell Journal of Economics, 14, 1983, 464-473

[55] Baltagi, B. H. and Levin, D. (1986). Estimating dynamic demand for cigarettes using panel data: the effects of bootlegging, taxation, and advertising reconsidered. Review of Economics and Statistics, 68(1), 148B55.

[56] A Simultaneous Model of Cigarette Advertising: Effects on Demand and Industry Response to Public Policy, Barry J. Seldon and Khosrow Doroodian; The Review of Economics and Statistics, Vol. 71, No. 4, 1989, pp. 673-677

Studies of tobacco advertising in the UK from the 1970s to the mid 1990s have for the most part found that aggregate cigarette advertising has little or no influence on total consumption. Duffy[575859] found cigarette demand in relation to advertising to be *"insignificantly different from zero".* His 1994 study found that advertising had negative effects on aggregate consumption, noting that *"the results presented here suggest that the general effect, if one exists, of brand advertisements which carry prominent health warnings may have been to restrain aggregate demand for cigarettes."*

Duffy's analyses are echoed in a report by Clive Smee et al for the UK DoH (1992)[60]. This is cited in the UK DoH consultation document as evidence supporting the claim that tobacco advertising affects tobacco consumption. However, a full reading of the Smee Report and its statistical analysis of the UK tobacco market finds that it does not in fact support the UK DoH position on tobacco advertising. Smee conducted his own analysis of the relationship between tobacco advertising and consumption from 1960-1987 and found that *"advertising does not have a statistically significant effect in any form."* Further, Smee reports that his model of advertising and smoking prevalence for UK adolescent men and women found that advertising was not a statistically significant factor. There are very few econometric studies which examine exclusively the relationship between tobacco advertising and youth smoking, and given that this fact is used as a justification for discounting all the econometric evidence about advertising and prevalence in young people, Smee's analysis and conclusion have added significance.

The UK DoH consultation document cites the Smee Report's conclusions with regard to the efficacy of advertising bans in support of its assertion about the association between tobacco advertising and consumption. It fails, however, to note that: 1) this conclusion is contradicted by Smee's technical analyses of

[57] Duffy, M. Advertising in demand systems: testing a Galbraithian hypothesis; Applied Economics, Volume 23, Issue 3 March 1991 , pages 485 - 496

[58] Duffy, M.; Advertising and Cigarette Demand in the United Kingdom - Manchester School of Management, University of Manchester- 1994

[59] Duffy, M. (1995). Advertising in demand systems for alcoholic drinks and tobacco: a comparative study. Journal of Policy Modeling, 17(6), 557–77.

[60] C Smee, M Parsonage, R Anderson, S Duckworth; Effect of tobacco advertising on tobacco consumption: a discussion document reviewing the evidence; Economics and Operational Research Division Department of Health, 1992

the effects of advertising in the UK market, particularly its null effect on the smoking prevalence of young people and 2) Smee's conclusion about the efficacy of advertising bans was based on a discredited analysis[61] which was itself judged to be flawed in the 1991 trial[62] in the Canadian Supreme Court in which the Tobacco Products Control Act was struck down. The data was rejected on the grounds that it *"contains serious methodological errors and a lack of scientific rigour which renders it for all intents and purpose devoid of any probative value."* The judge commented that the Canadian government had not presented enough evidence to justify a tobacco advertising ban.

The conclusions of the econometric evidence about the relationship between tobacco advertising and consumption in the US are very similar to those from the UK. Studies of tobacco advertising in the US from the 1970s to the mid-1990s have for the most part found that aggregate cigarette advertising has little or no influence on total consumption.

The econometric evidence about the relationship between tobacco advertising and consumption published since the mid-1990s has confirmed the fact that advertising has little or no effect on smoking. For instance, Duffy (2003) examined the seven categories of non-durable goods on the UK market from 1963-1996[63]. Concentrating on food, drink and tobacco advertising, Duffy found that while price has a substantial influence on consumer expenditure, there was little evidence to demonstrate that advertising had a statistically significant effect on consumer demand for any of these products.

Lancaster and Lancaster (2003) analysed 35 published studies of tobacco advertising and consumption from eight countries with 350 advertising demand co-efficients[64]. They report that 61.1% failed to find a significant relationship between advertising and consumption, and that 5.7% of the coefficients were significant and negative suggesting an association between advertising and reduced consumption.

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[61] Laugesen M, Meads C. Advertising, price, income and publicity effects on weekly cigarette sales in New Zealand supermarkets. Br J Addiction 1991

[62] RJRMacDonald Inc v A-G Canada, [1995] 3 SCR 199

[63] Duffy, M. Advertising and food, drink and tobacco consumption in the United Kingdom: a dynamic demand system; Agricultural Economics 28 (2003) 5 1-70

[64] Lancaster K.M., Lancaster A.R. The economics of tobacco advertising: spending, demand and the effect of bans - International Journal of Advertising, 2003

Finally, the most recent econometric analysis by Nelson (2006) presented a meta-analysis of cigarette advertising elasticities derived from econometric studies published in the US, UK and several other countries over the last 35 years. He concluded that *"any spill over effect of cigarette advertising on aggregate consumption was limited in duration and negligible in magnitude*[65]*."*

The Global Youth Tobacco Survey (2003), an international survey of youth smoking prevalence from the World Health Organization[66] found no statistically significant differences in youth ever-smoking prevalence between countries such as Norway, Finland and Canada with comprehensive advertising bans, and countries such as the United States, Russia and Israel with only broadcast advertising bans.

2.2.3. STUDIES OF ADVERTISING EXPOSURE AND RECALL

The final source of evidence about the association between tobacco advertising and consumption comes from studies of tobacco advertising exposure and recall. It is often claimed that these studies provide evidence of a causal connection between tobacco promotion and, for instance, smoking initiation (Lovato et al[67]). The UK DoH document relies exclusively on such studies in support of its claims about both tobacco advertising and display bans and plain packaging. Yet there are a number of substantial difficulties with these types of studies which render them unreliable for basing any conclusions about the relationship between tobacco advertising and consumption, particularly smoking uptake.

i) HIERARCHY OF EFFECTS MODEL

Virtually all such studies assume that advertising operates in a hierarchy of effects which moves consumers on from reading, seeing or hearing an

[65] Jon P. Nelson, Cigarette advertising regulation: A meta-analysis; International Review of Law and Economics, Volume 26, Issue 2, June 2006, Pages 195-226
[66] Global Youth Tobacco Survey. 2003 Available at: http://www.cdc.gov/tobacco/global/GYTS.htm
[67] Lovato C. et al. (2004). *Cochrane Review: Impact of tobacco advertising and promotion on increasing adolescent smoking behaviours.* The Cochrane Library, Issue 2. (3)

advertisement to remembering it, processing it, believing it, retrieving it, using it to make a purchase decision and behaving in accordance with it. This model of advertising has been substantially discredited. There are no studies which directly link the decision to purchase cigarettes in the marketplace and smoking on the basis of remembering an advertisement; a crucial requirement of establishing a causal relationship between advertising and tobacco consumption.

At any step the process can be broken; for example failing to retain the advertisement's content, failing subsequently to remember the advertisement, becoming sceptical about the advertisement's claims and making a decision based on something other than the advertisement. Despite this, exposure and recall studies assume that a subject's recall at a specific moment in time of a previously-seen tobacco advertisement is the cause of their subsequent smoking, even if they are unable to say anything specific about the advertisement. Any advertising exposure is assumed to be the cause of any subsequent smoking, rather than demonstrated to be so. Calfee observed the problems inherent in such assumptions:

> *"However successful a marketing campaign may be in the early stages of the hierarchy, that success is by no means bound to carry on through actual choices in the marketplace. But many, if not most, applications of this model work exclusively with intervening variables (i.e. after the advertisements but before market behaviour) and never actually test advertising's effects on market choices*[68]*."*

The hierarchy of effects model relies on path analysis which uses regression, econometric and factor analysis. A path analysis models both the direct and indirect effects of advertising as mediated through latent variables such as risk perception. The total advertising "effect" is thus a total of direct and indirect effects. As Nelson (2001)[69] observes, such path analyses are "*subject to the full range of econometric*

[68] Calfee J.E. The Historical Significance of Joe Camel.. Journal of Public Policy & Marketing 2000-Volume: 19 | Issue: 2 | Pps: 168-182

[69] Nelson, J.P. Alcohol Advertising and Advertising Bans: A Survey of Research Methods, Results, and Policy Implications

problems, including specification bias, measurement errors, sample selection bias, missing data, outliers, multicollinearity, lack of replication and the like." Most studies of tobacco advertising exposure and recall measure only indirect effects of advertising, and this seriously undermines any claim to have established advertising as a cause of smoking.

ii) FAILURE TO CONTROL FOR OTHER RISK FACTORS

None of the advertising exposure and recall studies have adequately controlled for other smoking risk factors. This means that the alleged causal factor of advertising has not been isolated from other risk factors so as to determine a genuine association. For instance, it might be true that 16 year olds who can remember tobacco advertisements are more likely to smoke when 20 year olds than 16 years olds who do not remember tobacco advertisements. It does not, however, follow that this association is because they remembered tobacco advertisements. It might well be that those 16 year olds share other characteristic such as being more inclined to risk-taking, or performing poorly at school, and it may be one of these factors - excluded from the study - rather than tobacco advertisements, which are the cause(s) of their subsequent smoking. Without controlling for these other factors their impact can never be known. The literature on smoking initiation reports dozens of such risk factors known to be predictors of smoking uptake. (These are described elsewhere in this submission.)

Selection issues are a central problem of statistical analysis and there are recognised techniques for dealing with them. There is no explicit mention in any of the exposure and recall studies that these have been addressed, which casts significant doubt on any causal conclusions about the connection between tobacco advertising and adolescent smoking.

iii) OBSERVATIONAL AND LONGITUDINAL STUDIES

Many of the exposure and recall studies are observational studies while some are longitudinal studies. In our view, these do not provide a sufficient basis for asserting that tobacco advertising causes youth smoking or an increase in tobacco consumption. Any claim of a causal connection could only be substantiated on the basis of a randomised clinical trial. Despite this, many observational and longitudinal studies claim to provide evidence of a causal connection between tobacco advertising and smoking initiation and consumption, including Lovato et al (2004), which provides the major support for the UK DOH claim about tobacco advertising. Lovato et al write that:

> *"Properly conducted longitudinal studies that examine the relationship between exposure to marketing approaches and subsequent changes in smoking behaviour, while controlling for possible confounding factors, can provide evidence supporting causal links between tobacco marketing and smoking behaviour[70]."*

This claim is false in two respects. First, there are no studies which control for all the confounding factors and second, in our view longitudinal and observational studies do not provide sufficient evidence *"supporting causal links".*

iv) PROBLEMS WITH EXPOSURE AND RECALL STUDIES

Many of the exposure and recall studies are problematic because they assume that the direction of influence between advertising and smoking uptake and consumption is one way. That is, exposure to advertising or owning a tobacco promotional item leads to an interest in smoking and thereby to smoking uptake. Yet there is little empirical support offered to support this and important sources cited by the UK DoH (e.g. Smee)

[70] Lovato C. et al (2004). Cochrane Review: Impact of tobacco advertising and promotion on increasing adolescent smoking behaviours. The Cochrane Library, Issue 2.

contradict it. Young people who are interested in and receptive to smoking can be assumed to have a smoking preference that would lead to their interest in and recall of tobacco advertising. Their preference for smoking could have been formed prior to and independently of any tobacco advertisement. Smee notes that adolescents *"disposed to smoke are more likely to react positively to tobacco advertising and show greater awareness of it."*[60] This would mean that discovering an association between remembering tobacco advertisements or owning tobacco promotional items and subsequent smoking does not constitute compelling evidence that the former has led to the latter.

v) FAILURE TO MEASURE EXPOSURE TO ADVERTISING

Although the tobacco advertising exposure and recall studies make claims about the effects of tobacco advertising on smoking uptake and consumption, it is clear that most have not measured the advertising exposure of any individual claimed to have become a smoker. Rather, these studies have in many instances used the possession of a tobacco promotional item as a proxy for exposure to tobacco advertising. In other studies, exposure has been determined by proxy through a subject's possession/reading of a magazine containing tobacco advertising. The possession of a magazine does not guarantee exposure to the advertising it contains. Pucci and Siegel, reviewed in Lovato et al and cited by the UK DoH, note *"the fact that subjects reported reading a magazine does not imply that they actually saw the cigarette advertisements*[71]*."* These studies cannot warrant what exposure to tobacco advertising, if any, has taken place.

These measurement issues raise the broader problem of whether such studies meet the fundamental standards of scientific evidence which minimally require that measurements can be warranted as accurate (along with a measurement error rate). It is uncertain whether any of these

[71] Pucci L G & Siegel M (1999) Exposure to brand-specific cigarette advertising in magazines and its impact on youth smoking. Preventive medicine 1999;29(5):313-20

studies meet this standard and as such they are of questionable scientific standing.

vi) METHODOLOGICAL ISSUES

Recall studies are subject to methodological issues which undermine their evidentiary validity. These are identified in the following review of each the individual studies used by the UK DoH in its discussion of display bans.

2.2.4. THE UK DOH EVIDENCE BASE ON TOBACCO ADVERTISING, SMOKING INITIATION AND CONSUMPTION

The UK DoH asserts that the *"evidence base shows that tobacco promotion encourages people to take up and continue smoking*[72]*".* This evidence base, however, is neither extensive nor particularly robust. The UK DoH consultation document references six studies in support of its claim about the relationship between tobacco advertising and consumption.

a) Lovato et al 2004

Lovato et al is a review of certain longitudinal studies of the association between tobacco advertising and consumption. It concludes, based on these studies that:

> *"Longitudinal studies consistently suggest that exposure to tobacco advertising and promotion is associated with the likelihood that adolescents will start to smoke … we conclude that tobacco advertising and promotion increases the likelihood that adolescents will start to smoke."* [67]

Lovato et al based their conclusion on nine studies. Each suffers from one or more of the defects that characterise exposure and recall studies and each is reviewed below.

[72] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.39

i) Alexander et al 1983

This study examined a group of some 6000 Australian school children aged between 10 and 12 years as part of a larger intervention in smoking prevention. Factors which distinguished those children who became smokers included being older; having friends and siblings who smoke; approving of cigarette advertising; and having a relatively large amount of money to spend each week. The study suffers from a number of defects.

First, the results were based on a self-administered questionnaire asking the children to recall and then report their behaviour. Aside from the numerous problems about accurate recall, there is a significant question as to whether what is being reported is changed behaviour as opposed to changed reporting of behaviour.

Second, the questionnaire did not measure whether the children were exposed to tobacco advertising, or to how much tobacco advertising they were exposed. It enquired about their attitude to cigarette advertising and then assumed exposure. It maintained that of all the various risk factors for smoking uptake, favourable attitudes to tobacco advertising led to changes in smoking behaviour, without measuring the extent of advertising exposure.

Third, the study failed to control for most of the risk factors for smoking initiation other than sibling, friends and parental smoking. This means that the study at best presents an association between a favourable attitude to tobacco advertising and subsequent smoking without properly controlling for most other concurrent factors which could also lead to smoking uptake. This is an unsound basis from which to conclude that tobacco promotion and advertising have any role in the process.

ii) Armstrong et al 1990

The authors examined the factors which *"had a significant effect on the smoking behaviour"* of Australian school children. Among the variables associated with smoking uptake, the children's response to tobacco advertising showed the strongest and most consistent association. The

more strongly a subject reported being influenced by advertising, the more likely they were to become a smoker. Several problems undermine the validity of these conclusions.

First, the study depended entirely on unverified and unverifiable subject reports about the perceived influence of advertising. It is therefore not a study about the influence of advertising on smoking uptake, but rather a study about the perceived influence of advertising. This assumes that the subjects understood both the nature and extent of advertising; something that critics of advertising insist is not the case. Numerous studies of smokers' psychology indicate that they prefer to ascribe their smoking behaviour to a force beyond their control, whether advertising or so-called addiction. It is thus entirely possible that a large number of students would ascribe their smoking uptake to being influenced by advertising.

Second, there is no objective measure of advertising exposure. There is no way of knowing to how much, if indeed any, advertising the subjects was exposed.

Finally, because there were no controls for other risk factors for smoking uptake, the alleged association between perceived advertising influence and subsequent smoking is not evidence of a causal connection between advertising and smoking uptake.

iii) Biener and Siegel 2000

Biener and Siegel reported that 46% of a non-smoking cohort of American adolescents who owned a tobacco promotional item and could also name a tobacco brand advertisement, moved from not smoking or smoking experimentation to regular smoking over the course of four years. The strength of this assertion, however, is attenuated by several factors.

First, though the authors claim to have controlled for other smoking initiation risk factors, they controlled for only eight. The literature reports dozens.

Second, the ability of the researchers to make inferences about exposure-uptake sequences is undermined by the fact that the report grouped together non-smokers with early experimenters, the latter of which might well have been disposed to pay attention to advertising because of their smoking, rather than moving to smoking because of their attention to advertising.

Third, the study reported that those who had the highest likelihood of becoming regular smokers by the end of the four year period were those who were already experimenting with smoking at the beginning, which strongly suggests that their exposure to advertising over the study period was not a major factor in their decision to smoke.

Fourth, there is no independent and verifiable measure of actual advertising exposure. Subjects were not asked to quantify the number of tobacco advertisements they had seen; they were simply asked to recall which brand's advertisements most attracted their attention.

Finally, students who owned a tobacco promotional item or who named a tobacco brand were designated as moderately receptive to tobacco advertising, but there was no statistically significant association between being moderately receptive to advertising and becoming a regular smoker, a finding which undermines the conclusion of the study.

iv) Charlton and Blair, 1989

This study looked at 1390 never-smokers aged 11-13 from northern England by means of a self-administered questionnaire which measured awareness of cigarette brands and favourite tobacco advertisements. The cohort was followed for a period of four months to examine the relationship between brand awareness and advertising on smoking initiation. The results of the study provide little evidence to support the claim that brand awareness of tobacco advertising leads to smoking uptake in adolescents. Moreover, the authors note that there was no controlling for other smoking variables.

Significantly for other advertising and recall studies carried out in the UK, Jarvis et al (1989), in a critique of Charlton and Blair, suggest that findings about never-smokers progressing to smoking status are extremely suspect given a problem of misclassification. They note that:

> *"[a] substantial minority of children who initially classify themselves as never-smokers admit to having tried a cigarette when prompted. These differ from confirmed never-smokers on relevant predictor variables, and are significantly more likely to agree that they will try a cigarette again before leaving school …. A similar group would be expected in Charlton and Blair's study and might wholly or partially account for the apparent predictive relationships found."*

v) Diaz et al 1998

Diaz et al, which is not available in English, reported on the factors that *"predict smoking"* based on a group of 1126 non-smokers. It is not clear what the advertising question was as Lovato et al reports it as *"Accept tobacco advertising: Agree/disagree"*. The results of the study were not statistically significant for those who became daily or weekly smokers.

vi) Pierce et al 1998

Pierce et al examined the progression to smoking of 1752 adolescent Californian never-smokers who were interviewed by telephone in 1993 and then followed up three years later. They found that young people who had a favourite tobacco advertisement and who had or were willing to use a tobacco promotional item were more likely to begin smoking than those who did not report an advertisement or possess a promotional item. This conclusion is undermined by a number of factors.

There was no attempt to control for relevant alternative explanatory variables; nor was there any theoretical explanation as to why such alternatives were omitted or whether any of these variables might be

correlated with the variables included in the study. Even the few variables that were included in the original survey were left out of the final model without explanation, which suggests omitted variable bias.

Widely reported predictors of smoking uptake such as exposure to peer smoking and family smoking were not found to be statistically significant.

There is no objective measure of the degree of exposure to tobacco advertising.

There is no independent verification of the baseline smoking status or the follow-up smoking status of any of the subjects. The conclusions of the study rest entirely on self-reported data.

Finally, among those who could name a cigarette brand but not a tobacco advertisement, there was no statistically significant association with becoming a smoker. Among those who named an advertisement the association was barely significant.

vii) Choi et al 2002

Choi et al, which was cited by Lovato et al but not used as a basis for its conclusions, examined the same cohort as Pierce to try and establish an association between tobacco advertising exposure and the progression from experimental to regular smoking. The results, like Pierce, failed to support a demonstrable link between advertising and smoking uptake.

Young people who were classified as moderately receptive to tobacco advertising were no more likely to become regular smokers than those who were unreceptive to such advertising.

The strongest predictors of becoming a regular smoker were having friends and family who smoked; poor family relations and believing that one could quit smoking at any time. The study's other associations, which were statistically significant, provided stronger alternative accounts of progression to smoking uptake than did the statistically non-significant *"receptivity"* to tobacco advertising.

viii) Pucci and Siegel 1999

Pucci and Segal reported on the correlation among a cohort of Massachusetts' youths between brand-specific exposure to tobacco advertising and the brand smoked by new smokers. The levels of adolescents' exposure to brand advertising in magazines correlated highly with the brand they subsequently smoked. The study claims that *"by documenting a relationship between brand-specific magazine advertising exposure and brand of smoking initiation among new smokers, this study provides strong new evidence that cigarette advertising influences youth smoking."* This conclusion is questionable.

First and most importantly, it is not clear that any of the subjects were actually exposed to tobacco advertising. Given that this purports to be a study about exposure to brand specific tobacco advertising, this failure to measure exposure is unusual. The study asked the subjects to recall (a month after the event) which magazines they read at baseline and from this the researchers determined which brands were advertised and the number of advertisements that appeared in each magazine. The study assumed that because a subject read a particular magazine in which a brand tobacco advertisement appeared, the subject was exposed to a particular tobacco advertisement. In other words reading the magazine equals seeing the tobacco advertisement. It presented no evidence that this was the case. It failed even to ask the subjects the extent to which they read the magazine. Since no individual subject was asked whether they had seen any tobacco advertisements in a particular magazine, the authors could not warrant anything as to their claimed measurement of advertising exposure. Instead, they noted *"we estimated the total potential exposure of each youth to brand specific advertisements in the magazines they reported reading, assuming that the youth read the magazine for the entire year."* Based on one month's recall of reading, the authors extrapolated that to a twelve month period. The authors acknowledged this fundamental design flaw when they wrote that the *"fact that subjects reported reading a magazine does not imply that they actually saw the cigarette advertisements."*

Second, like most such exposure and recall studies there is no independent confirmation of baseline or follow-up smoking status. There is thus no way in which the most important data can be verified upon which the claims about advertising effect rest (that a subject was a non-smoker at one time and a smoker at a subsequent time).

Third, it is not clear that exposure to brand advertising causes young people to decide to smoke as opposed to what brand to smoke. During the process of smoking initiation, studies have shown that young people are often unaware what brand they are smoking. This is supported by another study in the Lovato et al analysis, While et al, who reported that *"New smokers were more likely to smoke any available brand or a less advertised brand … than the most advertised ones."* That confirmed youth smokers smoke the most heavily advertised cigarette brands is entirely consistent with the evidence on branded advertising. It says nothing about the influence of advertising on the decision to smoke. The study provides little evidence of the influence of advertising on smoking initiation, something that the authors themselves acknowledge. *"It is important to note that these results alone do not imply that exposure to cigarette advertising causes youths to initiate smoking. These results merely suggest that the advertising is related to the youths' choices of cigarette brands … A correlation between patterns of brand-specific advertising exposure and patterns of cigarette brand use does not necessarily imply causation."* This aligns with the views of Imperial Tobacco.

ix) Sargent et al 2000

Sargent et al examined the relationship between owning a tobacco promotional item (TPI) and smoking. They found that owning or being willing to use a tobacco promotional item at baseline was associated with higher smoking uptake at the 18 month follow-up. The authors claimed that their study provided:

> *"evidence of a dose-response relation between the number of TPIs owned by adolescents and higher likelihood of experimental and*

established smoking …. These data provide further support of a causal relation between tobacco promotional campaigns and smoking behaviour among adolescents."

These conclusions do not follow. The study is not about exposure to tobacco advertising but about owning an item with a tobacco logo and being a smoker.

The cross-sectional character of the study makes it impossible to determine whether ownership precedes smoking. Young people who possess a tobacco promotional item may have it because they are interested in smoking which renders unjustified the causal conclusion that the promotional item made them interested in smoking. They note: *"Because of the cross sectional nature of this study, we are unable to infer directly that ownership of cigarette promotional items precedes smoking."* Given that this is precisely the issue at hand, this is an extraordinary concession.

Third, although the authors claimed to have controlled for other factors associated for smoking uptake, it was only done to a limited extent. They controlled for only six risk factors for smoking initiation.

Fourth, the study relied on self-reported and unconfirmed data both with respect to ownership of tobacco promotional items and smoking status at both baseline and follow-up.

Fifth, the study is only marginally statistical significant for owning a tobacco promotional item and smoking experimentation, at a level that renders the findings indistinguishable from chance.

Finally, the study found no association between owning a promotional item and smoking experimentation in students in grades 10-12, where there is generally a progression to established smoking.

b) While et al 1996

Through data from annual self-reported questionnaires involving 1450 school children aged 11-12 years in England, While et al found that girls who could

name one of the two most heavily advertised brands at the time (Benson and Hedges) were at greater risk of becoming smokers than those who named other brands. There was no statistically significant risk of becoming a smoker neither for boys who named Benson and Hedges, nor for boys or girls who named other brands. The authors concluded that *"Cigarette advertising … encourages [children] to take up the [smoking] behaviour."*

The study's data do not appear to justify this conclusion, particularly given that only a summary of the relevant data is presented. Aside from the usual problems with self-reported and recalled data, there is no evidence from the study that tobacco advertising was the reason children began to smoke.

c) Smee et al 1992

A second study supporting the UK DoH's contention that the *"evidence base shows that tobacco promotion encourages people to take up and continue smoking*[73]*"* is a research report prepared for the UK DoH in 1992. The UK DoH summary of the Smee report, in which only its findings with respect to the effect of tobacco advertising bans are referenced, fails to include all its relevant conclusions.

It is important at the outset to distinguish the two types of evidence that Smee et al relied on for their conclusion; firstly, evidence produced through their own econometric analyses of the relevant data for the UK; second, evidence from other studies of tobacco advertising, initiation, consumption and advertising restrictions. The first type led Smee et al to one conclusion; the second led to a different conclusion.

First, Smee's own analysis, as opposed to its summary of and interpretation of other studies, concluded that *"advertising does not have a statistically significant effect in any form."*

Second, Smee's own analysis of the data led the authors to reject the simplistic claim implicit in many of the advertising exposure and recall studies that recognition of advertisements leads to increased consumption. Smee et

[73] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.39

al distinguished between the necessary and sufficient conditions for advertising to affect consumption. *"Awareness of advertising is at most a necessary condition for coming under its influence. It is not reliable evidence that advertising increases consumption."* So, while young people might recognise tobacco advertisements it does not follow that this leads them to become smokers. Smee et al noted that the direction of causality could just as plausibly be interpreted in the opposite direction: young people *"disposed to smoke are more likely to react positively to tobacco advertising and show greater awareness of it."* Thus, Smee et al's caution about the conclusions that can be drawn from tobacco advertising exposure and recall studies seriously undermines the credibility of those exposure and recall studies cited by the UK DoH in its consultation document.

Third, Smee's own technical analysis of the influence of tobacco advertising on the uptake of smoking by teenagers in the UK concluded that it was not a significant factor. This contradicted Smee's own general conclusion about tobacco advertising and the position of the UK DoH with regard to tobacco advertising and youth smoking initiation in the UK. The DoH consultation document appears to be unaware that one of its major sources refutes its claims about the effect of advertising on smoking uptake in the UK market.

Fourth, with respect to the efficacy of advertising bans (decisive in demonstrating the link between advertising and tobacco consumption according to the UK DoH), Smee et al noted that the direction of the causal relationship between such bans and declining tobacco consumption is most likely opposite to that often assumed. Rather than advertising bans lowering consumption, such bans are introduced once consumption has already begun to fall and social attitudes to smoking have changed. This leads, according to Smee et al, to *"an association between the two without the controls causing the lower tobacco consumption."*

In addition to the evidence produced by Smee et al themselves, the Smee Report reviewed other external evidence about the relationship between tobacco advertising, smoking initiation and consumption. This evidence suffers problems in terms of its nature, scope and quality. The literature on tobacco advertising, consumption and advertising bans is enormous. While it

may not be necessary to examine all of the available evidence, it is important for a review to have examined a very broad range of it. Smee et al, however, looked at only a fraction of what was available and it is this failure that accounts for some of the Report's most significant weaknesses.

It is not just the nature and scope of the secondary evidence offered by Smee that is unsatisfactory; it is also its quality. In the Report's analysis of the incentive structure of the tobacco market it claims that advertising encourages smoking initiation. The Report offers no evidence in support of this claim. Its own evidence from the UK market directly contradicts it. The Report might at the very least be expected to provide an account of why this claim might be true in general but untrue with respect to the UK.

Similar problems with the quality of evidence mar the Report's conclusions about advertising and consumption. For instance, the Report pools studies of widely different quality in a crude outcome table which is an unacceptable statistical practice and from which any conclusion drawn is meaningless.

Of the UK studies purporting to demonstrate a link between advertising and consumption, none specify properly the advertising used. Of the two studies in which this is properly specified, including the Smee Report's own study, neither found that advertising had a statistically significant effect on consumption. This again undermines the Smee Report and also therefore the UK DoH's position in its consultation document with regard to tobacco advertising and consumption in the UK.

d) Pierce et al 1991

In support of its claim that *"children and young people are more receptive to tobacco advertising than adults*[74]*"* the UK DoH consultation document cites Pierce et al's [75]study of Californian adolescents based on telephone survey data. The study examined whether perception of advertising was age-related and whether market share followed the same pattern of perceived advertising.

[74] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.27
[75] Pierce J. et al. (1991). 'Does tobacco advertising target young people to start smoking? Evidence from California', *Journal of the American Medical Association,* 266(22), pp. 3154–3158.

The study, however, failed to present any evidence as to whether children and young people are more receptive to tobacco advertising than adults, in any meaningful sense of the word. The measure of receptivity used is not progression to smoking, but ability to name the most advertised tobacco brand. This is not a measure of tobacco receptivity but (if anything) a measure of tobacco advertising exposure. Pierce et al presented no data to support their claim that the ability to name the most advertised tobacco brand increases the risk of young people becoming a smoker, yet they still claim that cigarette advertising encourages youths to smoke.

e) Pierce et al 2002

This study, cited by the UK DoH as evidence that tobacco advertising can lead non-susceptible never-smokers to become smokers, is a study of the interaction of parenting styles - authoritative versus *"less authoritative"* - and receptivity to tobacco advertising. Once again there is no data on young people's exposure to advertising. The study simply reports what it terms *"receptivity to tobacco advertising"*, with the highest receptivity defined as *"willing to use an item with a brand image or to have obtained one."* But even this attenuated measure fails to provide compelling results about never-smokers progressing to smoking. Given the design and the results, it is difficult to see what support this study provides to the claim that tobacco advertising leads to smoking initiation.

f) Klitzner et al 1991

Klitzner et al is introduced as evidence of *"young people's greater sensitivity to the promotion and prominent display of tobacco products at point of sale."* It is difficult to understand what support this study provides about young people and point of sale display since it does not even discuss these.

g) Carter, 2003

Carter's analysis of the role of the retail environment in cigarette marketing in Australia is introduced as evidence for two points in the UK DoH consultation document. At 3.28 it is cited as evidence for the claim that *"Since bans on tobacco sponsorship and advertising on television, radio, print and the internet, point of sale promotion has become vital as virtually the only route for tobacco promotion - persuading existing smoker to keep smoking and encouraging young non-smokers to start."* At 3.43 it is cited as evidence that *"tobacco industry strategy documents have suggested that a more important aim [than informing adult customer about price and availability] is to attract new smokers."*

No evidence is presented in support of these claims nor is there any discussion of the claim that the retail environment is designed to prevent smokers from quitting or to encourage smoking initiation. Carter acknowledges that the purpose of the retail environment is as a *"communication vehicle"* for facilitating branded cigarette choices. Carter presents no industry documents as evidence to show that the point of the retail environment is to initiate smoking.

2.3. CONCLUSIONS ON THE RELATIONSHIP BETWEEN TOBACCO ADVERTISING AND CONSUMPTION

None of the evidence from the tobacco market, the econometric literature or advertising exposure and recall studies suggests a causal connection between tobacco advertising and consumption or between tobacco advertising and smoking initiation or between restricting tobacco advertising and changes in consumption or initiation. The fact that past restrictions of tobacco advertising have not been shown to reduce smoking initiation or consumption undermines the UK DoH's claim that the *"evidence suggests that we could expect to see fewer young people starting to use tobacco, and that smoking prevalence among young people could decline at a faster rate than*

we are currently experiencing[76]" should tobacco displays be restricted or tobacco packaging changed. It also negates the UK DoH's analysis of costs and benefits from instituting new tobacco control measures.

2.4. INVESTIGATING THE RATIONALE FOR FURTHER CONTROLS ON THE DISPLAY OF TOBACCO PRODUCTS IN RETAIL ENVIRONMENTS

2.4.1. THE CURRENT UK TOBACCO RETAILING ENVIRONMENT

The retail supply of tobacco to consumers is already strictly controlled. Tobacco products are one of the few fast-moving consumer goods (FMCG) products that can only be purchased in face-to-face transactions with the retailer, (or in only some one per cent of UK sales, via vending machines which are required by law to be under adult supervision). Tobacco products in shops are sited on gantries which are always situated behind the retailer and out of reach of the customer. This means that the customer must request the product from the retailer who is then able to verify age of purchase.

The display of tobacco at the point of sale is essential for efficient retailing. Most smokers make a daily purchase of their preferred brand of tobacco product - approximately 7.3 million retail tobacco transactions a day[77] in the UK. To manage efficiently such a high level of turnover, the product must remain close at hand for the retailer and be stocked in adequate quantities so that regular replenishment from a stock-room is unnecessary.

While small in size, tobacco products are the most valuable FMCG product in a retail outlet, with the average cigarette pack purchase costing £4.74[78]. Most of this value is returned to Government in the form of excise duty and VAT of around £3.67 per pack[79]. It is right and proper that such a small but valuable product should be stored directly within the visual control of the retailer.

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[76] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.39
[77] RAL, year ending June 2008.
[78] RAL, year ending June 2008.
[79] Calculated using Budget 2008 duty rates

The UK DoH consultation document states that *"stakeholders have expressed concern about the prominence of the display of tobacco products within the retail environment, including the apparent growth in the size of tobacco displays*[80]*".* This is entirely erroneous. The stakeholders referenced are making speculative assertions that cannot be justified. During 2004/2005, 64.7% of all Imperial Tobacco's shop units measured only 1.2 linear metres or less. By July 2008, continued reduction in the size of these units meant that the number measuring only 1.2 metres now represent 70% of all Imperial Tobacco's shop units in the UK.

Tobacco companies provide stock-holding tobacco gantries under contract to retailers. This is no different to any other FMCG supplier such as those that supply fridges, coolers or confectionery gantries. Imperial Tobacco asks retailers to ensure that Imperial's brands are positioned on the gantries so that adult smokers can readily verify their availability and price. We want existing adult smokers to choose our brands over those of our competitors. This is the essence of fair competition.

The assertion in the UK DoH consultation document that retail tobacco product displays can stimulate impulse purchases by those not intending to buy cigarettes is spurious. A survey conducted on behalf of ITUK by Albemarle Marketing Research[81] in 2000 revealed that 96% of those adults buying tobacco had planned to do so before visiting the store. A report undertaken in Canada by Meyers Research Centre indicated that 99% of those who purchase cigarettes in convenience stores make the purchase decision before entering the store.[82] The evidence on impulse purchasing of tobacco is examined in greater detail later in this chapter.

[80] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.25
[81] Albemarle Market Research, 2000, http://www.a-m-r.co.uk/
[82] Meyers Research Centre, North American C-Store Close-Up 2003. An in-store intercept category management research program (among shoppers 21 years and older) Report, December 03

2.4.2. THE EVIDENCE CITED BY UK DEPARTMENT OF HEALTH IN SUPPORT OF ITS CLAIMS

The UK DoH makes three claims concerning retail tobacco displays in its consultation document:

1) that retail displays of tobacco products encourage adolescent smoking uptake;
2) that such displays lead people to over-estimate the extent and acceptability of smoking; and
3) That such displays stimulate impulse purchases and impede smoking cessation[83].

Imperial Tobacco does not accept any of these claims and it is our view that the document places an over-reliance on a very small number of studies, each of which has significant methodological flaws and has been conducted in jurisdictions where there is an entirely different retail environment to the UK. Relying on such evidence flies in the face of the principles of good regulation as set out both by the Better Regulation Executive and others and referenced elsewhere in this submission.

The UK DoH claims that the evidence is "*strong*" in relation to these claims allegedly associated with displays of tobacco products at retail. The rationale for the control of displays is supported by references to research papers of varying quality, the authors of which offer conclusions – often speculative – about the impact of displays on youth and on those who wish to quit smoking. Given that this published research is used as a decisive factor in promoting the prohibition of displays, it warrants detailed critical examination.

The analysis provided below demonstrates that the DoH claims are incorrect; indeed it is apparent that the evidence is incomplete, over-stated and misconstrued. Moreover, there is a substantial body of relevant evidence which has been overlooked by the UK DoH which further undermines the purported probity of the UK DoH's claims.

[83] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.27, 3.30, 3.31, 3.33, 3.34

i) Encouraging Adolescent Smoking Uptake

Lavack & Toth, 2006 (Canada)

At 3.28, the UK DoH cites Lavack & Toth in support of its claim that:

> *"Display and the limited amount of advertising still allowed at the point of sale have become more important methods of promoting tobacco products as other promotional methods have been closed*[84]*."*

This study provides no evidence that the industry targets either non-smokers or quitting smokers through point of sale marketing. Lavack & Toth noted that the goal of the industry was *"to secure dominance in the retail setting".* This is quite different from attempting to initiate smoking in young people or to lead former smokers to relapse.

The tobacco industry documents cited by Lavack & Toth support the claim that tobacco advertising is branded advertising intended to affect brand decisions, not the decision to smoke. Despite the UK DoH claim that the discussion in this document is about initiating smoking, it is actually about making brand decisions. In common with the broad range of consumer goods companies, Imperial Tobacco seeks optimum visibility on the point of sale shelves (gantries) for our own brands over those of our competitors so that the adult consumer who has already made a decision to smoke will select our brands over those of our competitors.

ii) Over-estimating extent and acceptability of smoking

Henriksen et al, 2004 (USA)

At 3.27, the UK DoH consultation document discusses Henriksen et al's 2004 study of the exposure of 2,125 California adolescents aged 11 to 14 to tobacco marketing in convenience stores. The study's authors claim that the evidence suggests that *"retail tobacco marketing exposure distorts*

[84] Lavack & Toth, 2006, "Tobacco point of purchase promotion: examining tobacco industry documents, Tobacco Control, 15, pp 377-384

adolescents' perceptions about the availability, use and popularity of tobacco – normative beliefs that are precursors of smoking[85]*".*

It is our view that the social norms theory and the social norms studies cited do not support the claim that tobacco product displays cause misperceptions of adolescent smoking prevalence which in turn lead to smoking initiation.

1) Cited as a study about the influence of tobacco product displays on adolescent smoking, Henriksen et al was about tobacco advertising in retail stores generally and not specifically about tobacco product displays. Given the study design it is impossible in our view to determine whether the reported associations are with retail store advertising or with tobacco product displays. Given the very different nature of tobacco advertising in the United States, these findings have little relevance for the UK in 2008.

2) The literature on smoking initiation contains dozens of risk factors. Henriksen et al controlled for only three or four. Without controlling for the others it is impossible to conclude whether the association reported in the study is between smoking and tobacco advertising or between smoking and one of many other unidentified and uncontrolled-for risk factors.

3) Henriksen et al have assumed the causal progression from advertising exposure to recall, persuasion, use, decision and purchase. The authors assume that because the first step in the chain has occurred – exposure to advertising – that it is responsible for the ultimate outcome. Their study, however, provides no empirical evidence about the intervening variables that would support this assumption. Its other reported associations provide more robust predictions of smoking uptake than does its association with advertising.

[85] Henriksen et al (2004), Association of retail tobacco marketing with adolescent smoking, American Journal of Public Health, 94(12) pp 2081-2083

iii) Promoting smoking uptake; distorting prevalence and popularity

Wakefield et al, 2006 (Australia)

At 3.30 the UK DoH consultation paper states that the recruitment of new smokers *"is enhanced by point of sale display simply because children are exposed to the prominent cigarette gantries throughout their childhood, on every store visit*[86]*."* In support of this claim, the consultation document cites a study from Australia by Wakefield et al (2006).

Wakefield et al showed 605 ninth-grade Australian children edited photographs of a convenience store sales point which showed either cigarette advertising and tobacco pack display; pack display only; or no cigarette packs. Students then completed a questionnaire. Students who saw the photographs with either the pack displays or the advertising and pack displays *"perceived it would be easier to purchase tobacco from these stores."*

The study's results are compromised. Prior to the experiment, students took part in a discussion *"designed to increase the salience of general brand advertising and display."* This could have had the effect of biasing the study by priming the subjects about its purpose. The validity of the results is called into question by the fact that students who saw pictures of the shop without any tobacco products in it still rated it 3.2 for ease of purchasing tobacco on a scale of 1-5 (where 1 is very easy and 5 is very hard). The researchers do not explain how the students expected to find it anything less than very hard to obtain cigarettes from a shop that did not appear from the pictures they were shown to have any cigarettes for sale.

There were no statistically significant differences in perceived prevalence estimates between those who saw pictures of the convenience store with no cigarettes and those who saw pictures of the store with a cigarette display. The hypothesis that seeing tobacco products displayed will lead to distorted prevalence was not supported by the authors' results. Viewing tobacco products on display did not affect the adolescents' beliefs about how many of their peers or adults smoked.

[86] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.30

There were no statistically significant differences in the approval of smoking between students who saw pictures of the convenience store with no cigarettes and those who saw pictures of the store with a cigarette display. This is a finding which undermines a central claim about tobacco displays – that they encourage smoking by leading young people to have more favourable views of smoking. Moreover, there were no significant differences in assigning favourable attributes to teenagers who smoked between students who saw pictures of the convenience store with no cigarettes and those who saw pictures of the store with a cigarette display.

Crucially, there were no statistically significant differences between perceptions of the risks of smoking between students viewing pictures of the store with no cigarettes on display and those viewing pictures of the store with a cigarette display. This fails to confirm the hypothesis that seeing tobacco displays encourages smoking by altering perceptions about the risks of smoking.

Most significantly (given its close connection with an actual measure of smoking behaviour), there were no statistically significant differences in future intentions to smoke between those who saw pictures of the store with no cigarettes and those who saw pictures of the store with tobacco displays.

Apart from the difference between the perceived access to tobacco between those seeing pictures of the store with no tobacco products and those seeing pictures of a store with a tobacco display, this study does not confirm the claims about the ways in which tobacco displays allegedly cause youth smoking experimentation and initiation. The Wakefield et al 2006 study – which is the one piece of empirical evidence in the UK DoH consultation document on the effects of retail tobacco product displays – refutes most claims about the influence of such displays on adolescent smokers.

iv) Recruiting new smokers; underestimating smoking risks; preventing quitting

Pollay 2007 (Canada)

In addition to the empirical evidence offered by the Wakefield 2006 study (above), the UK DoH consultation document cites Pollay (2007) in which the claim is made (based on a review of tobacco industry documents) that tobacco displays are intended to recruit new smokers and prevent quitting.

Pollay's claims can be refuted both by the evidence cited and by the empirical evidence of Wakefield et al (2006). Pollay provides no evidence for his claim that retail tobacco product displays inflate the popularity of cigarette smoking: *"the size and volume of retail display creates a message to the entire retail traffic – that is both smokers and non-smokers – about the popularity of cigarette smoking".* It is also refuted by Wakefield et al's 2006 study which found that tobacco product displays had no statistically significant differences in perceptions of prevalence or in assigning favourable attributes to smokers.

Pollay's claim that displays cause people to *"underestimate"* the risks of smoking is refuted by Wakefield et al's finding that there were no statistically significant differences between perceptions of the dangers of smoking by subjects viewing pictures of a store with no cigarettes and those viewing pictures of a store with a cigarette display. Pollay's claim that product displays shape perceptions, not just brands, is unsupported and appears to be undermined by Wakefield et al's finding that there were no statistically significant differences in future smoking intentions between those who saw pictures of a store with no cigarettes and those who saw pictures of a store with tobacco displays.

v) Stimulating impulse purchases

Wakefield et al, 2008[87] (Australia); Rogers et al[88], 1995 (United States)

The UK DoH consultation document claims at 3.33: *"There is also evidence that point of sale displays can stimulate impulse purchase among those not intending to buy cigarettes…."* This evidence is not only limited but is contradicted by a substantial body of research which suggests that tobacco purchases are not impulse purchases.

It is important to be precise about what is meant by an impulse purchase. Those who promote retail display bans imply that tobacco purchases are impulsive in the sense that they are unplanned and would not have occurred if the tobacco product display had been absent. Their view is that a display ban would mean there would be no impulse buying of tobacco. This, however, represents a confusion between impulsivity in the sense of buying something previously unwanted, and impulsivity in the sense of being opportunistic – buying a regularly-used item on the spur of the moment. In studies involving impulse purchases, these are not items that a consumer does not regularly use. They are simply items that he had not planned to buy before coming to the shop. In other words, what is impulsive is the **time** of purchase, not **whether** the item is purchased.

Equally important is the fact that most impulse purchases are not category purchases but brand purchases, in which the consumer decides to try a different brand from the one normally used. As Inman and Winer 1998[89] note, some impulsive shoppers – often defined as those without a shopping list – do not enter a shop without planning their purchases but their shopping planning is only to the category level; the "impulsive" aspect of their purchase is the decision between brands in a category, not whether to purchase the category at all. This is congruent with the brand positioning of tobacco products in retail displays.

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[87] Wakefield et al, 2008, The effect of retail cigarette displays on impulse purchase, addiction 103(2), pp 338-347

[88] Rogers et al, 1995, Community mobilisation to reduce point of purchase advertising of tobacco products, Health Education Quarterly, 22, pp 427-442

89 Inman and Winer, 1998, Where the Rubber Meets the Road: A Model of In-store Consumer Decision Making, Marketing Science Institute Working Paper (98-122)

The fact that cigarette purchases are not impulsive, in the sense of deciding to start smoking based on seeing a tobacco display, follows from what is known about smokers' habits. Smokers tend to smoke approximately the same number of cigarettes each day[90]. They do not suddenly decide to smoke more – contradicting Pollay's claims about displays reminding smokers to *"smoke now and more often".* This means that they usually know when they will need to buy more cigarettes, which also means that cigarette purchases are commonly routine and planned, both with regard to location and to brand availability.

A PriceWaterhouseCoopers study[91] of consumer buying patterns found that the most important factor in a smoker's decision as to where to purchase cigarettes is whether a store carried his brand; a fact that supports the careful planning of tobacco purchases. The non-impulsive as opposed to routine purchases of cigarettes was also confirmed in a study of purchasing patterns at US convenience stores by the Point of Purchase Advertising Institute[92] (POPAI) which found that cigarettes were the product category least often purchased on impulse. For instance, 51.9% of consumers leaving convenience stores reported purchasing sweet snacks on impulse and 40.1% bought confectionery, chewing gum or mints, compared with only 4.4% buying cigarettes.

Marketing professor Marvin Goldberg, cited in the UK DoH consultation document, observes about the routine nature of tobacco purchases:

> *" … the adult smoker routinely needs to replace his/her inventory of cigarettes and plans accordingly. His purchase will be at least generally planned (plan to purchase product before entering the shop) and indeed will usually be specifically planned (plan to purchase specific brand before entering the shop)."*[93]

[90] Gayle North, Positive Change Institute, http://www.gaylenorth.com/TheyAreJustExcuses.htm
91 PriceWaterhouseCoopers and the NACS "Future Study Consumer Survey" September 1999
92 In-Store Advertising Becomes a Measured Medium: Convenience Channel Study POPAI, 2002

93 The Queen vs BAT, Imperial et al 2004 Witness Statement of Professor Marvin Goldberg 14 July 2004 p. 7

The carefully planned (as opposed to impulsive) character of cigarette purchasing is confirmed in studies of the purchasing patterns of smokers. Dr. Klaus Wertenbroch of Yale University's School of Management[94], for example, found that a large majority of regular smokers bought their cigarettes by the pack rather than by the large carton, even though this required more careful planning in order not to run out of cigarettes.

It might be argued that such evidence applies only to adult smokers and not to young people who might still purchase cigarettes on impulse. Two evidential factors argue against this. First, according to the research literature,[95] young experimenters do not purchase their cigarettes but obtain them largely from social sources; impulsivity is largely irrelevant to this group. Second, several studies that have looked at impulsive purchasing in adolescents have found that cigarettes are not an impulsive purchase for this age group. Verplanken & Herabadi[96] for example required a group of students to rank 36 frequently purchased items as to whether their recent purchase of the item was planned or impulsive, and rational or irrational. Products purchased impulsively included CDs, novels, clothes, perfumes, snacks, make-up, confectionery and wine. Products that were not purchased impulsively but were planned included shampoo, magazines, cheese, fizzy drinks, meat, coffee, tea and, importantly, both manufactured cigarettes and rolling tobacco.

The claim that tobacco impulse purchases increase by as much as 28% because of POS displays is frequently repeated in this debate. However:

- the evidence shows that cigarettes are the item least often purchased on impulse;

[94] Dr. Klaus Wertenbroch, "Consumption Self-Control by Rationing Purchase Quantities of Virtue and Vice", *Marketing Science*, 1999

[95] Castrucci et al Adolescents' acquisition of cigarettes through non-commercial sources Jn of Adolescent Health 2002 31: 322-326; Forster and Wolfson Youth Access to Tobacco: Policies and Politics Annu Rev Public Health 1998 19:2-3-35; Forster et al Social exchange of cigarettes by youth Tobacco Control 2003 12: 148-154; Croghan et al The importance of social sources of cigarettes to school students Tobacco Control 2003 12: 67-73; Robinson et al, Gender and Ethnic differences in young adolescents' sources of cigarettes, Tobacco Control 1998 7:353-59.

[96] Verplanken & Herabadi, 2001, Individual differences in impulse buying tendency: Feeling and not thinking. European Journal of Personality, 15, S71-S83

- the evidence, including from one of the UK DoH's cited experts (Professor Goldberg), shows that smokers rarely buy cigarettes on impulse due to their smoking patterns; and
- an increase in the category "impulsive cigarette purchase" as defined by POPAI (see above) does not mean an increase in cigarette purchases that would not have taken place, but merely a shift of purchases normally made from a subsequent time to the present time.

Wakefield et al's conclusion about the role of retail displays in prompting impulse cigarette purchases is based on telephone surveys of 2996 Australian adults in 2006. Of the sample, 526 (around 16%) were smokers. This group was asked to recall how often they had decided, when shopping for something else, to purchase cigarettes as a result of seeing a cigarette display. According to Wakefield et al, 30.3% of the smokers noticed cigarette displays at least sometimes, with 25.2% deciding sometimes to buy cigarettes as a result of seeing them displayed. There are fundamental problems with this study's methodology and its findings.

First, the study's data comes from unvalidated self-reports obtained from telephone interviews. This methodology is different from that used in measuring both unplanned purchases and the association between retail displays and unplanned purchases. Typically, research about planned versus unplanned purchases involved either observation studies of actual consumer behaviour or intercept studies in which consumers are asked about their purchases at the time of purchase, not retrospectively. Moreover, the response rate to the study's telephone survey was much lower than those typically reported in the research literature. Refusal rates for telephone surveys have been increasing for the last 30 years, and as recently noted by the Chairman of the Harris Poll, Humphrey Taylor, this threatens to bias their results substantially by reducing the ability of the sample accurately to reflect the population under study.

Second, unverified self-reports pose a significant problem in terms of validity. Self-reported data may be inaccurate because of situational factors

associated with the social desirability of the behaviour being studied. The research literature notes that self-reports are plagued by the social desirability bias, with subjects often reporting what they believe the interviewer wishes to hear or what is the socially preferred option, rather than what is actually the case. Luepker et al 1989 found that *"reported quitting [smoking] by telephone was an unstable category because of relapse and misreporting with 35% of self-described quitters in the telephone interview admitting to being smokers in a face-face interview."* [97] Given that Wakefield et al base their conclusions on telephone interview data about purported quitters, the unreliability of telephone interviews to determine quitting status seriously undermines their results.

Third, self-reported data may be inaccurate because of the cognitive processes which underlie the survey process. Research has found that at least four different cognitive processes are involved in answering survey questions. These include comprehension of the question; retrieval of the required information; decision-making as to whether the retrieved information matches the question; and providing the response. Errors occur at each stage in this process, as well as through unconscious rationalisation and outright deception. Some studies have shown that the likelihood of untruthful responses rises with the degree of threat posed by the question.

But even setting aside the question of conscious deception, there is the possibility of significant inaccuracy due to faulty recall. As Brener et al 2003 observe:

> *"It has been hypothesized that error potentially arises at each of these stages, which in turn contributes to validity problems…. [B]ecause the specific cognitive operations employed in responding to a question may differ depending on such factors as the length of the reference period and the type of response required (e.g. frequency of a behaviour*

[97] Luepker et al, 1989, Validity of Telephone Surveys in Assessing Cigarette Smoking in Young Adults, American Journal of Public Health, February 1989, Vol. 79, No. 2, pp202-204

versus simply whether the behaviour occurred), validity can vary from question to question." [98]

Self-reported data, assuming that it is not self-consciously deceptive, is less reliable than an objective report in that people can only report what they remember seeing, doing, believing and what they think they saw, did, or believe; both of which are different from what they actually saw, did or believed. As Agostinelli and Grube 2003 write *"People are notoriously inaccurate in making attributions for the causes of their behaviour."* [99]

The Wakefield et al 2008 study highlights several of these problems. With regard to the issue of question comprehension and accurate retrieval of information, smoking research contains many errors involving question comprehension, deciding between retrieved information and the question being posed (according to Pokorski et al 1994[100]). Wakefield et al asked their subjects a complicated two part question; to recall when they had been shopping for something and had purchased cigarettes, and to recall whether this purchase was the result of seeing a cigarette display.

Wakefield et al asked their subjects not simply to report their behaviour but to make an attribution of its cause by asking for them to explain their cigarette purchase as a function of seeing a tobacco display. Given that smoking is perceived by many as undesirable, smokers have considerable impetus to mis-report their reasons for buying cigarettes by attributing them to the prompting of a display as opposed to their own pre-planned decision to smoke.

Similarly, Wakefield et al asked their subjects to make an attribution with regard to quitting. *"When you tried to quit smoking, was there ever a time when seeing the cigarette pack display in the store gave you an urge to buy cigarettes?"* Given that research has shown that quitting smokers already attribute their failure to stop smoking to sources other than themselves, e.g.

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[98] Brener et al, 2003, Reliability of the Youth Risk Behavior Survey Questionnaire, American Journal of Epidemiology Vol. 141, No. 6: 575-580

[99] Agostinelli and Grube, 2003, Tobacco counter-advertising: a review of the literature and a conceptual model for understanding effects, Journal of Health Communications, Mar-Apr;8(2):107-27

[100] Pokorski TL, Chen WW, Bertholf RL. Use of urine cotinine to validate smoking self-reports in US Navy recruits. Addict Behav 1994; 19:451–4.

being "addicted", so-called recidivist smokers may have good reasons to attribute their apparent failure to urges prompted by viewing tobacco packages. As Ruiter and Kok 2006 note in discussing the reliability of self-reported smoking data:

> *"… even if people do what they report, people are not capable of adequate introspection into what motivated their behaviour. The only way to garner convincing evidence is by applying experimental designs with reliable behavioural measures."* [101]

These problems with self-reported, recalled and self-attributed data are important because they help to explain why Wakefield et al's 2008 findings appear at odds with the rest of the literature on impulse purchases and tobacco. Wakefield et al report that 15.2% of their subjects purchased cigarettes as a result of sometimes seeing displays, but the POPAI data on convenience stores found that fewer than 5% of consumers purchased tobacco on impulse. As identified, there is a consensus amongst researchers into smoking behaviour that smokers smoke in predictable ways and do not normally increase their tobacco consumption. Professor Goldberg reports that tobacco purchases are planned[102]. This means that even an "impulse" tobacco purchase does not result in more smoking; it simply means that the time at which a tobacco purchase has been made has been changed or that a different tobacco purchase from usual might have been made.

The Wakefield 2008 results are not statistically significant. First, younger smokers were not significantly more likely to notice tobacco displays than older smokers, a finding which contradicts the statement in the UK DoH consultation document that tobacco advertisements are particularly attractive to young people. Second, daily store visits – frequent exposure – were not significantly associated with the impulse purchase of cigarettes. Third, the level of cigarette consumption was not significantly associated with impulse purchases, confirming the predictability of smokers' buying patterns. Fourth, attempting to quit smoking in the previous 12 months was not significantly

[101] Ruiter RAC, Kok G. Saying is not (always) doing: cigarette warning labels are useless. *Eur J Public Health* 2005;15:329

[102] The Queen vs BAT, Imperial et al 2004 Witness Statement of Professor Marvin Goldberg 14 July 2004 p. 7

associated with impulse purchases. The only statistically significant variable associated with impulse purchase for the entire sample was noticing tobacco displays *"at least sometimes*[103]*",* and even then it was only marginally significant.

vi) Impeding cessation; encouraging relapse

The Wakefield et al 2008 study is also cited in the UK DoH consultation document to support the claim that seeing tobacco displays impedes quitting through creating an impulse to buy cigarettes. At 3.34 it notes that Wakefield et al found that:

> *"Some 38% of smokers who had tried to quit in the past 12 months and 34% of recent quitters experienced an urge to buy cigarettes as a result of seeing the retail cigarette display."*

This is a frequently found claim in discussions about tobacco product displays.

However, Wakefield et al's 2008 results and conclusions about quitting and tobacco displays are questionable for two reasons.

First, the results are unique in the literature of smoking, quitting and relapse. Despite the enormous literature on the factors which predict smoking relapse and successful quitting, there is no other evidence which suggests that there is a statistically significant association between viewing tobacco displays and having difficulty quitting smoking or in relapsing. In a representative study of smoking relapse among smokers abstinent for 6-12 months, Wetter et al 2004[104] list the most reliable predictors of smoking relapse as:

- duration of abstinence;
- lower levels of education;
- motivation/readiness to change;

[103] Wakefield et al, 2008, The effect of retail cigarette displays on impulse purchase, addiction 103(2), pp 338-347

[104] Wetter et al, Prevalence and predictors of transitions in smoking behavior among college students, Health Psychology 2004 168-77.

- self-efficacy/confidence;
- social support;
- higher levels of nicotine dependence;
- alcohol use;
- negative affect/stress;
- exposure to other smokers; and
- psychiatric co-morbidity.

Exposure to tobacco displays is notably not included.

The Cochrane analysis of relapse prevention from 2005[105] discusses 40 rigorous studies on the sources of smoking relapse and does not identify retail environments with tobacco displays as a high risk factor for resuming smoking.

Marlatt & Donovan 2005[106], in a major study of relapse prevention for addictive behaviours, identifies three high risk situations for relapse with interpersonal conflict and social pressure accounting for 75% of relapse. Exposure to retail tobacco displays is not documented as a risk for smoking relapse.

Finally, and significantly, Slater et al 2007[107] which examined the association between point of sale advertising, tobacco displays and youth smoking uptake and relapse, found no statistically significant association between exposure to cigarette advertising or cigarette displays and adolescent relapse.

Given the problems with the design of the Wakefield et al's 2008 study, its outlier status in terms of the literature on smoking relapse, its non-replicated character and its marginal statistical significance, it is our view that it should not be accorded significant probative weight.

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[105] Hajek P, Stead LF, West R, Jarvis M, Lancaster T. Relapse prevention interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD003999. DOI: 10.1002/14651858.CD003999.pub2

[106] Marlatt, G.A., Donovan, D.M. (Eds.).(2005). Relapse Prevention: Maintenance strategies in the treatment of addictive behaviors (2nd Ed). New York, NY, Guilford Press.

[107] Sandy J. Slater, PhD; Frank J. Chaloupka, PhD; Melanie Wakefield, PhD; Lloyd D. Johnston, PhD; Patrick M. O'Malley, PhD, The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake, Arch Pediatr Adolesc Med. 2007;161(5):440-445

2.4.3. EVIDENCE NOT CITED BY UK DEPARTMENT OF HEALTH WHICH DOES NOT SUPPORT ITS CLAIMS

The UK DoH consultation document argues that the *"evidence about the public health benefits of prohibiting the display of tobacco products in retail environments is strong*[108]*".* . This claim is, in our view, unfounded. As discussed, the empirical evidence base cited by the UK DoH consultation paper consists of three studies by two principal researchers (Henriksen and Wakefield). This compares to a total evidence base of thousands of studies about smoking uptake, prevention and cessation. It is of concern that a significant public policy measure could be advanced for consideration on the basis of such limited evidence which, as demonstrated above, may itself be seriously flawed.

In analysing the lack of merit and the paucity of the evidence cited by the UK DoH to support its claims, we have already highlighted significant areas of evidence which have been entirely overlooked. This section considers further important evidence which has been excluded from the consultation document. This further undermines the credibility of the UK DoH's claims.

i) Wakefield et al, 2002 (Australia) (two studies)

Two Wakefield et al studies from 2002 have not been included in the UK DoH consultation document. These are *"The cigarette pack as image: new evidence from tobacco industry documents"* [109] and *"Association of Point-of-Purchase Tobacco Advertising and Promotions with Choice of Usual Brand among Teenage Smokers".*[110] These are studies about tobacco packaging and point of sale advertising and promotion in the retail environment as being focused on the branded decisions of smokers.

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[108] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.45

[109] Wakefield et al, 2002, The cigarette pack as image: new evidence from tobacco industry documents, Tobacco control, vol.11, UP1,[Note(s): i73-i80]

[110] Wakefield, MA, et al., "Association of Point-of-Purchase Tobacco Advertising and Promotions with Choice of Usual Brand among Teenage Smokers," Journal of Health Communications 7:113-121, 2002.

The Wakefield et al "Cigarette Pack as Image" study appears to suggest that the design characteristics of tobacco packs make *"them more attractive to teenage smokers",* even while it provides absolutely no evidence to support this claim. The Cigarette Pack as Image study also speaks about the importance of brands to smokers not making a choice about smoking but *"making a brand choice."* It also talks about packs assisting smokers to *"select one brand over another"* as opposed to deciding to smoke. Wakefield et al observe *"the unappealing images now used on cigarette packs in Canada to warn consumers of health risks effectively represent a form of anti-smoking advertising and may lessen the need to withdraw cigarette packs from plain view in retail outlets."*

The Association of Point-of Purchase Tobacco Advertising study looked at the relationship between brand-specific advertising and promotions in retail settings and choice of usual brand among students. It found that choice of a particular brand was associated with greater brand advertising in a store, a fact that is consistent with the brand choice function of advertising, but inconsistent with Wakefield's 2006 claims and Pollay's claims about brand advertising being used as a smoking initiation tool.

ii) Slater et al[111] 2007

A further omission is *"The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake"* 2007, with Slater as lead author and Wakefield as co-author. The article examines the association of point of sale advertising, displays, promotions and prices with youth smoking uptake and relapse. It fails to find a statistically significant association between smoking across all levels of uptake (puffer, experimenter, etc) and smoking relapse and tobacco displays. It is co-authored by one of two researchers who provide the authority for the UK DoH's position on tobacco displays, and so this omission from the consultation document is unfortunate.

[111] Sandy J. Slater, PhD; Frank J. Chaloupka, PhD; Melanie Wakefield, PhD; Lloyd D. Johnston, PhD; Patrick M. O'Malley, PhD, The Impact of Retail Cigarette Marketing Practices on Youth Smoking Uptake, *Arch Pediatr Adolesc Med.*2007;161(5):440-445.

iii) The ESPAD Survey

A further omission is the discussion of the correlates of adolescent substance use from the European School Survey Project on Alcohol and Other Drugs (ESPAD) survey[112] which was cited by the UK DoH for evidence about the effect of display bans in Iceland. The omission is unfortunate because these correlates represent risk factors for smoking uptake other than display bans, which are not discussed in the ESPAD survey. The factors discussed in the ESPAD survey are, unlike display bans, generally recognised as strong predictors of smoking uptake. They have important policy implications, but the UK DoH consultation document prefers instead to focus on display bans for which the evidence is extraordinarily weak and for which the ESPAD survey provides no statistically valid support.

For instance, living with one parent was significantly associated with increased tobacco use in 23 of the 29 ESPAD countries. As the survey notes *"These results thus show a clear and consistent pattern of increased smoking among European adolescents that do not live with both biological parents …."* Or to take another strong predictor for smoking uptake – school connection and academic performance – the ESPAD results found that in every country there was a statistically significant association between school truancy and cigarette use. As the survey notes *"It can therefore be concluded with considerable confidence that truancy is associated with increased use of cigarettes, alcohol and cannabis among European students."* Finally, the ESPAD data found that cigarette use by an older sibling was associated with increased tobacco use by the younger sibling in all ESPAD countries.

2.4.4. EXPERIENCE OF SIMILAR TOBACCO CONTROL REGULATIONS FROM OTHER JURISDICTIONS

i) The Icelandic experience

The UK DoH consultation document references the display ban in Iceland as pointing to the *"potential benefit in reducing prevalence among young*

[112] European School Survey Project on Alcohol and Other Drugs, ww.espad.org/sa/node.asp?node=730

people[113]*."* In doing so it adds the caveat that this evidence is *"not definitive*[114]*"*, and notes that Health Canada found that whether a display ban would reduce tobacco consumption was *"very speculative*[115]*."*

The UK DoH consultation document is right to be cautious about using this evidence from Iceland. This is not simply because the data is generated by student self-reports but also because it is impossible to draw accurate conclusions about changes in prevalence when:

a) data is reported only in multiple year increments; and

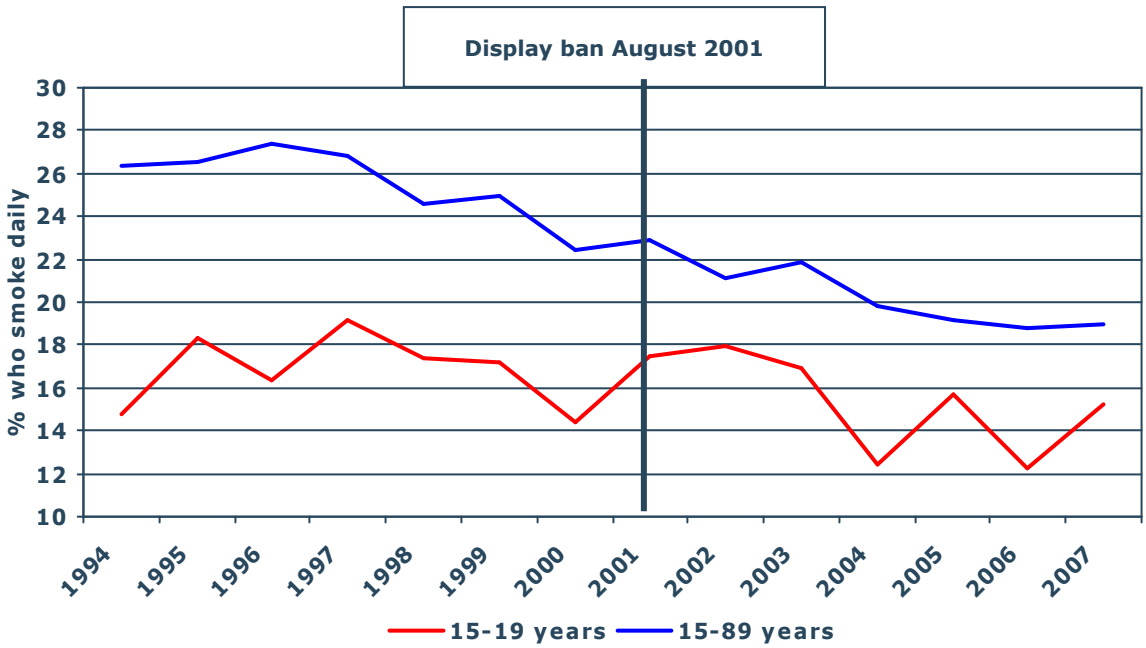
b) there are no controls for any of the other factors which might account for changes in smoking prevalence.

Given that the display ban was introduced in 2001 the relevance of comparing student returns from 2003 with those from 1995 must be questioned. Not only is much of the early part of this period irrelevant to understanding the impact of the display ban, other regulatory and fiscal changes were introduced over this eight year period, including the implementation of the Tobacco Control Act in 2002. The data must also be interpreted against a backdrop of progressive decline in the rates of smoking prevalence and consumption.

It is useful to compare this self-reported, non-annual data with the official year-by-year data on prevalence provided by Statistics Iceland. As the chart illustrates (Figure 2.1), there was little or no impact on the smoking prevalence of 15-19 year olds after the ban was introduced. During 2001 when the ban was introduced, smoking prevalence among this age group **rose by 3.1%** from 14.4% to 17.5%. During 2002, the first full year after the ban was introduced, smoking prevalence among this age group was the highest it had been for 5 years at 17.%. Although smoking prevalence then fell from this peak in 2007, the latest year for which data is available, smoking prevalence was 15.2%; still higher than it had been before the display ban was introduced.

[113] Department of Health, Consultation on the Future of Tobacco Control, para 3.29 [113]
[114] Department of Health, *Consultation on the Future of Tobacco Control*, 33
[115] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.45

Figure 2.1 Smoking Prevalence in Iceland[116]



It is important to be aware that comparisons between different jurisdictions on prevalence and life-time tobacco use may not always be meaningful in understanding the sources of the differences in adolescent smoking. For instance, low smoking prevalence rates are found in Cyprus, Iceland, Sweden and Turkey[117], yet these countries have significantly different tobacco control policies. The fact that countries such as Cyprus, Sweden and Turkey have low prevalence rates without tobacco display bans strongly suggests that the low prevalence of tobacco use in Iceland is due to factors other than the tobacco display ban.

It is surprising that the UK DoH draws any conclusions from the data available, let alone an optimistic one about the effect of introducing a single variable (such as a display ban).

[116] www statice.is/Statistics

[117] European School Survey Project on Alcohol and Other Drugs, ww.espad.org/sa/node.asp?node=730

ii) The European experience

The European School Survey Project on Alcohol and Other Drugs (ESPAD) commentary on changes in cigarette smoking (p 64ff) highlights how difficult it is to make any inferences as to the causes of these changes. For example, with respect to smoking during the last 30 days, ESPAD notes that:

"Some countries with relatively high prevalence rates in 1999 have lower figures for 2003, including Denmark, Finland, France, Ireland and Norway. However, this also occurred in countries with somewhat lower prevalence rates such as Greece, Iceland, Malta, Sweden and the United Kingdom." [118]

Thirty day prevalence rates have declined in countries with previously high rates and which did not have display bans, as well as in countries with lower prevalence rates which did not have display bans. Prevalence rates also declined in the UK without a display ban, which was already in the lower band of thirty day prevalence rates along with Iceland.

According to ESPAD *"no country shows a "continuous decrease" in lifetime cigarette use, regardless of tobacco control policies, including display bans."* Using another measure, daily smoking at age 13 and below declined substantially in only two countries, the Republic of Ireland and the United Kingdom, neither with a display ban.

iii) The Canadian experience

The evidence from Canada provides more reasons for scepticism about the alleged association between display bans and reduced prevalence and initiation as well as increased quitting, though it is subject to many of the same problems as those surrounding the ESPAD data. Unfortunately, the UK DoH consultation document does not provide any data from the Canadian provinces that have introduced display bans. This is a significant omission and all the more surprising given that such data is readily obtainable from the

[118] European School Survey Project on Alcohol and Other Drugs, ww.espad.org/sa/node.asp?node=730

Health Canada Annual CTUMS (Canadian Tobacco Use Monitoring Surveys) which is claimed to be:

> "*one of the largest surveillance undertakings for Health Canada, conducted under the auspices of Statistics Canada. CTUMS continually tracks changes in smoking status and consumption, and is Canada's most comprehensive indicator of trends in tobacco prevalence.*"[119]

The UK DoH consultation document claims that tobacco product displays prompt smoking uptake, maintain consumption, impede cessation and tempt former smokers to resume being smokers. It could therefore be expected that reduced instances of some or all of these measures would be found in jurisdictions such as Canadian provinces that have instituted display bans. In effect, the experience of these jurisdictions in smoking control would provide a real-time experiment, given the usual limitations of such data and methodologies, of the effectiveness of display bans. The Canadian data is aptly suited for this purpose, since it comes from a single country that in 2006 had display bans in just five provinces or territories. It cannot be assumed that display bans are the only difference between the provinces or territories that have display bans and those that do not. But it is instructive to compare the differences in factors such as youth prevalence, general prevalence and quitting attempts in those provinces and territories with display bans with those without them.

The results from the Canadian data[120] suggest that there are no statistically significant differences between those provinces or territories with display bans and those without them in terms of youth prevalence and total prevalence. CTUMS writes that the *"results showed that the Provinces were all within +/- 5% of the National average smoking rate."* The highest prevalence was found in Saskatchewan (24%) which was the first province to institute a display ban,

[119] Website of Health Canada: http://www.hc-sc.gc.ca/hl-vs/pubs/tobac-tabac/report-rapport/role4-eng.php

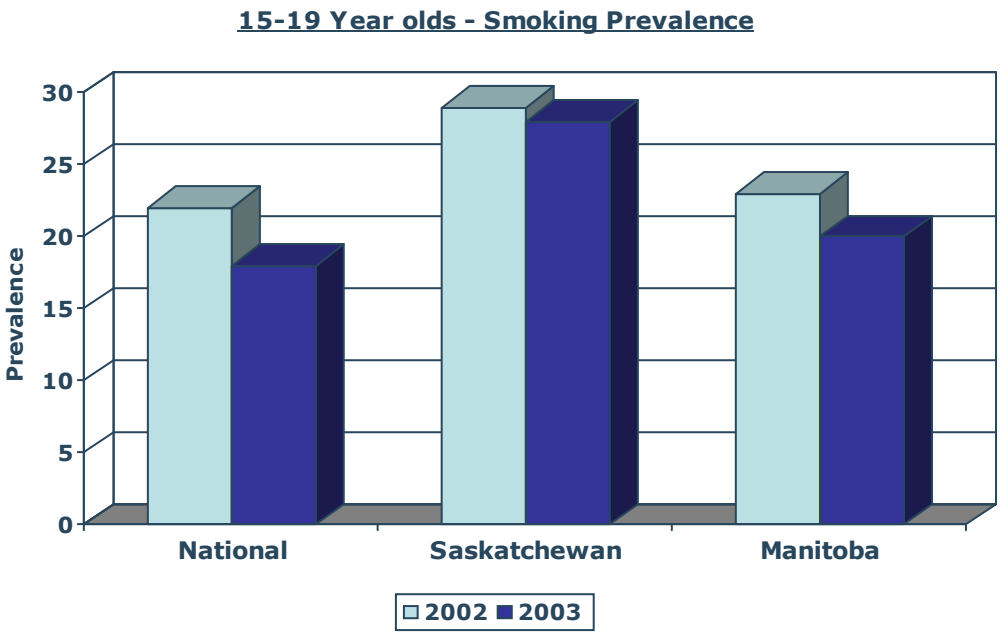
[120] Health Canada - Tobacco Control Programme Canadian Tobacco Use Monitoring Survey (CTUMS) Smoking Prevalence 1999 – 2007 November 7, 2007

while the largest province, Ontario, which has no display ban, reported a total prevalence of just 17%.

Year-on-year changes in youth prevalence are also interesting. Manitoba, with a display ban, had a youth prevalence rate of 20% in 2005 and 19.7% in 2006, a statistically non-significant difference. Prince Edward Island, also with a display ban, had a youth prevalence rate of 13% in 2005 and 14.1% in 2006. Saskatchewan, with Canada's longest display ban, had a youth prevalence rate of 25% in 2004 and 25% in 2005. Moreover, since the display ban was reintroduced in 2005, the overall prevalence in Saskatchewan has increased from 22 to 25% while the rest of Canada has experienced a decline in overall prevalence. Given that display bans are meant to enhance quitting, it is instructive that Saskatchewan had the second worst percentage of smokers intending to quit in Canada. Alberta, for instance, with no display ban had a higher percentage of smokers intending to quit than either Saskatchewan or Manitoba, both with display bans.

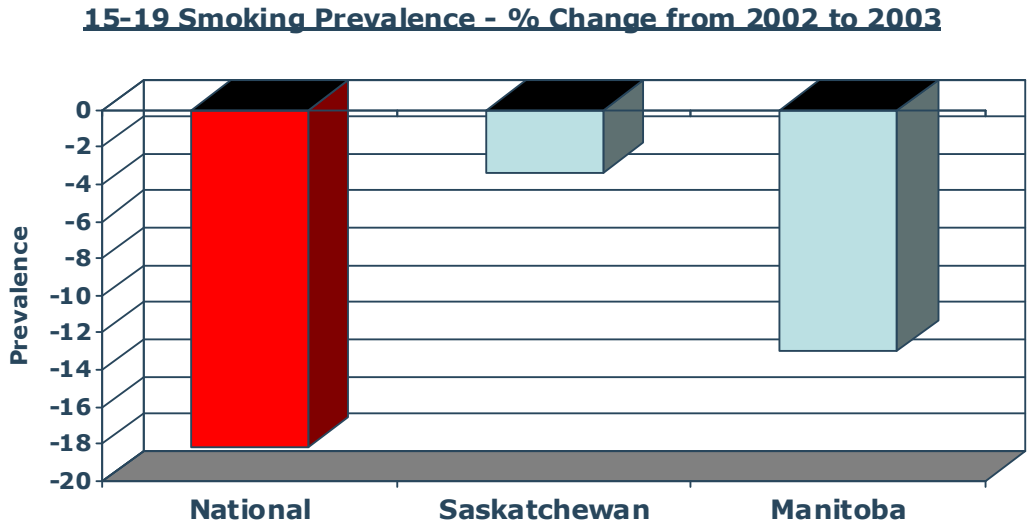
The experience of Saskatchewan with display bans is instructive with regard to the claim that they address underage smoking. Saskatchewan banned displays in March 2002. The ban was in effect for 18 months until overturned by a Court decision. During that period, youth smoking prevalence rates in the rest of Canada declined by 18% while in Saskatchewan the decline was only 3.5%. In the neighbouring province of Manitoba, without a display ban, youth prevalence during the same period declined from 23% to 20%, a 13% decline, as the following chart (Figure 2.2) based on the Health Canada data[120] indicates.

Figure 2.2 Smoking Prevalence Data – Canadian Provinces[120]



Smoking Prevalence (%)

	2002	2003
All Canada	22	18
Saskatchewan	29	28
Manitoba	23	20



Unfortunately, the UK DoH consultation document does not provide Canadian prevalence or quitting data for those provinces with display bans, but concedes the "*speculative*"[121] nature of such measures having any significant effect on tobacco consumption or youth uptake.

iv) Past tobacco control regulations

The empirical track record of past tobacco control measures is an additional reason to be sceptical that a display ban will bring about any meaningful reduction in smoking uptake or tobacco consumption.

Pampel 2007[122] examines data from 145 countries and finds that a range of tobacco control measures, including advertising restrictions and bans, have had no statistically significant effect on smoking prevalence.

There is little empirical support for the UK DoH's claim that tobacco advertising bans have reduced smoking uptake or consumption or that such bans have increased quit rates. There is also strong evidence from Canada that the most recent tobacco control initiative in that country (graphic health warnings) has not had a statistically significant effect in any major measure.

A Health Canada-commissioned series of surveys pre- and post the introduction of graphic health warnings (CTUMS referenced elsewhere), found that the warnings were not associated with a statistically significant decline in adolescent consumption; a statistically significant increase in the number of adolescents who attempted to quit smoking; a statistically significant change in adult smoking prevalence or consumption; or a statistically significant increase in the percentage of adult smokers who tried to quit smoking.

It is worth noting that some of these findings parallel the data on display bans and changes in youth and adult smoking. These were confirmed in an econometric study by Gospodinov & Irvine 2004[123] who found that the new packages with graphic health warnings were not associated with a statistically

[121] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.45
[122] Fred C. Pampel. 2007. "National Income, Inequality, and Global Patterns of Cigarette Use." Social Forces 86:455-466.
[123] Nikolay Gospodinov & Ian Irvine, 2004. "Global Health Warnings on Tobacco Packaging: Evidence from the Canadian Experiment," Topics in Economic Analysis & Policy, Berkeley Electronic Press, vol. 4(1), pages 1304-1304

significant decline in smoking prevalence or consumption in either young people or adults. These also have relevance to the issue of plain packaging.

2.4.5. YOUTH SMOKING AND TOBACCO PRODUCT DISPLAYS – THE VIEW OF IMPERIAL TOBACCO

a) Guiding Principles

Imperial Tobacco supports sound, reasonable, proportionate and practical regulation of tobacco products. We believe tobacco products are for adults and support the enforcement by the appropriate authorities of existing legal minimum age restrictions that apply to the retail sale of tobacco products (including vending).

However, we encourage governments to respect the principles of adult choice and freedom of competition when regulating tobacco products. We are opposed to regulation that restricts or prohibits retailers from displaying tobacco products to at the point of sale and believe that such restrictions would:

- be anti-competitive;
- undermine the principle of adult choice;
- create additional work and cost burdens for retailers, Trading Standards and the police; and
- fuel the existing illicit trade in non duty-paid and counterfeit tobacco products.

Furthermore, in our view, such a proposal:

- undermines the right to commercial free speech under Article 10 of the ECHR[124] by denying suppliers and consumers the ability to impart and receive information relating to the price, quality, heritage and brand values of lawful products, which is a further and excessive curtailment of already significantly limited rights; and

[124] European Charter of Human Rights

- is contrary to the principles of free movement of goods enshrined in Article 28 of the EC Treaty because it will prejudice the ability of new entrants and brands to access the UK market, thus disadvantaging them by comparison to well established UK rivals and restricting intra-Community trade.

The freedoms protected by Articles 10 of the ECHR and 28 of the EC Treaty may be qualified if this is justified for the protection of health. However, any such curtailment must be proportionate i.e. relevant to the objective (of reducing tobacco consumption, particularly among younger smokers) but not going beyond what is necessary to achieve it. Imperial Tobacco believes that the recent UK tobacco control measures[125] have not been stringently enforced nor has their effect yet been sufficiently evaluated; neither has it been possible to evaluate the effects of graphic health warnings as these are not due to be introduced until October 2008. We consider that a display ban would be misguided and disproportionate.

b) Adult Choice and Fair Competition

At least 11 million adult smokers in the UK have made the decision to smoke against a background of numerous tobacco control measures and educational campaigns conducted by successive governments. Some people may find it difficult to stop smoking, but we believe it is important for them to understand that they are able to stop if they choose to do so. Millions of people have stopped smoking, the majority without assistance, and there are now more ex-smokers in the UK than smokers[126]. As smokers have made an informed choice, it is our view that they should have the same rights and freedoms to view the range of products available to them as consumers of other legal products.

It is our view that it is reasonable for an adult smoker to be able to view their choice of legal product in an appropriate display area behind the counter, to help him to make an informed brand and price choice whilst contributing to fair

[125] PoS Regulation, increase in minimum purchase age
[126] According to the "Smoking Behaviour and Habits" and "General Household Survey 2005", 26% of men are smokers while 30% are ex-smokers; 23% of females are smokers while 24% are ex-smokers.

and undistorted competition between tobacco manufacturers and retailers. A ban on tobacco product displays would favour dominant brands and suppliers and would act as a barrier of entry for new brands and suppliers. Accordingly, we do not believe that the UK DoH consultation document passes the Competition Assessment Test[127].

c) Illicit Trade

A display ban would further fuel the existing and problematic illicit trade in tobacco products already acknowledged by UK Treasury and by HM Revenue & Customs and discussed elsewhere in this submission. The distinction between tobacco products that are sold legally and counterfeit or other non-duty paid tobacco that is illegally traded on street corners, in pubs and at car boot sales will become further blurred. If consumers are further displaced from the legitimate retail chain to illicit channels, it is inevitable that public health objectives and government revenue streams will be compromised.

A small minority of retailers sell non-UK duty paid (counterfeit or smuggled) tobacco products from under the counter. Any proposal to hide tobacco from view will increase the opportunities to stock and sell smuggled or counterfeit products which will make the work of Trading Standards and anti-illicit trade authorities more difficult. Consumers will be unable to differentiate between legal products (which they could reasonably assume would be displayed correctly) and illegal products, which are currently more likely to be stored under the counter and out of sight.

A display ban which could lead to an eventual reduction in the number of retail outlets selling tobacco seems to be an inappropriate policy when at least 27% of the market is already in non-UK duty-paid cigarettes. A display ban would diminish the consumers' perception of difference between legal and illegal products, and increase the level of participation in illicit trading and purchasing of illicit products.

[127] P80, DoH consultation document

2.5. CONCLUSIONS ON RETAIL PRODUCT DISPLAYS

In view of the lack of credible evidence presented in the UK DoH consultation document that restricting or banning retail tobacco product displays will have any positive impact on youth smoking initiation or consumption, and mindful of the negative effects it would have on competition and the illicit trade, Imperial Tobacco supports **Option One** as set out in the consultation document.

2.6. PLAIN PACKAGING

2.6.1. INTRODUCTION

Imperial Tobacco supports sound, reasonable and practicable regulation of tobacco products. We recognise that it is the role of governments to provide the general public with clear and consistent messages about the health risks to smokers that are associated with their smoking. We do not challenge those messages.

We believe that plain packaging for tobacco products is unnecessary, unreasonable and unjustified. Such measures would not be based on sound public policy, or on compelling evidence. They would not make any overall contribution to the public awareness of the risks associated with smoking, which we believe are well known, nor would they address the problems identified in the UK DoH consultation document by reducing the appeal of tobacco products or by making it any easier for smokers to quit, as the consultation document asserts.

i) Plain packaging does not address the "problem": smoking and smoking initiation by young people and discouraging existing smokers to quit

The main reasons young people start to smoke have long been identified and are clearly documented [128] as largely socio-economic and educational; they are primarily:

[128] See amongst others Conrad et al 1992 and Goddard 1990.

- Rebelliousness;
- Peer group pressure;
- Parental and older sibling example;
- Self image, including low self-esteem and low coping skills; and
- Poor educational performance.

Packaging of tobacco products is not one of these risk factors and its introduction would make no contribution to addressing youth smoking initiation.

The UK DoH consultation paper claims that the plain packaging of cigarettes will eliminate the so-called advertising function of tobacco packs and thus reduce smoking, particularly by young people. In support of these claims, it offers a minimal and flawed evidence base consisting of studies which each have serious defects in their design, methodology and execution.

We reject the premise in the consultation document that packaging either encourages young people to start smoking or discourages existing smokers from quitting. In any event, tobacco packaging has not been identified in the literature as amongst the main reasons why young people start to smoke, or why adult smokers continue to smoke.

The UK DoH consultation paper does not include a number of relevant studies including one commissioned by Health Canada[129] which found that packages were not a major factor in young people starting to smoke, and another commissioned by the Canadian Cancer Society[130] (CCS) which contradicts several of the UK DoH claims about packaging.

Finally, in its consultation paper the UK DoH claims that it is not aware of any research that suggests young people might be encouraged by plain packs to take up smoking. Two of the UK DoH's cited studies[131] report substantial evidence of potential "reactance" (opposite behaviour) on the part of young people should plain packs be introduced. Reactance is also discussed in

[129] Northrup and Pollard, 1995 Plain Packaging of Cigarettes, Event Marketing to Advertise Smoking and Other Tobacco Issues: A Survey of Grade Seven and Grade Nine Ontario Students Institute for Social Research, York University

[130] Wakefield et al 2003 " Role of the media in influencing trajectories of youth smoking" Addiction 98: 79-103

[131] (1) Rootman & Flay 1995 and Northrup and (2) Pollard 1995 - the same study as Rootman & Flay but a different version not referenced by the DoH.

Wakefield et al 2003[132] which found that anti-smoking measures had mixed results.

ii) There is a lack of accurate, compelling and objective evidence

The balance of the available evidence (including that upon which the UK DoH claims to rely) does not provide a compelling argument to suggest that the plain packaging of tobacco products would have the effect of deterring young people from smoking. In fact, certain evidence suggests potential for the contrary (see below).

Current tobacco packaging has not been identified as a sufficient, real and substantial problem to justify introducing plain packaging regulations - particularly regulations that expropriate valuable trademarks in which there has been significant investment, often over many decades.

The UK DoH consultation document itself concedes: *"As there are no jurisdictions where plain packaging of tobacco products is required, the research evidence into this initiative is speculative ..."*[133]

Tobacco packs already display large health warnings. These account for a large percentage of the packaging and, together with long-running public debate, ensure that consumers are aware of the health risks associated with smoking. From October 2008 the current text health warnings will be replaced by graphic pictorial health warnings.

As set out in this chapter, it is our view that there is no accurate, compelling and objective evidence that the existing packaging of tobacco products either reduces consumers' perceptions of the health risks associated with tobacco, or leads young people to start smoking or encourages existing smokers to continue to smoke.

Indeed, the UK DoH consultation document is outdated in this regard, relying on Canadian and New Zealand studies from 1995 which have subsequently been extensively analysed and criticised. The document also excludes a number of published studies that provide an alternative viewpoint. These are referenced later in this chapter.

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[132] Wakefield et al 2003 " Role of the media in influencing trajectories of youth smoking" Addiction 98: 79-103

[133] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.75

Taken as a whole, it is our view that the evidence is inconclusive and may even go so far as to confirm that there will be significant consequences opposite to those intended should plain packaging be introduced.

iii) Plain packaging would infringe intellectual property rights and freedom of expression and restrict fair competition

As highlighted in this chapter, there is no rational connection between plain packaging and the achievement of the DoH's stated objectives. We believe that there is no reliable evidence to establish that plain packaging could be a proportionate measure.

The possible future adoption of plain packaging would deprive Imperial Tobacco of the use of its trade mark property and contravenes its right under Article 1 of the First Protocol of the ECHR[134] to enjoy its property without interference.

Plain packaging would undermine the right to commercial free speech under Article 10 of the ECHR by denying suppliers and consumers the ability to impart and receive information relating to the quality, heritage and brand values of lawful products.

Plain packaging would be contrary to the principle of the free movement of goods enshrined in Article 28 of the EC Treaty by restricting the import and marketing of goods which are lawfully manufactured and marketed elsewhere in the EU. National provisions governing, for example, product characteristics such as packaging, could constitute obstacles to the free movement of goods (even if they apply to all products of a certain type within a Member State) and distort competition.

The freedoms protected by Article 1 of the First Protocol, Article 10 and Article 28 may be qualified if justified for the protection of health. However, any qualification must be proportionate i.e. relevant to the objective of reducing tobacco consumption, particularly among younger smokers. However, a qualification may not go beyond what is necessary to achieve it. We believe

[134] The European Convention on Human Rights – Article 1 of the First Protocol

that a plain packaging measure would go beyond and would be disproportionate.

Adopting plain packaging measures would infringe EU and national laws[135] covering trademarks and tobacco packaging as well as international treaties[136] to which the UK is a party. The introduction at national level of plain packaging would interfere with the registered trade marks regimes (and the rights afforded under those regimes) which exist under EU legislation and international treaties. EU member states are not permitted unilaterally to limit the use of trade marks on tobacco product packaging other than as provided for in the relevant EU legislation.

UK plain packaging measures would therefore be invalid due to conflict with the relevant EU legislation and international treaties.

iv) Plain packaging interferes with the legitimate retail environment

Plain packaging will have a negative effect on competition. A reduction in the diversity of tobacco brands available to consumers will reduce competition. There would be little incentive for retailers to stock new brands and it would be impossible for a new competitor to enter the market, or for an existing competitor to better compete with others by successfully launching new brands.

The UK DoH consultation document concedes: *"If plain packaging was to be introduced it could be more difficult for retailers to conduct inventory checks and customer service could be made more difficult at the point of sale[137]."*

If all packs look the same, except for the brand name, it will take considerably longer for the retailer to identify the requested product. This will lead to delays at the point of sale which will have an adverse impact on customer service and add to retailers' costs by either requiring them to employ more staff or lose trade.

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[135] Trademark Directive (First Directive 89/104/EEC of 21 December 1998), the Community Trade Mark Regulation (Council Regulation (EC) No 40/94 of 20 December 1993), UK Trade Marks Act of 1994 Tobacco Product Directive (Directive 2001/37/EC of 5 June 2001)

[136] Paris Convention for the Protection of Industrial Property and Trade-related Aspects of Intellectual Property Rights Agreement (TRIPs).

[137] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.80

v) Plain packaging facilitates illicit trade

Plain packs would facilitate counterfeiting and undermine the excellent work that has been done jointly by tobacco manufacturers and UK HMRC over a long period of time to eliminate illicit trade.

As discussed elsewhere in this submission, counterfeiting is an increasing problem throughout the world and tobacco products are very much a part of this criminal activity. According to recent World Customs Organisation estimates circa 5% of the 5,700 billion cigarettes[138] consumed annually on a world wide basis are counterfeit.

The UK with its particularly high excise regime for tobacco products is a prime target for smugglers, who are turning increasingly to counterfeit tobacco products as a source for the UK market.

The trade in counterfeit tobacco products has increased steadily in the UK over the last 5 years. Year on year the seizure data from HMRC illustrates a steady increase in the levels of counterfeit imported into the UK (now at about 4% of total market or 2.6 billion sticks – representing an annual loss to the UK Exchequer of more than £500 million). This is despite substantial endeavours by tobacco manufacturers including Imperial Tobacco working with UK HMRC and other regulatory authorities world-wide to combat the production and importation of counterfeit products.

Tobacco products themselves are relatively easy to counterfeit. Counterfeiters also have relatively little difficulty in acquiring the non-tobacco materials used in the manufacture of cigarettes such as filter tow and cigarette paper. Our intelligence tells us that counterfeit tobacco products are often manufactured 'to order' and the operations are often conducted in countries where the regulatory authorities have great difficulty in eliminating this production (eg China, Eastern European and the Middle East).

There is a growing problem of counterfeit fine cut tobacco brands, exacerbated because of the ease with which fine cut tobacco can be packed

[138] World Customs Organization 2005

and the standard type of machinery required. The tobacco and the packaging materials can be imported into the UK separately making detection much more difficult.

The key component in the fight against counterfeit by the legitimate manufacturers is the pack. This is the item that is presented to the consumer and it is the clearest overt method by which a legitimate manufacturer, the authorities and the consumer can identify counterfeit products. Tobacco companies introduce subtle packaging design changes and both overt and covert elements into the packaging specifically to frustrate the efforts of counterfeiters. Whilst modern technology is of great assistance to counterfeiters in replicating complex packaging designs, counterfeiters still find difficulty in doing this consistently and with the quality of printing necessary to avoid detection.

Counterfeit products are not manufactured according to the regulatory requirements demanded of products from legitimate manufacturers. Nor do they adhere to stringent production quality controls that apply to our brands. Counterfeit products by their nature do not carry UK excise duty or VAT, nor do those who sell them contribute to the UK economy. All of this should be of considerable concern to the UK Government.

It should be obvious that any attempt through regulation to require tobacco manufacturers to introduce plain packaging will make the counterfeiters' job substantially easier and lead to a consequent increase in counterfeit tobacco products on the UK market. In fact, the introduction of plain packaging regulations could be described as a 'Counterfeiter's Charter'.

2.6.2. THE CLAIMED BENEFITS OF PLAIN PACKAGING ARE NOT SUPPORTED BY THE EVIDENCE

The UK DOH consultation document suggests that requiring all tobacco products to be produced in plain packages would result in a number of significant health benefits, including:

- Reducing the *"brand appeal of tobacco products, especially among youth";*

- Reducing smoking due to unattractive perceptions of cigarettes in plain packages;
- Increasing the *"salience of health warnings";*
- Eliminating the *"potentially pro-smoking messages implicit in the current forms of attractive package design";*
- Eliminating the ability of tobacco packages to act as *"portable advertisements";*
- Strengthening the *"message about the seriousness of the harmful effects of tobacco";*
- Breaking the association with past advertising campaigns and the *"continuing advertising presented by the package*[139]*".*

In support of these claims, the UK DoH offers six research pieces. Only two have been published in a peer-reviewed journal; the last of which appeared as long ago as 1999. The bulk of the support for this proposal comes from just three out-dated Canadian reports: the 1995 Expert Panel report to Health Canada[140], the 1995 Rootman & Flay Study (Youth Smoking: Plain Packaging, Health Warnings Event Marketing and Price Reduction) [141] and the 1999 one page report by Goldberg et al (The Effect of Plain Packaging on Response to Health Warnings).[142]

In 1994 Kent Foster, then Canadian Assistant Deputy Minister of Health, told the Canadian House of Commons Standing Committee on Health: *"I think it should be clear at this point that we don't feel we know enough about those effects [of plain packaging], what they are, and how best to approach this. We need to do that work, and that's what we are doing."* [143]

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[139] Department of Health, *Consultation on the Future of Tobacco Control*, pg 40 - 41

[140] Goldberg ME, Liefeld J, Kindra K, Madill-Marshall J, Lefebvre J, Martohardjono N and Vredenburg H. *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products: Expert Panel Report to Health Canada, Ottawa, 1995.*

[141] Rootman, I.; Flay, B.R.; Northup, D.; Foster, M.K.; Burton, D.; Ferrence, R.; Raphael, D.; Single, E.; Donovan, R.; d·Avernas, J. 1995. A study on youth smoking: plain packaging, health warnings, event marketing and price reductions. Key findings. University of Toronto; University of Illinois at Chicago; York University; Ontario Tobacco Research Unit; Addiction Research Foundation, Toronto, ON, Canada

[142] Goldberg ME, Liefeld J, Madill J, Vredenburg H. The effect of plain packaging on response to health warnings. Am J Public Health 1999;89:1434-5.

[143] Canadian House of Commons Standing Committee on Health 1994

Since the acknowledged lack of research to justify plain packaging in 1994, there have been only three further studies, and only one of these (Goldberg) has appeared in a peer-reviewed journal (the American Journal of Public Health). Judging from the evidence cited in the UK DoH consultation document, there has been no research on plain packaging in the last decade. It is our view that if plain packaging is considered to be a substantial and pressing policy issue, the research record would be current, significant and compelling, none of which is the case.

Neither is the quality of these studies examined; the UK DoH accords each of them with equal validity and status, yet all the studies have serious defects in their design, methodology and execution.

Each of the studies shares two largely unsupported assumptions. The first is that people do what they say. The studies rely on unvalidated reports (often from focus groups) of what individuals say they intend to do, or make inferences about future behaviour based on a response to an exposure or recall situation. As Agostinelli and Grube 2003 note, the research from focus groups is plagued by this problem, amongst others. *"Focus groups only inform us of what certain individuals think influence them and not what actually does influence them … People are notoriously inaccurate in making attributions for the causes of their behaviour … Further, with the public format of focus groups, there are conformity pressures …"*[144] In other words, none of the studies presents validated behavioural evidence in support of the claims they make about the effects of packaging on smokers' individual smoking behaviour. Moreover, one piece of quantitative behavioural evidence that is presented - the attractiveness of plain packages to young smokers as evidenced by their choice of cigarettes packaged in such a way as a reward for participating in the study - is dismissed by the researchers as an embarrassment rather than evidence that plain packages may be more attractive to young smokers.

The second assumption is that unattractive, plain packages will result in a lower level of smoking uptake and consumption. While the UK DoH offers various opinions that this is the case, it presents mainly qualitative research.

144 Agostinelli, G. and Grube, J.W. "Tobacco counter-advertising: A review of the literature and a conceptual model for understanding effects," Journal of Health Communication, 8:107-127, 2003

Qualitative research involving surveys and focus groups is distinguished in several ways from standard, quantitative research. The samples need not be (and, indeed, rarely are) representative; the findings cannot be generalised across the population from which they are drawn; no quantitative inferences can be drawn from the data; and no standard statistical techniques can be applied to the findings. Such studies are not usually accorded scientific status due to the fact that they are not objective, reliable, formalised, valid, hypothesis-based or generally applicable. They do not, for the most part, meet the standards of evidence-based medicine or provide evidence of sufficient standing alone to justify significant changes in public policy.

This failure to provide any credible quantitative behavioural evidence and the unsupported assumption that less attractive tobacco packages reduce either consumption or youth uptake substantially undermines any claims that the UK DoH may make about the ability of plain packaging to reduce smoking uptake or consumption, to increase quitting or to sustain cessation.

Many of the major claims of the document are completely unsupported. For instance, the assertion that *"Following restrictions on tobacco advertising and promotion, tobacco packaging has become one of the key promotion vehicles for the tobacco industry to interest smokers and potential smokers in tobacco products*[145]*"* is supported by nothing more than a quote from Morgan Stanley's research department.

Finally, in the studies referenced by the UK DoH there are contradictions in terms of their claims and findings. For instance, Beede & Lawson claim that plain packaging enhances the effectiveness of health warnings, yet Rootman & Flay[146] report that *"recall of the health warning does not appear from our research to be affected by plain packaging".* [147]

Examining each of the studies relied on by the UK DoH in turn:

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[145] Department of Health, *Consultation on the Future of Tobacco Control*, para 3.71

[146] Rootman, I.; Flay, B.R.; Northup, D.; Foster, M.K.; Burton, D.; Ferrence, R.; Raphael, D.; Single, E.; Donovan, R.; d·Avernas, J. 1995. A study on youth smoking: plain packaging, health warnings, event marketing and price reductions. Key findings. University of Toronto; University of Illinois at Chicago; York University; Ontario Tobacco Research Unit; Addiction Research Foundation, Toronto, ON, Canada

[147] Beede P, Lawson R. The effect of plain packages on the perception of cigarette health warnings. *Public Health.* 1992 Jul; 106(4):315–322.

a) Health Canada 1995: When Packages Can't Speak: possible impacts of plain packaging of tobacco products[148]

This Health Canada report from 1995 states that young people do not decide to smoke on the basis of tobacco packages, that they do not have images of brands that are connected to lifestyles, that packages do not lead to smoking, that changing the package will not *"have any major effect on the decision(s) to smoke or not to smoke",* and that plain packaging is not the most effective way of reducing smoking.

The question in a policy discussion about plain packaging is whether the absence of branded cigarette packages from the marketplace would result in reduced smoking uptake and consumption, higher quit rates and less smoking recidivism. This study asserts that plain packaging *"would be important and would have perceived utility for encouraging teen and adult smokers to stop smoking, and for discouraging non-smoking teens from starting to smoke" but* fails to provide evidence in support of these claims. The research literature on smoking uptake emphasises that:

(i) most adolescents begin smoking without buying cigarettes but rather by obtaining them from friends or family. Indeed, numerous studies have shown that a majority of young smokers never buy cigarettes in a retail setting but rely entirely on "social sources". They are thus not involved in typical purchase decisions.

(ii) Most adolescents are not brand loyal until they become regular smokers. Brand interest and adoption follows smoking uptake, rather than preceding it.

The panel's own evidence concedes this as it notes that *"in most first trials there are little package, brand or brand promotion elements. Most kids receive their first cigarette from friends. There is no brand choice - the choice is simply to smoke or not to smoke."*

The evidence offered by the panel is reported in its Appendix C "Preliminary Qualitative Study" which presents the results of a survey of 1200 Canadian adolescents. The survey presents qualitative research findings about what

[148] Goldberg ME, Liefeld J, Kindra K, Madill-Marshall J, Lefebvre J, Martohardjono N and Vredenburg H. *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products: Expert Panel Report to Health Canada, Ottawa, 1995.*

young people say they will do in a particular situation, as opposed to quantitative data about what in fact they did do. All such findings have significant problems with validity. The panel observes that the magnitude of any effect *"cannot be validly determined by research that is dependent on asking consumers about what they think or what they might do if all cigarettes were sold in the same plain and generic packages."*

The expert panel report, whose findings are based on the largest number of subjects of any plain packaging research cited by the UK DoH, provides little or no evidence in support of the key public health benefits advanced as justification for plain packaging. Instead, the report contradicts the central claims of the UK DoH consultation document in that it found that:

(i) cigarette packaging does not affect the smoking uptake stage of adolescent smoking, and

(ii) *"the package will not have any major affect on the decision(s) to smoke or not to smoke."*

These findings complement what is known about how many cigarettes have been sold during the 20th century. Professor R Power, associate Professor of Psychology at Macquarie University, Sydney observed in commenting on the Expert Panel report[149], "*For a considerable part of this century, plain packaging was common. Cigarettes were often transferred to more or less elegant cigarette cases, and the panel reports that teens often repackage to avoid their possession of cigarettes being detected. Neither process has been reported as reducing smoking."*

b) University of Toronto Centre for Health Promotion: D'Avernas & Foster 1993: Effects of Plain Cigarette Packaging Among Youth[150]

The D'Avernas and Foster study is the only empirical test of the effect of plain packaging. It reported that male subjects preferred plain packaged cigarettes over branded cigarettes as their reward for participating in the study.

[149] Professor R Power, 1998, in "Plain Packaging & the Marketing of Cigarettes", Admap Publications.
[150] Josie D'Avernas and Mary Foster, 1994, Effects of Plain Cigarette Packaging Amongst Youth, Toronto Center for Health Promotion

This report concludes that it provides *"strong support for public policy to legislate plain packaging, as part of a comprehensive program to reduce tobacco use."* It bases this conclusion on the assumption that *"plain packaging makes the package, therefore the product, less interesting in its own right."* This assumption confuses the product with the packaging and assumes that because reactions to plain packaged cigarettes might be unfavourable in an environment where they are compared to traditionally packaged cigarettes, they will also be unfavourable in an environment in which they are the only cigarettes on offer. These assumptions provide the basis for the UK DoH claim at 3.68 that *"Researchers have suggested that smokers who perceive cigarettes to be of inferior quality to the product that they are used to, and are faced with no viable alternative … may adjust their behaviour by smoking less."* This conclusion is the researchers', not the subjects', and the evidence from the subjects does not support it. Indeed, the study's only genuinely behavioural component rejects it.

c) Beede & Lawson 1992: The effect of plain packages on the perception of cigarette health warnings[151]

The Beede and Lawson study fails to confirm the authors' claims about plain packages aiding recall of health warnings, given that there were no statistically significant differences in recall between plain packs and branded packages.

This study consisted of eighty focus group interviews with 568 New Zealand adolescents, with an average age of 13. Branded and plain packs from New Zealand and the US were shown to focus group subjects and, after being withdrawn, the subjects were asked to illustrate the packs they had observed. Students were then provided with a list of ten health warnings and asked to identify any health warnings that they remembered from the cigarette packages. The authors conclude that adolescents give limited attention to the health warnings on tobacco packages compared to the brand information. They also say that if tobacco was to be sold in plain packages, the awareness of health risks would be heightened and the promotional messages on the

[151] Beede P, Lawson R. The effect of plain packages on the perception of cigarette health warnings. *Public Health.* 1992 Jul; 106(4):315–322.

packages would be inhibited. *"The practical implications of this finding suggest that presentation of cigarettes in plain packs would increase the probable retention and impact of health warning messages."*

There are several problems with this study. First, though appearing to be a quantitative study, this report cannot warrant reliability, validity or generalisation. No information is provided as to whether the subjects are smokers or non-smokers, even though such differences are extremely relevant to the study, for example.

Second, the results (when examined closely) fail to support the authors' conclusions. For instance, the difference in recall of health warnings between New Zealand brand packs and New Zealand plain packs was not statistically significant.

Third, the researchers argue that with the plain packs *"a greater proportion of available information can be retained, and consequently the health warnings achieved a greater impact."* However, the study provides no evidence of this "greater impact" since impact was not measured. The researchers assume that greater recall of information leads to greater impact, but only a behavioural study which investigated the impact of higher recalled warnings on smoking could validate this claim.

Moreover, the results of the Health Canada 1995 Report (When Packages Can't Speak) contradict these findings. In that study respondents reported that they were well aware of the current package warnings and that *"most people don't care if there is a warning there, if they are going to smoke they are going to smoke".* As the panel itself concluded, after examining the respondents' replies, *"The evidence regarding recall, recognition, awareness and knowledge dimensions suggest that plain and generic packaging would lead to lowered recall, recognition and knowledge of brands, but may not have significant effects with respect to the recall and recognition of health warning messages."*

Rootman & Flay (referenced elsewhere) also report that plain packaging did not affect the recall of health warnings by Ontario adolescents.

It is not clear, based on the Canadian experience with graphic health warnings which fulfil a significant part of the plain packaging agenda by seeking to drastically reduce the branded space of the tobacco package, that such

enhanced warnings change smoking behaviour. For instance, according to Health Canada's Wave studies[152], following the introduction of the graphic warnings which were argued to enhance recall and behavioural change, there was no statistically significant decline in the number of adolescents who believed that smoking was not a health problem; there was no statistically significant change in the number of adult smokers who believed that smoking is a major source of disease; there was a decrease in the number of adult smokers who looked at the warnings several times a day; and there was an increase in the number of both smokers and non-smokers who never looked at or read the warnings. Thus, by each of these indicators of warning enhancement and effectiveness, graphic health warnings were a substantial failure.

Wakefield et al 2006(cited by the UK DoH) examined smokers' health beliefs as part of their analysis of point of sale exposure to tobacco advertising and displays, in an effort to determine whether these beliefs were affected by tobacco advertising and displays. They did not find that there was a statistically significant difference in their subjects' estimates about the risks of smoking between being exposed to a retail environment with no cigarettes, and one with tobacco advertising or one with tobacco displays. Further they found that most of their subjects knew that smoking posed a health risk. These findings suggest that neither tobacco advertising nor branding on packs reduce adolescents' risk perceptions about smoking. If this is the case, then Beede & Lawson's claims about the necessity of plain packaging to enhance health warnings are misplaced since these warnings are already satisfactorily performing their function in an advertising-display environment.

Fourth, there is no evidence in the study to support the claim that there are promotional marketing messages on branded tobacco packages.

Finally, there is no evidence in the study that supports the UK DoH claim at 3.69 following the introduction of the Beede & Lawson study that *"Health warnings on plain packs are seen as being more serious than the same*

[152] Environics Research Group Limited (2004a and b etc). *Wave 9 Surveys: The Health Effects of Tobacco and Health Warning Messages on Cigarette Packages – Survey of Adults and Adult Smokers* . Ottawa: Health Canada

warnings on branded packs, suggesting that brand imagery dilutes the impact of health warnings."

d) Goldberg et al 1999: The effect of plain packaging on response to health warnings[153]

The Goldberg et al study, which consists of just one page, provides no evidence that its key assumption – that greater recall of health warnings makes them more effective - is true since it has no behavioural component that measures smoking. Moreover, its findings are contradicted by the results of the Health Canada Wave Studies[154] which were undertaken following the introduction of graphic warnings in Canada, which found that such warnings made no difference in either youth or adult prevalence or consumption.

As with the other qualitative studies on plain packaging, this study cannot warrant its results as representative, reliable, or capable of generalisation. For example, there is no data provided on the numbers of smokers and non-smokers or of the differing responses of smokers and non-smokers. Given that part of the claimed advantage of plain packaging is in discouraging smoking uptake or encouraging cessation, in our view this is a strange and fundamental omission.

The findings are contradicted by the results of the Health Canada Report and Wave studies. As Wakefield et al 2006 reported, exposing adolescents to tobacco advertising and displays did not unfavourably alter their already high appreciation of the risks of tobacco use. The findings are also contradicted by Rootman & Flay who found that Ontario adolescents' recall of the health warning was not statistically different on plain packs from regular packs.

The implicit assumption about the relationship between health warnings and tobacco packages - unsupported by validated empirical evidence - that certain features (which are never properly specified) diminish the effectiveness of the warnings - rests on a further assumption that health warnings on tobacco packages change smoking behaviour. There is little evidence that this is in

[153] Goldberg ME, Liefeld J, Madill J, Vredenburg H. The effect of plain packaging on response to health warnings. Am J Public Health 1999;89:1434-5.

[154] Environics Research Group Limited (2004a and b etc). *Wave 9 Surveys: The Health Effects of Tobacco and Health Warning Messages on Cigarette Packages – Survey of Adults and Adult Smokers* . Ottawa: Health Canada

fact the case. There is also evidence which suggests why it is likely not to be the case. For such warnings to change smoking behaviour they must increase adolescents' risk perceptions. Professor Kip Viscusi of Harvard University has shown in a number of studies[155] that adolescent smokers already over-estimate the risks of smoking substantially in terms of risk of premature death, years of life lost and risk of death from lung cancer. It is improbable to expect that these perceived risks of smoking will be increased, regardless of what types of warning or packaging adolescents are exposed to.

The UK DoH's own expert evidence contradicts the claim that adolescent perceptions of smoking risks can be changed because they are inaccurate. Fuller, 2007 (Smoking, drinking and drug use among young people in England in 2006) reports that *"Almost all pupils thought smoking causes lung cancer (98%) ... harms unborn babies (97%), can harm non-smokers' health (96%) and can cause heart disease (94%)."* These figures represent risk awareness levels that cannot be increased. As Fuller observes *"These proportions have remained at similar levels since the early 1990s."*

e) Rootman & Flay 1995: A Study of Youth Smoking: Plain Packaging, Health Warnings, Event Marketing and Price Reductions[156]

The Rootman and Flay study in our view provides evidence against plain packaging. 80% of its Grade Nine subjects who were light smokers reported that plain packages would result in students either smoking the same or more, while 96% of daily smokers thought that young people would either smoke the same or more when presented with plain packaging.

This report is the second part of the D'Avernas, Foster University of Toronto Center for Health Promotion study (see above). It provides data from a classroom survey of 2,132 (complete surveys numbered 1,559) Ontario

[155] Viscusi et al 2000 Smoking Risks in Spain Jn of Risk and Uncertainty 21: 213-34 Viscusi 1999 Public Perception of Smoking Risks in Valuing the Cost of Smoking C. Jeanrenaud and N. Soguel Eds. Viscusi, 1990 Do Smokers Underestimate Risks? Jn of Political Economy 98: 1253-69 Viscusi Smoke Filled Rooms, University of Chicago Press 2002, Fuller 2007 Smoking, drinking and drug use among young people in England in 2006 NHS National Statistics

[156] Rootman, I.; Flay, B.R.; Northup, D.; Foster, M.K.; Burton, D.; Ferrence, R.; Raphael, D.; Single, E.; Donovan, R.; d·Avernas, J. 1995. A study on youth smoking: plain packaging, health warnings, event marketing and price reductions. Key findings. University of Toronto; University of Illinois at Chicago; York University; Ontario Tobacco Research Unit; Addiction Research Foundation, Toronto, ON, Canada

students aged 12-14 in 1994. The report claims that its results are applicable across *"the Ontario population of Grade 7 and 9 students."* These students were selected for the study *"because they are most likely to be influenced by cigarette packaging"* as well as by the fact that it is at *"this age range that many are contemplating smoking, or experimenting."*

The study claims the following:

- *"Believability of the health warning is enhanced by plain packaging."*
- *"Plain packs make the health warnings easier to see."*
- Plain packs are *"more boring"* and *"uglier"* than regular packs.
- *"The evidence is strong that plain packaging of cigarettes would reduce the positive imagery associated with smoking particular brands for many young people*."

From these claims the UK DoH consultation document concludes (at 3.70) that *"Plain packaging presents an opportunity to further 'denormalise' tobacco products and change the social acceptability of tobacco use. Attractive packaging can give legitimacy to tobacco products and imply that the product is safe. Requiring plain packaging would separate tobacco products from other consumer products on the marketplace, which would send out a strong message about the seriousness of the harmful effects of tobacco."*

There are significant problems with these claims. First, given that the study provides no information about how the subjects were chosen or even the distribution between smokers and non-smokers, it is difficult to accept that the results can be generalised; nor that they are reliable or valid or that the methodology is objective.

Second, there is no evidence in the study that the "believability" of the health warning in relation to plain packaging was studied. Instead, students were asked a different question: *"Which package makes the health warning look more serious?"* While seriousness might have a relationship with believability, it is not a legitimate proxy for it. There is no evidence in the study that making the cigarette warnings easier to see had any effect on smoking. Indeed, the evidence from the study suggests that the students had a very high recall of the current warnings on tobacco products, as the authors note that *"warnings*

are prominent and remembered by four out of every five Ontario students in Grade 7 and 9". 96% of respondents replied that *"Smoking is addictive",* while even 92% agreed that *"Tobacco smoke can be harmful to the health of non-smokers."*

Third, it is not at all clear that the finding that plain packs are *"more boring"* or *"ugly"* is in any way related to smoking uptake, consumption or quitting given the responses to the questions about the effect of plain packaging on starting and continuing to smoke. The crucial issue is whether if only "boring" or "ugly" packs are available, students will continue to smoke. The survey evidence indicates strongly that they would.

Fourth, on the most crucial measure - the effect of plain packaging on youth smoking if all cigarettes were sold in plain packages - 67% of grade 7 students, 80% of grade nine students, 86% of light smokers and 96% of daily smokers thought that young people would either smoke the same or more.

Fifth, the survey asked about the potential effect of plain packaging on the likelihood of young people who do not smoke starting to smoke. 60% of Grade 7 students, 68% of Grade 9 students and 90% of daily smokers reported that that plain packaging would either result in no change or more likelihood of starting to smoke.

Sixth, the study fails to report data about the reasons for students' brand choices; data which calls into question one of the key assumptions about plain packaging. When the students were asked why they smoke their brand, 58% responded because they like the taste, followed by almost 20% who said because families or friends smoked that brand. Students did not identify any characteristics associated with the packaging of the brand as a reason for choosing that brand.

Seventh, aside from the already considerable problems associated with qualitative research, this report suffers from some additional problems. Though we are assured that the results are capable of generalisation, there is no summary of the study's methodology; for instance, why the survey was carried out where it was, and/or how this ensured that the results were representative of the entire population. Most importantly, it fails to provide complete data on any question, instead relying on selective reports of

percentages reporting one response as opposed to another response. Indeed, it fails even to supply the questions that comprised the survey.

Finally, there is no evidence in this study to support the UK DoH claim at 3.70 that *"attractive packaging can give legitimacy to tobacco products and imply that the product is safe"* or that *"plain packaging presents an opportunity to further 'denormalise' tobacco use"*, since the Rootman & Flay study does not deal with the denormalisation of tobacco products. Given that its evidence shows that plain packages would make little difference to current smoking rates or initiation, it is difficult to see the basis for the claim that such packages would change the *"social acceptability of tobacco use."* The very strong recall of the explicit health warnings on current tobacco packages by the student sample in fact suggests that these students are already aware of the health risks associated with smoking and understand that tobacco products are different *"from other consumer products on the marketplace."*

f) Morgan Stanley

At 3.71 the UK DoH consultation document asserts that *"Following restrictions on tobacco advertising and promotion, tobacco packaging has become one of the key promotion vehicles for the tobacco industry to interest smokers and potential smokers in tobacco products"* and cites Morgan Stanley research [157] in support of this claim. The quotation used is nothing more than a single statement of opinion from within a Morgan Stanley research report. There is nothing else in this Morgan Stanley report that either justifies the statement or refers to plain packaging.

2.6.3. THE UK DOH HAS OVERLOOKED PROBATIVE EVIDENCE WHICH UNDERMINES THE PURPORTED JUSTIFICATION FOR PLAIN PACKAGING

The UK DoH overlooks significant and relevant evidence which contradicts the UK DoH's justification for plain packaging. The unexplained absence of this evidence from the consultation document is contrary to the DoH's obligation to

[157] Morgan Stanley Research Europe (2007), Tobacco: Late to the Party, Morgan Stanley Research, London

present the full range of evidence about plain packaging. Some of this evidence is reviewed below.

i) Northrup & Pollard 1995: Plain Packaging of Cigarettes, Event Marketing to Advertise Smoking, and Other Tobacco Issues: A Survey of Grade Seven and Grade Nine Ontario Students Institute for Social Research, York University[158]

An important omission from the UK DoH consultation document is the 1995 study on plain packaging by Northrup & Pollard. This study is a fuller report on the same data from Ontario Grade Seven and Nine students referenced in the Rootman & Flay study cited by the UK DoH. Indeed, the overall research project was designed by the same group of researchers.

Whereas the Rootman & Flay study cited by the UK DoH consists of 10 pages and provides a minimum of information about design and methodology, the Northrup & Pollard study provides a substantial amount of information. More importantly, where the Rootman & Flay study simply reported percentages on a few selected measures of comparison, the Northrup & Pollard study reports on the full range of questions and responses.

Several of the findings of the Northrup & Pollard study are relevant to the plain packaging debate.

First, whilst it is contended by the UK DoH consultation document (and rejected by Imperial Tobacco) that tobacco packages serve as tobacco advertisements and that such advertisements are one of the principal reasons for smoking initiation, when smokers are asked why they smoke or why they started to smoke they almost never mention advertising. This study reports that the major reasons given by grade seven and nine Ontario students for smoking are because *"they like it",* it makes them *"feel good"* and it helps them to *"relax".* No students cite advertising as a reason for starting to smoke or for smoking. These results are not reported by Rootman & Flay.

Second, given the contention that tobacco packaging reinforces brand imagery which in turn is entirely created by advertising, it is interesting to note

[158] Northrup, David, and Pollard, J. 1995. Plain Packaging of Cigarettes, Event Marketing to Advertise Smoking and other Tobacco Issues: A Survey of Grade Seven and Grade Nine Ontario Students. Toronto, Ontario: York University.

that, for these young people, smoking a particular brand has everything to do with taste or friend and family preferences. The students understood that the packages that the cigarettes came in - whether branded or plain pack - made no difference to the taste (69% said there would be no difference in taste in the plain packages.) Thus, if young smokers are making branded decisions primarily on taste, and they know that plain packaging will make no difference to taste, plain packaging is unlikely to affect their smoking behaviour in an environment where only plain packs exist.

Third, when asked *"Which package would turn people like you off smoking?"*, 49% said that there would be no difference between plain packs and regular packs, 59% of light smokers said that there would be no difference between plain packs and regular packs, and 66% of daily smokers said that there would be no difference between plain packs and regular packs.

Fourth, when asked whether, if all cigarettes were sold in plain packs, young people would smoke more, less or the same, 67% of grade 7 students said more or the same, 80% of grade 9 students said more or the same, and 96% of daily smokers said more or the same.

Fifth, when asked about the potential effect of plain packaging on the likelihood of young people their age who are not smokers starting to smoke, 60% of grade seven students said that it would not make any difference or make it more likely, 68% of grade nine students reported the same and 90% of daily smokers said it would not make any difference or make it more likely.

Sixth, the study reported a significant degree of reactance among smokers toward the introduction of plain packages. 10% of daily smokers reported that they would smoke more if plain packs were introduced. As the researchers note about this response *"It may suggest that … students who smoke on a daily basis are frustrated with tobacco policies …."* When subjects were asked about the likely effect of plain packaging on young people who do not currently smoke, 11% of daily smokers indicated that it would make them more likely to start smoking, again suggesting a substantial degree of reactance.

This finding undermines the UK DoH's claim at 3.77 that it is *"not aware of any research evidence that supports the concern that children may be encouraged to take up smoking if plain packages were introduced."*

ii) Liefeld 1999: Health Canada: The Relative Importance of the Size, Content and Pictures on Cigarette Package Warnings Messages[159]

This is a study commissioned by Health Canada as part of its on-going research on tobacco packaging and health warnings. Its omission from the UK DoH consultation document is highlighted here given the reliance that the consultation document places on Canadian studies in general and on Health Canada research in particular. Liefeld is a co-author of the Goldberg et al study which the UK DoH cites and which was also published in 1999[160].

Liefeld showed pairs of test tobacco packages to adult and teenage smokers. These were both conventional branded packages and packages dominated by health warnings. In asking the subjects about what would prevent them from smoking, they reported that tobacco packages were not the major factor that would influence them not to start or to quit smoking.

iii) Amit 1994: Review of the Report "Effects of Plain Cigarette Packaging Among Youth"[161]

During the Canadian consideration of plain packaging in 1994, several critiques of the research relied upon by the UK DoH in its consultation document were produced. Professor Z Amit of the Centre for Studies in Behavior Neurobiology at Concordia University, Montreal provided an extensive critique of the methodology and conclusions of the D'Avernas & Foster report (see above), a critique which was presented to the Standing Committee on Health of the Canadian House of Commons in May 1994. Professor Amit's critique was one of several presented to this Committee. This critique is part of the public record which makes its omission from the UK DoH's consultation document all the more glaring.

Professor Amit noted that the study by the University of Toronto Center for Health Promotion has five major weaknesses: the sample sizes of the focus groups preclude drawing any legitimate statistical conclusions; the study's

[159] Liefeld JP, The relative importance of the size, content and pictures on cigarette package warning messages, University of Guelph, 1999

[160] Goldberg ME, Liefeld J, Madill J, Vredenburg H. The effect of plain packaging on response to health warnings. Am J Public Health 1999;89:1434-5.

[161] Evidence provided to the Standing Committee on Health of the Canadian House of Commons in May 1994

design is flawed in that it fails to frame questions about the effect of plain packaging in an environment without regularly packaged tobacco products; the conclusions do not generally reflect behavioural outcomes but speculation about behaviour; the study's sole behavioural component - in which smokers were offered a reward for their participation - resulted in subjects preferring plain packaged cigarettes, thus refuting the research hypothesis.

2.7. CONCLUSIONS ON PLAIN PACKAGING

The balance of the available evidence (including evidence upon which the UK DoH claims to rely) does not provide a compelling argument to suggest that the plain packaging of tobacco products would have the effect of deterring young people from smoking. In fact, certain evidence suggests the potential for the contrary.

In addition, the erosion of intellectual property rights risks compromising legal and treaty obligations to which the UK Government is beholden. It would set a dangerous legal precedent for other companies and sectors outside of the tobacco sector.

The diminution of brand competition caused by the prohibition of branded packaging would be detrimental to the retail sector and would restrict the market to current brands currently occupying positions of market prominence.

Finally, the imposition of compulsory plain packaging would simplify the job of the counterfeiter by removing the need for complex processes to copy current packaging. It would also be significantly harder for tobacco companies and the UK authorities to mark and track packaging in order to frustrate and disrupt the illicit market. This could only lead to an increase in the share of the market occupied by the illicit trade in tobacco products and a further loss in government revenues.

3. TOBACCO ACCESSORIES, VENDING MACHINES AND MINIMUM PACK SIZE

3. TOBACCO ACCESSORIES, VENDING MACHINES AND MINIMUM PACK SIZE

3.1. SUMMARY

Tobacco accessories

Imperial Tobacco is implacably opposed to the suggestion that there should be restrictions on the advertising and promotion of tobacco accessories (such as rolling papers, lighters, filters and matches).

The demand for tobacco accessories is determined by the extent of tobacco smoking and not vice versa. Non-smokers who do not use tobacco products are not encouraged to start smoking by seeing an advertisement for a brand of rolling papers or an advertisement for a cigarette lighter. Similarly, brand advertising of rolling papers has neither the purpose nor the effect of increasing the consumption of hand-rolling tobacco. There is no evidence for either supposition made in the consultation document.

The advertising of rolling papers or of any other tobacco-related accessory has the purpose and effect of promoting one specific brand over competitor brands to consumers who already require the product (i.e. those who already enjoy tobacco).

No evidence is presented to demonstrate that a ban on the advertising of rolling papers would reduce the incidence of cannabis use. This would be as illogical a step as restricting the advertisement of drinks in plastic bottles because these are known to be delivery systems for illegal drugs.

Vending machines

Imperial Tobacco supports reasonable solutions to reduce the illegal access by minors to cigarettes through vending machines. With this in mind, we support Option Two - restricted access mechanisms - as a proportionate measure.

Imperial Tobacco does not believe that minors access cigarettes from vending machines in great numbers, and the incidence appears to be declining, as demonstrated by a 2006 Government study[162].

The implementation of the smoking ban in public places (including licensed outlets such as pubs, bars and restaurants) has caused a major decline in vending sales. Less than 1 per cent of all tobacco sales come from vending machines. It is highly unlikely that many licensed outlets would opt to continue to sell tobacco (i.e. over the bar) in the event of a ban on vending. In such a scenario it is most likely that, if smokers are unable to purchase tobacco from a vending machine, the void would be filled by illegal sellers who move from pub to pub selling UK non duty paid cigarettes.

It is our view that a ban on vending would be a disproportionate response to a diminishing problem and would create other unintended unfortunate consequences.

Minimum Pack Sizes

Imperial Tobacco does not believe that the proposal to increase the minimum size of cigarette packets has any merit as an initiative to reduce smoking uptake by young people – or anyone else. We believe it may in fact be counterproductive as it may encourage both increased consumption and the illicit trade.

Many adult smokers use smaller packs to manage their daily consumption and/or their daily expenditure. Rather than stopping smoking in the event of a ban, those who would otherwise buy smaller packs would migrate instead to packets of twenty cigarettes, both legitimate and non-duty paid.

Since the ban on smaller packs in Ireland, overall sales volumes have increased in the market although unit pack sales have decreased. This demonstrates that, rather than encouraging smokers to quit, there has been a transfer from smaller packs to packets of twenty[163].

A ban on smaller packs may encourage the price-sensitive consumer who cannot afford to purchase a larger pack to seek a cheaper alternative. This is

[162] Smoking, Drinking & Drug Use, 2006, The Information Centre for Health & Social Care.
[163] Nielsen Ireland based on 60% of retail universe

most likely to be derived from the black market (smuggled and counterfeit) through the many illegal selling networks which are present throughout the UK.

Non-duty paid volumes in Ireland have also increased markedly since the ban on smaller packs. It can be assumed that this is partly attributable to Non-duty paid volumes in Ireland have also increased markedly since the ban on smaller packs. It can be assumed that this is partly attributable to consumers seeking cheap cigarettes from the black market via street markets and other illicit channels. It is also of note that Imperial Tobacco is not aware of any instances of packs of ten cigarettes being counterfeited and no instances in the UK of such packs being smuggled.

3.2. ADVERTISING AND PROMOTION OF TOBACCO ACCESSORIES INCLUDING ROLLING PAPERS

Imperial Tobacco is strongly opposed to the suggestion in the DoH consultation document that there should be restrictions on the advertising and promotion of tobacco accessories (such as rolling papers, cigarette lighters, filters and matches), with specific regard to cigarette papers.

None of the available data, including data available from market intelligence, supports the claim made in the consultation document that the advertising of tobacco accessories (including rolling papers) has the effect of encouraging young people to smoke, prevents existing smokers from giving up or causes relapse in ex-smokers. This claim is based on supposition and not on any supporting evidence. This is acknowledged in the consultation document itself, which states: “Although there is no hard evidence on the issue, it may be that advertising of smoking accessories encourages young people to smoke.”[164] This type of claim without any supporting evidence is in direct contradiction to the principles of good regulation as already set out elsewhere in this document.

The demand for tobacco accessories is determined by the extent of tobacco smoking and not vice versa. Non-smokers who do not use tobacco products do not start smoking because they have seen an advertisement for a brand of

[164] DoH consultation on the future of tobacco control, May 2008. p 29

rolling papers or an advertisement for a cigarette lighter or a brand of matches. Similarly, brand advertising of rolling papers has neither the purpose nor the effect of increasing the consumption of hand-rolling tobacco. There is no evidence for either supposition made in the consultation document.

The advertising of rolling papers or of any other tobacco-related accessory has the purpose and effect of promoting one specific brand over competitor brands to adult consumers who already require the product (i.e. those who already enjoy tobacco).

When placing any advertisements for rolling papers, Imperial Tobacco adheres strictly to the UK Committee of Advertising Practice (CAP) Code on the advertising of rolling papers.

Imperial Tobacco is concerned about the continued increase in availability of counterfeit rolling papers sold in the UK. This trade damages legitimate retailers and manufacturers of genuine products and denies consumers quality products that have been produced in regulated circumstances. Banning the advertising of rolling papers will make it easier for counterfeit papers to enter the retail supply chain as consumers will find it increasingly difficult to distinguish between genuine and counterfeit packs.

The DoH consultation document raises a concern about the potential use of rolling papers for the smoking of cannabis. We assume that this assertion has been added to the consultation document as a highly tenuous reason to encourage support for a ban on the advertising of rolling papers and represents an entirely specious position. Restricting the advertising of a legal product (rolling papers) would have no influence on reducing the use by some individuals of an illegal substance. Indeed, no evidence is presented to demonstrate that a ban on the advertisement of rolling papers would reduce the incidence of cannabis use. This would be as illogical a step as restricting the advertisement of drinks in plastic bottles because these are known to be used as delivery systems for illegal drugs. Our position on this matter is unequivocal. Imperial Tobacco does not condone the use of rolling papers for smoking cannabis.

3.3. VENDING MACHINES

Vending machines currently account for less than 1% of overall cigarette sales volumes in the UK[165].

However, Imperial Tobacco supports reasonable solutions to reduce illegal access to cigarettes by minors via vending machines. With this in mind, we support Option Two in the DoH consultation document (restricted access mechanisms) as a proportionate measure.

Existing regulations already require adult supervision and labelling of vending machines to ensure that they cannot be accessed by children. In addition the National Association of Coin Machine Operators has in place its own relevant code. The vast majority of vending machines are situated under direct adult supervision in adult licensed premises such as pubs, bars and restaurants.

Vending packs are sold at a premium price over products available through other retail channels. This makes them an expensive and unlikely source for children who genuinely seek to make a tobacco purchase.

Imperial Tobacco does not believe that minors access cigarettes from vending machines in great numbers, and the incidence appears to be declining, as demonstrated by a 2006 Government study[166]. While we would prefer a 0% rate of access by minors, we welcome information which shows that the trend is going in the right direction.

The implementation of the smoking ban in public places (including licensed outlets such as pubs, bars and restaurants) has caused a major decline in vending sales. It is highly unlikely that many licensed outlets would opt to continue to sell tobacco (ie over the bar) in the event of a ban on vending. In such a scenario it is most likely that, if smokers are unable to purchase tobacco from a vending machine, the void will be filled by illegal sellers who move from pub to pub selling UK non duty paid cigarettes from 'hold-all' bags and rucksacks. As the street price for such tobacco products is approximately

[165] Retail Audit Ltd Pipeline Survey, 2008
[166] Smoking, Drinking & Drug Use, 2006, The Information Centre for Health & Social Care.

£2.50 per pack[167], a ban on vending would simply encourage the displacement of a tax paid premium purchase from a vending machine to a much cheaper illegal alternative, which may even be counterfeit.

With this growth in an illegal, unregulated and untaxed channel of distribution, the UK Government will suffer a further immediate decline in tax and duty revenues which could be expected to continue in the coming years.

It is our view that a ban on vending would be a disproportionate response to a diminishing problem and would create other unintended unfortunate consequences.

Under our preferred Option Two, we believe that there should be flexibility for vendors to select from a range of different age-restricted access mechanisms, such as those highlighted in the consultation document. This flexible approach is also important in enabling smaller vending companies to compete on level terms in the market.

Sinclair Collis, the UK's largest tobacco vending operator and a member of the Imperial Tobacco Group, will make a separate submission to the consultation.

3.4. MINIMUM PACK SIZE

Imperial Tobacco does not believe that the proposal to increase the minimum size of cigarette packets has any merit as an initiative to reduce smoking initiation by young people – or anyone else. We believe it may in fact be counterproductive as it may encourage both increased consumption and illicit trade.

Many adult smokers use smaller packs to manage their daily consumption and/or their daily expenditure.

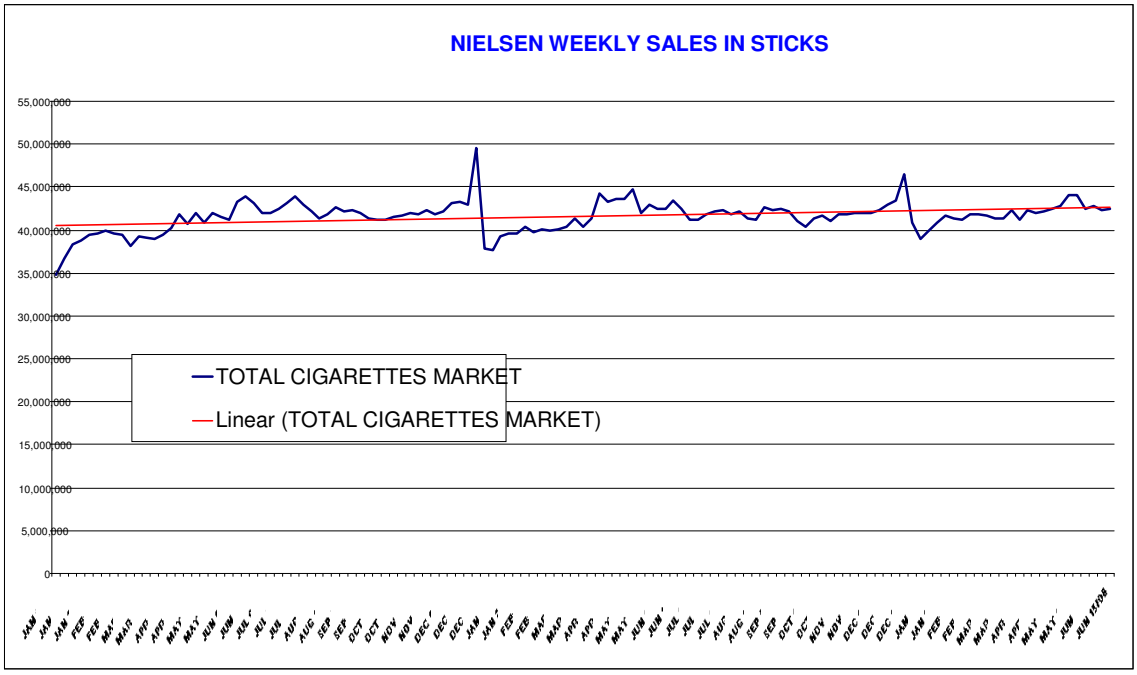
A ban on smaller packs may encourage the price-sensitive consumer who cannot afford to purchase a larger pack to seek a cheaper alternative. This is most likely to be derived from the black market (smuggled and counterfeit)

[167] Tobacco Manufacturers Association Pack Swap Survey, 2007/08

through the many illegal selling networks which are present throughout the UK.

Small packs act as a buffer between the lowest price point for a pack of ten cigarettes in the legitimate retail chain (£2.61)[168] and the price of an illegal packet of twenty on the street (approx £2.50). We reject the emotive notion in section 3.82 of the consultation document that a packet of ten cigarettes is a 'kiddie-pack' because the street price of a black market pack of twenty is cheaper than the recommended retail price of a legitimate pack of ten.

Illegal sellers will sell to children; they do not demand proof of age, unlike legitimate retailers.



Imperial Tobacco's Irish division advised its retail customers to increase their orders for packs of twenty in anticipation of the ban on smaller packs in that jurisdiction. This was done as it was expected that former purchasers of packs of ten would migrate to packs of twenty. Since the ban on smaller pack sizes in Ireland, overall sales volumes have increased in the market although unit pack sales have decreased. This demonstrates that, rather than

[168] 10 pack Lambert & Butler, August 2008

encouraging smokers to quit, there has been a transfer from smaller pack sizes to packs of twenty[169].

At the same time, non-duty paid volumes in Ireland have also increased markedly since the ban on smaller packs. It can be assumed that this is partly attributable to consumers seeking cheap cigarettes from the black market via street markets and other illicit channels.

In the UK, packs of ten cigarettes account for around 20% of all legitimate retail cigarette purchases[170]. Any ban on smaller packs would increase consumption as consumers migrate to packs of twenty, and would increase purchases of illicit non duty paid products. Imperial Tobacco is not aware of any instances of its brands in packs of ten cigarettes being counterfeited, and no instances in the UK of such packs being smuggled.

Differing pack sizes are available in most products across the FMCG sector. This gives consumers flexibility when making a purchase choice to manage their consumption and their expenditure. Tobacco is no different from any other category in this regard.

[169] Nielsen Ireland based on 60% of retail universe
[170] Retail Audit Ltd Survey 2008

4. YOUTH SMOKING

4. YOUTH SMOKING

4.1. SUMMARY

Evidence outlined in this submission suggests that the root causes of youth smoking have nothing to do with tobacco advertising, displays or packaging. Instead, the principal causes include factors such as rebelliousness and risk taking, family structure and relationships, socioeconomic status, school connection and educational success. As such, the determinants of youth smoking are not advertising, tobacco displays or tobacco packaging but more fundamental factors.

A tobacco strategy focused on advertising, displays and packaging will be disconnected from these factors and is unlikely to achieve the DoH's stated objective.

Imperial Tobacco does not believe we are qualified or sufficiently well informed on broader socio-economic issues and how those might be successfully influenced by Government policy. However, we are certain that further tobacco control measures as those outlined in the consultation document are not the measures which will address the Government's objectives of reducing youth smoking initiation. If the UK Government are serious about achieving those objectives they should look more closely at all the evidence and propose solutions that address its indications rather than seeking out 'easy targets' which can be introduced at little cost to the Government but will be entirely ineffective.

This should be supported with greater enforcement of current minimum age laws together with additional resources to support enforcement agencies in their efforts to tackle illegal sales.

We would not oppose legislation which would make it an offence for an adult to purchase tobacco on behalf of a minor (proxy purchasing) should the UK Government wish to reconsider complementing existing age of sale laws. As it may be difficult to enforce proxy purchasing regulation we would encourage careful consideration to be given to the practicality of effective enforcement.

4.2. INTRODUCTION

Elsewhere in this submission, Imperial Tobacco has challenged the evidential basis for a number of the suppositions advanced in the UK DoH consultation document. Imperial Tobacco also maintains that the consultation document ignores a very large amount of evidence concerning the reasons why young people begin smoking. This evidence, most of it the result of research commissioned by governments (including that of experts cited by the UK DoH itself), suggests that the root causes of youth smoking have little or nothing to do with tobacco advertising, displays or packaging. Instead, the principal causes include personal factors such as rebelliousness and risk-taking and other factors such as family structure and relationships, quality of schools and educational success and socioeconomic status.

The UK DoH itself recognises at least some of these causes for smoking in its discussion of socioeconomic status and smoking at 2.10. Indeed, the DoH's own experts, Jarvis and Wardle, stress such things as education, housing and employment as targeting the *"underlying social conditions which foster high levels of smoking."*[171] Lloyd and Lucas, in a study commissioned by the UK DoH, stress the importance of family relationships and schools' cultures which are predictive of smoking uptake. Jefferis et al, in a study following a group of British subjects over 41 years, found that not only do educational factors predict adolescent smoking, but also the future course of adult smoking[172]. Finally, in the few studies cited by the UK DoH on tobacco advertising and youth smoking which do control for factors other than advertising, those such as Henriksen et al 2004 found that factors such as age, having friends who smoke and proclivity for risk-taking were far better predictors of smoking uptake than exposure to tobacco advertising[173].

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[171] Jarvis M. and Wardle J. (2005). 'Social patterning of health behaviours: the case of cigarette smoking', in Marmot M. and Wilkinson R. (eds.), Social Determinants of Health, Oxford University Press, Oxford.

[172] Jefferis B.; Graham H.; Manor O. ; Power C.; Cigarette consumption and socio-economic circumstances in adolescence as predictors of adult smoking; Addiction; 2003, vol. 98, n°12, pp. 1765-1772

[173] Henriksen L. et al. (2004). 'Association of retail tobacco marketing with adolescent smoking', American Journal of Public Health, 94(12), pp. 2081–2083.

All this suggests that:

1) the real determinants of youth smoking are not advertising, tobacco displays or tobacco packaging but more fundamental factors, and;

2) that a tobacco strategy focused on advertising, displays and packaging will be disconnected from these factors and unlikely to work.

In the face of such evidence, Imperial Tobacco suggests the adoption of a strategy that will address that evidence rather than further tobacco control measures that will not address the Government's concerns. This should be supported with greater enforcement of current minimum age laws together with additional resources to support enforcement agencies in their efforts to tackle illegal sales.

4.3. YOUTH SMOKING INITIATION

In response to the DoH consultation, Imperial Tobacco has demonstrated that, taken in its totality, the evidence (both that considered in the UK DoH document and that excluded from it) suggests that it is highly improbable that tobacco advertising and product displays cause young people to start smoking or to continue to smoke, or cause adults to continue or to return to smoking.

If this is the case, then further restrictions on tobacco advertising (as it is defined by the UK DoH) – a premise with which we disagree strongly - through restricting the display of tobacco products or requiring that all tobacco products be sold in plain packs, will have little impact on youth or adult smoking. This is because there will continue to be a profound mismatch between what causes young people to begin or to continue to smoke and what in fact might dissuade them from beginning or would point them toward quitting. In effect, the UK DoH believes that it knows what causes youth smoking and has fashioned a series of policies based on those alleged causes. At the same time, it acknowledges that the *"research is speculative"* and that the proposed strategy is based to a large extent on the assumption that *"changes in the packaging will lead to changes in behaviour."*

4.4. PREDICTORS OF YOUTH SMOKING: ALTERNATIVE EVIDENCE

An alternative, evidence-based approach to smoking policy in the UK would begin with a clear understanding of the most crucial risk factors that reliably predict youth smoking and then attempt to address each of these. Proceeding in this fashion would provide a clear, evidence-based link between causes and remedies, as opposed to a strategy based on speculation and disputed assumptions. Such a strategy for addressing smoking would lead tobacco control policy in the UK in quite a different direction as we have suggested elsewhere in this submission.

The following section reviews the alternative evidence related to predictors of youth smoking that appear to have been disregarded in the UK DoH consultation document.

One way in which the claims about the causal role of advertising, displays and packaging can be tested is through an examination of alternative accounts of what leads young people to start smoking. (See DiFranza et al 2006 who rely on certain criteria in concluding that tobacco advertising initiates tobacco use.[174]) These alternative accounts follow young people who are exposed to tobacco promotions, packaging and displays and provide different explanations as to why they become smokers.

These alternative accounts, which are largely ignored by those advancing the "advertising as cause" theory, are put forward by a large number of respected researchers who focus on youth substance use. The accounts explain other forms of substance use beside tobacco and are richly supported in the research literature. A sample of these studies is examined below.

4.4.1. Goddard 1990 Why children start smoking HMSO and 1992 Why children start smoking[175]

This study by Eileen Goddard for the UK Office of Population Censuses and Surveys reports on secondary school children who were interviewed three

[174] DiFranza et al., Tobacco Promotion and the Initiation of Tobacco Use: Assessing the Evidence for Causality, PEDIATRICS 117: 1237-1248 (2006).
[175] Why Children Start Smoking by Eileen Goddard HMSO (AND OPCS (Office of Population Censuses & Surveys) 17 December 1990

times in 1986, 1987 and 1989 when they were at the beginning of their (then) second, third and fourth academic years. The goal of the survey was to *"see which of a range of factors were most closely associated with children starting to smoke."*

Goddard identified seven factors:

1) "being a girl;
2) having brothers or sisters who smoke;
3) having parents who smoke;
4) living with a lone parent;
5) having relatively less negative views about smoking;
6) not intending to stay on in full-time education after 16; and
7) thinking that they might be a smoker in the future."

Several of these risk factors, particularly living with a single parent and not intending to remain in school, have been identified as crucially important to smoking uptake in other studies. All the risk factors, according to Goddard, are associated independently with smoking; none has any direct connection with tobacco advertising and; there is no single, simple explanation as to why adolescents begin to smoke. As Goddard notes *"the onset of smoking in young people is a complex process - no simple combination of a small number of factors can be put together to form a good explanation of why some children start to smoke at this age while others do not …"*

Goddard argues that the *"data lend some support to the view that tobacco advertising promotes smoking among young people",* but she concludes that *"the effect appears to be small in comparison with some of the other influences on children."* One reason she notes for scepticism about the alleged effect of advertising is the low correlation between the brands whose advertisements were most recognised and those brands most likely to be smoked. Indeed, she does not identify advertising as a cause of youth initiation and the survey data provides no support for the claim that children smoke because of advertising.

4.4.2. Conrad et al 1992 Why Children Start Smoking Cigarettes: Predictors of Onset[176]

The research of Conrad et al (one of the co-researchers is B Flay, co-author of the Centre for Health Promotion study on plain packaging cited by the UK DoH) echoes the conclusions of Goddard. These authors confined their analysis of the factors associated with youth smoking to longitudinal studies that were published from 1980 onwards. The age of the adolescents in the studies ranged from 10-17 with the median age being 12-13. The studies lasted from four months to two years and were conducted in the US, Europe and Australia. They provide data drawn from a diverse range of societies.

Conrad and her colleagues grouped their analysis of the *"process of becoming a smoker"* around five different categories of smoking predictors or risk factors:

1) socio-demographic
2) social bonding
3) social learning
4) intrapersonal/personal/self-image and
5) knowledge, attitudes, and behaviour predictors.

They then discussed the findings by examining the predictive reliability of each group of risk factors in terms of youth smoking.

Only two studies in the author's review examined exposure to tobacco advertising and sponsorship as factors in smoking onset and both of these factors were found to be non-predictive of smoking initiation.

Socio-demographic predictors such as socio-economic status, age and gender were consistent with theoretical expectations 76% of the time, with the strongest predictors of starting to smoke being socio-economic status and age.

[176] Conrad et al., 1992 K.M. Conrad, B.R. Flay and D. Hill, Why children start smoking cigarettes: predictors of onset, Br. J. Addict. 87 (1992), pp. 1711–1724

Social bonding predictors, including family and peer bonding and school influences, were consistent in predicting smoking initiation 71% of the time.

Social learning predictors - family smoking, family approval of smoking, other adult influences (including tobacco advertisements), peer influences and the availability of tobacco were consistent 72% of the time.

Intra-personal, personal and self-image predictors which included such things as tolerance of deviance, independence, rebelliousness, risk-taking, alienation and locus of control were consistent in 77% of the cases. What is particularly important is that the most reliable predictor in this grouping of risk factors was rebelliousness / risk-taking.

Knowledge, attitude and behaviour predictors, including understanding of and beliefs about the physical consequences associated with smoking; "addiction"; expected utility from smoking; approval of cigarette advertisements; alcohol and substance use were predictive in 75% of the cases. Approval of cigarette advertisements was predictive in one study and non-predictive of smoking initiation in another.

Three things about this extensive study of the research literature on the risk factors for youth smoking uptake are particularly important.

First, from the few studies included in this research that looked at tobacco advertising, it appears that there is a substantial difference in the importance that this risk factor is accorded by Government and tobacco control lobbies and those who study substance abuse.

Second, of those studies that did look at advertising as a risk factor for smoking uptake, neither found exposure to it to be predictive of smoking initiation. In other words, this research (which relies only on longitudinal as opposed to the qualitative research that comprises much of the evidence relied on by the UK DoH), undermines the UK DoH's claim about the effects of exposure to tobacco advertising. The authors' findings, including those of UK DoH authority Flay, directly contradict Pierce, Biener and Siegal & Sargent about the link between tobacco advertising exposure and smoking initiation.

Finally, one of the strongest predictors of smoking initiation in all of the studies was rebelliousness and risk-taking. Given how strongly these characteristics

are associated with reactance, the risks of reactance in smokers to display bans and plain packaging raise serious concerns about the potentially counter-productive aspect of such measures.

Conrad et al's analysis of the longitudinal research on youth smoking initiation has been confirmed in other research that has taken predictor variables and combined them into single studies. For instance, Smith & Stutts combined the major predictor variables of youth smoking in a single study that found that all variables related to advertising and anti-smoking information ranked low as reliable predictors. They concluded that *"exposure to cigarette advertising, paying attention to cigarette ads, being familiar with cigarette characters and brands, and exposure to antismoking information are not good predictors of smoking levels*[177]*."*

4.4.3. Lloyd and Lucas 1998 Smoking in Adolescence: Images and Identities[178]

In 1998 two UK researchers - Barbara Lloyd and Kevin Lucas - published a significant work on youth smoking. Their research, commissioned by the UK DoH but never subsequently cited by the Department, was based on a decade of interviews with London and Sussex adolescents about smoking. It argued that many of the traditional anti-smoking interventions, including school-based education programmes, needed to be re-evaluated as they failed to connect with the actual causes of youth smoking. Criticising the inadequate research methods and assumptions of studies such as those employed by the UK DoH, they write that:

"Health promotion programmes for young people must be theory driven and also based on research that uses adequate, representative samples which are capable of rigorous objective analysis. The inadequacy of strategies based on myth and popular opinion has been illustrated by the failure of many intervention programmes to date. Moreover, a danger exists whereby the

[177] Smith, K. and M. A. Stutts. 2000. Factors that Influence Adolescents to Smoke. Journal of Consumer Affairs, 33 (2), 321-357

[178] Lloyd, Barbara, Kevin Lucas, Janet Holland, Sheena McGrellis and Sean Arnold; Smoking in adolescence: images and identities; Published by Routledge, 1998 (London)

adoption and promulgation of such myths by health professionals results in their being accepted as fact and threaten to produce a self-fulfilling prophecy … Sound research may sometimes yield uncomfortable truths. Such truth is the accumulating evidence that many smokers enjoy smoking."

Lloyd and Lucas also stress that the main reasons for adolescent smoking uptake are found in:

- the structures and functioning of families; and particularly the quality of parent-child relationships;
- the nature of school cultures and the academic success of children;
- the adolescent need for stress and mood control; and
- the fact that smoking provides considerable physical pleasure.

They note that *"There is now … compelling evidence to support the view that the quality of an adolescent's home environment will impact on his or her health-related behaviour, including the likelihood of taking up cigarettes."* And *"…poor family relationships predict teenage smoking independently of parental smoking behaviour."* Further, it is not simply the quality of the home environment but the quality of *"relationships within a family"* which "*also influences the likelihood of an adolescent becoming a smoker. Adolescents value open, communicative relationships with their parents. For some, such relationships obviated the need to use smoking as a symbol of rebellion."* It should be noted that Pierce et al (themselves cited by UK DoH) also found such parenting relationships of interest[179].

They observe that *"Our evidence highlights the significance of individual school cultures … The contribution of school culture to health-related values and behaviour cannot be underestimated …"* And finally, with regard to stress, they found that their subjects responded to this by using cathartic coping devices and viewed *"smoking as a coping resource"* for stress. Their statistical analysis showed that *"adolescents who smoke perceive more stress in their lives; report making less use of problem-focused coping and more use of cathartic coping strategies; perceive smoking as a coping resource."*

[179] Pierce J. et al; Does Tobacco advertising target young people to start smoking? Evidence from California. Journal of the American Medical Association, 1991, 266(2), pp3154-3158

There is a nod to reducing tobacco advertising. But the reference to tobacco advertising and youth smoking occurs only once, at the beginning of a 200 page study. Moreover, it is mentioned in the context of another study, Reid et al 1995[180], which identifies banning tobacco promotion as a necessary step. About Reid et al, Lloyd and Lucas write *"we support the view that all of these measures are likely to be necessary …"* However, this conclusion comes before the study is discussed, it is never mentioned again and (most crucially) it is not supported by any data from the study. Nor is a recommendation about tobacco advertising included in the suggested adolescent smoking strategies with which the study concluded.

4.4.4. Jessor 1977 Problem behaviour and psychosocial development: A longitudinal study of youth[181], 1995 Protective factors in adolescent problem behaviour[182]

A further alternative account of smoking uptake is found in the work of Richard Jessor and his colleagues in the US. For Jessor, as for many researchers, smoking is part of a cluster of risk-taking behaviours, rather than a unique adolescent activity. Jessor has looked at a number of these behaviours, including alcohol use and smoking, delinquency and sexual precocity, in order to identify the factors that serve to protect adolescents from engaging in them. He has identified seven protective factors as crucial:

1) positive orientation towards school;
2) positive orientation towards health;
3) intolerant attitudes toward deviance;
4) positive relations toward adults;
5) strong perceived controls;

[180] D. J. Reid, A. D. McNeill, and T. J. Glynn; Reducing the prevalence of smoking in youth in Western countries: an international review; Tobacco Control 1995; 4: 266-277.
[181] Jessor, R., & Jessor, S. L. (1977). Problem behavior and psychosocial development: A longitudinal study of youth. New York: Academic Press
[182] Jessor, R., Van Den Bos, J., Vanderryn, J., Costa, F.M., and Turbin, M.S. 1995. Protective factors in adolescent problem behavior: Moderator effects and developmental change. Developmental Psychology, 31, 923-933.

6) friends who engage in conventional behaviours, and;

7) involvement in pro-social activities (e.g. volunteering).

Contrasting with these seven protective factors are six risk factors which, according to the author, increase the likelihood of problem behaviours:

1) low expectations for success;

2) low self-esteem;

3) general sense of hopelessness;

4) friends who engage in problem behaviours;

5) a greater orientation towards friends than towards parents, and;

6) poor school achievement.

4.5. DETERMINANTS OF HEALTH

A final alternative account of the sources of youth smoking focuses, like the work of Jessor, on adolescent problem behaviours in general and explains smoking uptake within the context of this general account of predictive factors for risky adolescent behaviour. Known as the "determinants of health" approach, it argues that the health of populations and individuals is based on four major factors:

1) living and working conditions (the social and economic environment, income, social status, education, the community, social support networks);

2) the physical environment including the human constructed environment;

3) personal capacities, especially for coping and personal health behaviours; and,

4) the health services.

4.6. CONCLUSIONS AND RECOMMENDATIONS

The factors that influence children to start smoking or to continue to smoke are complex, but are widely acknowledged as primarily socio-economic. These include personal factors such as rebelliousness and risk taking and other factors such as family structure and relationships, quality of schools and educational success and socioeconomic status. It is notable that none of the many studies that have reached this conclusion have been cited in the UK DoH consultation document. It is our view that government policies that recognise and tackle these issues would be the most appropriate and effective response to youth smoking initiation; not penalising retailers, demonising adults who have made an informed choice to smoke and interfering with a range of rights and freedoms including fair trade and competition.

Imperial Tobacco, does not believe we are qualified or sufficiently well informed on broader socio-economic issues and how those might be successfully influenced by Government policy. However, we are certain that further tobacco control measures as outlined in the consultation document are not the measures which will address the Government's objectives of reducing youth smoking initiation. If the UK Government is serious about achieving those objectives they should look more closely at all the evidence and propose solutions that address the evidence rather than seeking out 'easy targets' which can be introduced at little cost to the Government but will be entirely ineffective.

Imperial Tobacco also recommends supporting this evidence-based strategy with greater enforcement of legal minimum age restrictions for the sale of tobacco products, which were recently increased from 16 to 18 years in England, Wales and Scotland and from 1 September 2008 in Northern Ireland. We are a significant contributor to the "No ID No Sale" youth access prevention scheme we have taken steps to ensure that retailers have been supplied with appropriate materials to help them refuse underage sales.

We would not oppose legislation which would make it an offence for an adult to purchase tobacco on behalf of a minor (proxy purchasing) should the UK

Government wish to reconsider complementing existing age of sale laws. As it may be difficult to enforce proxy purchasing regulation we would encourage careful consideration to be given to the practicality of effective enforcement.

It is also our view however that Trading Standards are under-resourced when it comes to tackling illegal selling on street corners, at markets and car boot sales, in pubs and from house to house. Increased resources and additional professional training in this area would be beneficial. Local Councils were provided with significant resources to police the ban on smoking in public and work places in 2007; diversion of this resource to tackling illegal selling and illicit trade could have a significant impact.

5. IMPACT ON COMBATING ILLICIT TRADE

5. IMPACT ON COMBATING ILLICIT TRADE

5.1. SUMMARY

Imperial Tobacco defines the illicit trade in tobacco as the sale of tobacco products on which UK taxes and excise duties have not been levied (non UK duty paid or NUKDP); including smuggled and counterfeit products. The "grey" market consists of NUKDP tobacco products that have been imported legitimately for personal consumption.

We are totally opposed to the illicit trade and work closely with governments and customs and excise authorities around the world to combat such activities.

Smuggling benefits only the criminals involved. It creates an uncontrolled and unregulated market that is untaxed and unaccountable. The illicit trade undermines public health policy and law and order and threatens the livelihoods of tobacco retailers.

The UK Tobacco Manufacturers' Association estimates that 27 per cent of all cigarettes consumed in the UK are non-UK duty paid. This is very close to the HMRC estimate of 26 per cent[183]. Around 70 per cent of all large seizures of illegal cigarettes are counterfeit, as opposed to genuine product smuggled from other countries.

The illicit trade in tobacco products is driven by the potential profits for smugglers. The source for such profit is in price differentials which are, in turn, created by tax differentials. The highest profits for smugglers are derived from counterfeit tobacco products, as these are entirely free of tax. The price differentials derived from counterfeit products in the UK make the UK a very attractive market in which smugglers and counterfeiters can operate.

Imperial Tobacco believes that regulation to introduce plain packaging, ban retail product displays and reduce availability by increasing the minimum pack

[183] HMRC, October 2007, Measuring Indirect Tax Losses 2007, p.11

size and banning vending with a potential consequent reduction in legal points of sale, is likely to increase the illicit trade.

Display bans will make distribution of illicit tobacco products easier. If legal products are hidden from view, it will be more difficult for retailers, customers and enforcement officers to distinguish between legal, duty paid products and illegal, non-duty paid products. This could lead to an increase in the market for illicit tobacco products.

The job of the Trading Standards and anti-illicit trade authorities would become significantly more difficult, since all products will be hidden from the view of the authorities as well as the consumer.

A display ban could lead to a reduction in the number of retail outlets legitimately selling tobacco. Any reduction in the legitimate retail universe is likely to lead to an increase in illicit sales as those channels replace legitimate ones.

Plain packs are likely to lead to an increase in counterfeit products that are sold in the UK. Plain packs are easier for a counterfeiter to copy and the scope for design changes would be dramatically reduced, making it easier for counterfeiters to keep up to date with manufacturers' genuine products. Consumers and enforcement agencies would have much more difficulty in differentiating between genuine and counterfeit products.

Any ban on vending machines is likely to increase the illicit trade. In a large number of venues, tobacco products are not stocked behind the counter and are only available through vending machines. If vending machines are removed from those outlets, tobacco products would not be legitimately available and uncontrolled vendors selling illicit products would be likely to replace them.

Smokers use smaller packs (i.e. those containing fewer than twenty cigarettes) to manage their consumption and expenditure. If cigarettes in packs of fewer than twenty were banned, the illicit trade would be very likely to increase. Smokers who could not afford a legitimate pack of twenty would be likely to seek alternative sources of supply from the illicit market.

Imperial Tobacco enjoys a constructive and fruitful relationship with HMRC which has seen a reduction in the illegal tobacco market in recent years. On the back of its significant expertise and experience in combating the spread of non-duty paid tobacco globally, Imperial Tobacco makes a number of policy recommendations in this submission.

5.2. ILLICIT TRADE: OUR VIEW

Illicit trade in tobacco is a significant and growing problem around the world. In our view, smuggled and counterfeit tobacco products:

(i) reduce potential Government tax and excise revenues;

(ii) undermine law and order;

(iii) support corruption and criminals;

(iv) finance serious crimes including terrorism and trafficking in weapons, drugs and people;

(v) undermine public health objectives;

(vi) put jobs at risk;

(vii) are often counterfeit, of uncertain origin and manufactured using uncertain materials and under unknown standards of hygiene;

(viii) are freely sold to any customer, including children and young people; and

(ix) impose significant costs on Government, industry and society to combat.

5.3. THE NATURE OF, AND DRIVERS BEHIND, THE ILLICIT TRADE

The UK DoH consultation document includes a detailed section on the illicit trade in tobacco products. However, it contains some fundamental errors of fact which could lead to the nature of the illicit trade being misinterpreted and appropriate interventions being discounted.

5.3.1. TAXATION

Section 2.28 of the UK DoH consultation document rightly states that *"illicit tobacco products are available in our communities at less than half the price of their duty-paid equivalent".*

Section 2.12 of the UK DoH consultation document demonstrates that smoking incidence is at its highest in the lowest net income quintile in England. This means that smuggled and counterfeit cigarettes are a far more attractive price proposition for that section of the population. Section 2.33 of the consultation document also recognises that the poorest groups *"have the greatest incentive to source tobacco products from the illicit market".*

If the affordability of domestic duty paid products for lower income groups is eliminated (not just reduced), smuggled and counterfeit tobacco is the readily-available option.

The illicit trade in tobacco products is driven by the potential large profits for smugglers. The sources of profit for smugglers are the price differentials, which in turn are created by the tax differentials.

In Section 2.37, the UK DoH consultation document refers to the link between the level of excise tax and illicit trade stating that the illicit tobacco trade is high in Spain and Italy despite those markets' relatively low levels of excise tax. This is erroneous. The quoted source (Joossens & Raw, 1998) on which this assumption is based is now some ten years old and indeed in 2000, the same authors noted that in Spain, illicit trade had reduced to only 5% by mid 1999[184]. The illicit trade in tobacco is now nearly non-existent in Spain and official assessments and industry figures agree that the market share of non-domestic duty paid cigarettes is well below five percent.

The illicit trade is also nearly non-existent in Russia, Ukraine, Luxembourg and many other countries where cigarette taxation is low. The share of the illicit trade in tobacco products is highest in those countries where excise taxes are highest, such as the UK, France, Scandinavia and Germany.

[184] Joossens and Raw, BMJ Vol 321, 14 October 2000, p 947

A good example of how taxation directly impacts the illicit market can be found in Sweden. The Swedish government reduced excise taxes on cigarettes in August 1998[185] by approximately 25%[186] after earlier significant tax increases were recognised to have immediately encouraged an increase in the illicit trade and severely reduced the legal market. Following the excise tax decrease, the legal market recovered significantly.

5.3.2. CROSS-BORDER SHOPPING

Cross-border shopping has a similar impact to the illicit trade on government revenues and on those of legal businesses. According to UK HMRC estimates, cross border shopping accounts for 8%[187] of total cigarette consumption in the UK.

The UK tobacco industry does not speculate about the nature or size of the split between the illicit trade and cross-border shopping as there is no practical methodology to produce reliable calculations. However, the UK Tobacco Manufacturers' Association estimate that 27% of all cigarettes consumed in the UK are NUKDP is very close to UK HMRC's own estimate, with the upper bands of the illicit trade (18%)[188] and cross-border shopping (8%) resulting in around 26% of the UK market consisting of NUKDP cigarettes.

Although recent declines in cigarette smuggling have been encouraging, our experience in the UK reinforces our concern that successive Government-initiated tax increases only serve to fuel the growth of the illicit trade, as well as to increase the levels of legitimate cross-border shopping.

5.3.3. ENFORCEMENT

Against this background, all current enforcement efforts are having only a limited impact on the illicit trade.

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[185] Joossens and Raw, BMJ Vol 321, 14 October 2000, p 947
[186] Industry sources
[187] HMRC, October 2007, Measuring Indirect Tax Losses 2007, p33
[188] HMRC, October 2007, Measuring Indirect Tax Losses 2007, p11

Potential regulation to introduce plain packaging, ban retail product displays and reduce availability by increasing the minimum pack size and banning vending, with a potential consequent reduction in legal points of sale, is unlikely to have any effective impact on reducing cross-border shopping or on the illicit trade. In fact, it is our view that such regulatory interventions will increase the illicit trade as consumers search for affordable products that they can no longer find in their local shops, and counterfeiters find it easier to produce and distribute fake products in fake packs.

More effective enforcement would help to diminish the illicit trade, but only under the assumption that the increased share of seized smuggled products would significantly change the current profit and loss balance for the criminals.

We recognise that this target is extremely difficult to achieve in a trade-based economy with a large number of incoming containers and vehicles and which is a part of the EU Single Market. So long as the level of large seizures continues to have little negative impact on the profits of criminal gangs, the availability and consumption of smuggled products is likely to at least remain at the current levels.

Imperial Tobacco understands it is difficult to fight the illicit trade once the product has arrived in the UK as smuggled bulk quantities are subsequently delivered to a large number of small (often street-based) dealers. A strong focus should continue to be on preventing such product from entering the UK in the first place. However, inland initiatives must also be a priority; tackling illegal sales on street corners and in local markets and pubs, utilising consumer awareness campaigns and relying on all enforcement authorities working closely with the tobacco manufacturers to achieve maximum success.

5.4. THE LIKELY INCREASE IN ILLICIT TRADE

Elsewhere within this submission we explain, in detail, our concerns that the proposals and possible measures contained in the UK DoH consultation document could (if introduced) have unintended consequences in terms of the illicit trade. These concerns are described briefly here.

5.4.1. DISPLAY BANS

A display ban would further fuel the existing and problematic illicit trade in tobacco products in the UK. If retailers are forced to sell tobacco products from under the counter the distinction between tobacco products that are sold legally and those that are sold illicitly (including counterfeit) will be blurred and the job of Trading Standards and other enforcement agencies will be more difficult. Consumers will not be able to differentiate between legal products, which they would assume will be provided to them, and illicit products.

A display ban could lead to a reduction in the number of retail outlets legitimately selling tobacco. Any reduction in the legitimate retail universe is likely to lead to an increase in illicit sales as those channels replace legitimate ones.

5.4.2. PLAIN PACKS

The distribution of counterfeit tobacco, particularly cigarettes and fine cut tobacco, continues to increase in the UK. Plain packs are likely to lead to yet further increases in the quantities of counterfeit sold in the UK. Plain packs are easier for a counterfeiter to copy than existing branded packs. The scope for legitimate manufacturers' pack design changes would also be dramatically reduced, making it easier for counterfeiters to keep up to date with manufacturers' genuine products. Consumers would have much more difficulty in differentiating between genuine and counterfeit products than currently.

Counterfeit products are not manufactured to established standards of quality nor is there any likelihood that they comply with regulations covering the manufacture, content and sale of tobacco products in the UK. Counterfeit products by their nature do not carry UK excise or VAT.

Plain packaging could be described as a 'Counterfeiters Charter'.

5.4.3. VENDING MACHINES

Any ban on vending machines is likely to increase the illicit trade. In a large number of venues (mostly licensed premises), tobacco products are not stocked behind the counter but are only available through vending machines, which are already subject to age control and adult supervision legislation. If vending machines were to be removed from those outlets, tobacco products would not be legitimately available and uncontrolled vendors selling illicit products would be likely to replace them.

5.4.4. SMALLER PACK SIZES

Smokers use smaller pack sizes to manage their consumption and expenditure. If cigarettes in packs containing fewer than twenty were to be banned, the illicit trade would inevitably increase. Smokers who could not afford a legitimate pack of twenty cigarettes would be likely to seek alternative sources of supply from the illicit market.

5.5. POLICY RECOMMENDATIONS

For the reasons summarised here, Imperial Tobacco believes that some of the proposals or discussions in the UK DoH consultation document will have the unintended consequences of fuelling the market for illicit (smuggled and counterfeit) tobacco products. We believe that such measures should not be introduced. However, Imperial Tobacco believes that particular attention should continue to be paid to the following activities to counter the illicit trade.

a) Continued and enhanced cooperation between enforcement authorities and the tobacco manufacturers will drive success, and should continue to be developed at all levels. Imperial Tobacco and the other UK tobacco manufacturers frequently encounter barriers to positive engagement with enforcement and regulatory agencies and these frustrate the shared development and implementation of truly effective strategies.

b) Initiatives that target notorious street-selling hotspots must continue. These should continue to be a focus for Trading Standards officers, the police and HM Revenue and Customs.

c) Implementing a risk profile analysis of people and vehicle movements could increase the number of seizures of illicit tobacco products that are coming into the UK.

d) Improving inter-EU cooperation between enforcement agencies has significant potential for the more efficient combating of the illicit trade.

e) Sharing information about smuggling operations would significantly improve the ability of manufacturers to follow up on seizures and enable further useful intelligence to be generated. Revising existing legislation that currently prevents enforcement authorities from sharing relevant information with manufacturers would also be likely to reduce the illicit trade.

f) Additional resources such as more mobile X-ray machines, additional personnel and the deployment of more trained tobacco sniffer dogs could increase the number of seizures of illicit tobacco products.

g) Appropriate controls could be carried out while suspect vehicles are still on board cross-Channel ferries and trains.

h) The majority of genuine (as opposed to counterfeit) NUKDP tobacco products that are smuggled into the UK are now in small quantities that have mostly been bought duty paid or duty free by tourists and European travellers, then brought into the UK. Greater resource and focus should be directed to passenger traffic on ferries, trains and at airports.

i) Air travellers are often reported as a key source of individual small- and mid-scale smuggling seizures. As air travellers' bags are regularly screened for security reasons, the capability to seize excessive quantities of tobacco products is realistically achievable.

j) The government should intensify and improve its communications and public education campaigns to increase understanding about the wider

concerns and consequences of purchasing smuggled and counterfeit tobacco products. The aim should be to provide a highly visible deterrent in every community that not only discourages criminals from taking part in the trade, but also educates the public about the risks of purchasing and consuming products from unknown sources and of funding criminal networks.

k) Imperial Tobacco believes that in order to effectively address the problems attributable to the illicit trade, enforcement needs to be more extensively funded. A direct remit for enforcement should be devolved to Trading Standards, supported by the police. Funds should be made available to dedicate sufficient resources to the anti-counterfeit operations on the ground.

6. NICOTINE AND SMOKING CESSATION

6. NICOTINE AND SMOKING CESSATION

6.1. SUMMARY

Imperial Tobacco believes that the underlying assumptions of Parts C ("Supporting smokers to quit") and D ("Helping those who cannot quit") of the consultation document fundamentally misinterpret why people choose to smoke and the role that nicotine plays in smoking. This chapter provides a complete and balanced view of the relevant evidence.

Smoking is a complex behaviour and different people smoke for different reasons. Fundamentally however, people smoke cigarettes because they enjoy smoking. It brings them pleasure and they derive a variety of benefits from smoking.

Imperial Tobacco agrees that smoking can be characterised as addictive as the term is commonly used today. Some people may find it difficult to stop smoking, but we believe it is important for them to understand that if they choose to stop, they are able to do so. Millions of people have stopped smoking, the majority without assistance. There are, however, many people who exercise an adult choice to continue to smoke and use tobacco.

When pharmacologists first established standards for distinguishing addictive substances from ordinary substances that people use, smoking fell into the category of habit and not addiction. The pharmacological definitions of addiction and habit were promulgated by the World Health Organization ("WHO") in 1957 and later used by the Advisory Committee to the US Surgeon General ("Advisory Committee"), in preparing its 1964 Report. The 1964 report concluded that smoking is a habit, not an addiction.

As the field of addiction, or more properly "dependence", fell under the provenance of psychiatrists and psychologists (behaviouralists) as opposed to pharmacologists, the definition of dependence expanded and became more flexible and less objective.

The term "addiction" was never used in the various versions of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental

Disorders (DSM), and the term was replaced with "dependence" by the World Health Organisation in its International Classification of Diseases (ICD) as early as 1965. The term "addiction" was reintroduced into the public discourse on smoking primarily by the US Surgeon General in its 1988 report entitled "Nicotine Addiction". This is now widely acknowledged to have been a deliberate move to apply pejorative connotations to a smoking habit – the term "addiction" carries with it not only a sense of moral judgement, but also the convenient comparison to the abuse of illicit substances.

The use of the term "addiction" in connection with smoking has also become commonplace in the UK. The view that smokers are "addicted" to smoking or nicotine has fostered an environment in which the term "addiction" and related concepts, such as "dependence," "hooked," "diminished autonomy," etc. are used without qualification.

A view of smoking as the equivalent to "nicotine addiction" in which the smoker has no choice but to smoke is also inconsistent with the way in which society views the ability of individuals to make informed decisions. It also flies in the face of the fact that millions of people have stopped smoking. Cigarette smoking is not an "addiction" if the use of that term is intended to mean that a person is unable to stop smoking. While some smokers might have difficulty in stopping, anyone can stop if they choose to do so.

If the consultation's assertion that "nicotine dependence is a major determinant of the ease of quitting" (section 2.15) is true, it would be expected that use of Nicotine Replacement Therapy ("NRT") would be highly effective in assisting smokers in stopping smoking. Contrary to this, the Tobacco Advisory Group of the Royal College of Physicians in its 2007 Report noted that NRT *"is not as efficacious as would be anticipated if tobacco dependence reflected a 'simple' addiction to nicotine."*[189] This conclusion confirms that, *"The most*

[189] Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP; 2007. p. 54.

well-known anomaly to the nicotine addiction thesis is the modest efficacy of nicotine replacement therapy (NRT) for smoking cessation."[190]

A recent meta-analysis of 111 NRT studies found that in almost 60% of those trials, NRT either had no effect or was less effective than placebo. [191] In studies claiming that NRT is effective, the actual differences between NRT and placebo are small and, in fact, a recent study found that after 48 weeks, only 10% of people using NRTs had stopped smoking, in contrast to 12% of people using placebo.[192]

It might also be expected that if nicotine were "addicting," nicotine administered in an NRT would be abused like heroin and other drugs of abuse. However, there is no convincing evidence to suggest that NRTs are abused. A leading commentator observed that "*evidence of nicotine replacement product abuse is essentially nonexistent."*[193]

The lack of efficacy of NRTs and the fact that they are not abused like usual drugs of abuse, present major challenges to the claim that cigarette smoking can be explained as an addiction to nicotine.

To attempt to explain an individual's lack of success in smoking cessation as the result of "addiction" lacks explanatory power. It is merely a convenient way to try to explain a behaviour ("smoking") by attributing a reason for the behaviour (*"people smoke because they are addicted"*).

It is more useful to analyse why people may find it difficult to stop smoking in the context of why people generally may find it difficult to alter other habits. When one considers that smoking confers many and different benefits to smokers in different times and situations, it is understandable that altering this habit and stopping smoking might be difficult for some people.

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190 Dar R, Frenk H. Reevaluating the nicotine delivery kinetics hypothesis. *Psychopharmacology (Berl)* 2007; 192: 1-7.

191 Stead L, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Datab Syst Rev* 2008; CD000146

192 Id.

193 Hughes JR. Part IV. Behavioural toxicity of nicotine: Dependence on and abuse of nicotine replacement medications: An update. In: Benowitz NL, editors. Nicotine Safety and Toxicity. New York: Oxford University Press; 1998. pp. 147-57.

6.2. INTRODUCTION

The following provides Imperial Tobacco's contribution to the Department of Health Consultation on the Future of Tobacco Control with regard to statements set forth and evidence referenced in Parts C and D of the publication ("Supporting smokers to quit" and "Helping those who cannot quit"). Imperial Tobacco believes that, taken together, these Parts present an incomplete discussion of the complex issue of why people choose to smoke and the role that nicotine may play in smoking. These Parts also reiterate a number of assumptions about smoking and stopping smoking that are belied by a more thorough consideration of the evidence. In this submission, Imperial Tobacco will endeavour to provide the Department of Health with a more complete and balanced view of the relevant evidence.

6.3. IMPERIAL TOBACCO'S VIEW

Smoking is a complex behaviour and different people smoke for different reasons. Fundamentally however, people smoke cigarettes because they enjoy smoking. It brings them pleasure and they derive a variety of benefits from smoking.

Imperial Tobacco agrees that smoking can be characterised as addictive as the term is commonly used today. Some people may find it difficult to stop smoking, but we believe it is important for them to understand that if they choose to stop, they are able to do so. Millions of people have stopped smoking, the majority without assistance. There are, however, many people who exercise an adult choice to continue to smoke and use tobacco.

We recognise that it is the role of governments to provide the general public with clear and consistent messages about the health risks to smokers that are associated with their smoking and we do not challenge those messages. The risks associated with smoking are well known, and we believe that adults should continue to be allowed to make a choice as to whether or not to smoke.

6.4. SMOKERS ENJOY AND DERIVE BENEFITS FROM SMOKING

People have long used substances such as coffee, tea, alcohol and chocolate for pleasure and enjoyment, mood enhancement, and for various social reasons. Likewise, people smoke cigarettes because they enjoy smoking and derive a variety of benefits from smoking. Smoking is a complex behaviour and different people smoke for different reasons. Some may smoke more for taste and enjoyment, others more for social reasons, and others as a means to improve performance or to cope with negative mood. In addition, the same smoker smokes for different reasons throughout the day and at different periods in the smoker's life. The same person can smoke during the day to improve performance at work and later at the pub to facilitate socialising. At other times, a smoker may find that smoking helps to cope with stressful situations.

In surveys designed to explore why people smoke, enjoyment and pleasure are usually the most common reasons smokers give for their smoking.[194,195,196] Many factors contribute to the enjoyment people experience when they smoke. The sensory aspects of smoking play an important role. As one commentator reported: *"There is substantial evidence that smoking-produced sensory effects are important in various aspects of smoking behaviour."*[197] Smokers often describe liking the taste and flavour of the cigarette.[198] Smokers can discriminate between different cigarettes and typically have preferences for a particular brand of cigarette.[199] Smokers also describe

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194 Tate JC, Stanton AL. Assessment of the validity of the Reasons for Smoking scale. *Addict Behav* 1990; 15: 129-35.

195 Etter J-F, Humair J-P, Bergman MM, Perneger TV. Development and validation of the attitudes towards smoking scale (ATS-18). *Addiction* 2000; 95: 613-25.

196 Juniper Z, Hajek P, McRobbie H. Smoking for pleasure versus smoking to cope: relationship to dependence and treatment outcome.[abstract POS1-028]. *SRNT* Proceedings of 11th annual meeting held jointly with the 7th annual SRNT European conference: 2005 proceedings and on-site program; 3/20-23/2005; Prague, Czech Republic. 2005; p. 50.

197 Robinson ML, Houtsmuller EJ, Moolchan ET, Pickworth WB. Placebo cigarettes in smoking research. *Exp Clin Psychopharmacol* 2000; 8: 326-32.

198 Nil R, Battig K. Separate effects of cigarette smoke yield and smoke taste on smoking behaviour. *Psychopharmacology* 1989; 99: 54-9.

199 Boren JJ, Stitzer ML, Henningfield JE. Preference among research cigarettes with varying nicotine yields. *Pharmacol Biochem Behav* 1990; 36: 191-3.

enjoying the aroma of tobacco and tobacco smoke.[200] In addition, smokers frequently describe enjoying the feel of the smoke in the mouth and the distinctive sensations attendant to inhalation.[201,202,203,204,205] In line with the contribution of the sensory aspects of smoking,[206, 207] it has been shown that blocking smoking-related sensations reduces smokers' satisfaction.[208, 209]

In addition to the sensations related to the smoke, smokers count the physical aspects of smoking, including the smoking ritual, as part of the enjoyment. The ritual includes removing the cellophane from a new pack of cigarettes, removing the cigarette, tapping the cigarette, striking the match or firing the lighter, and lighting the cigarette.[210] Smokers also refer to the handling of the cigarettes before and during smoking[211, 212] and describe the pleasure of exhaling and watching the exhaled smoke.[213]

Smokers report using cigarettes as a social tool.[214] Smokers smoke to be sociable or as a way of fitting into a group.[215] In addition, smokers may

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200 Battig K. Nicotinic and non-nicotinic aspects of smoking: motivation and behavioural effects. In: Snel J, Lorist MM, editors. Nicotine, caffeine and social drinking: behaviour and brain function. Amsterdam: Harwood Academic Publishers; 1998. pp. 83-113.

201 Ashton H, Stepney R. The importance of nicotine. Smoking psychology and pharmacology. London and New York: Tavistock Publications; 1982. pp. 18-41.

202 Rose JE, Behm FM, Levin ED. Role of nicotine dose and sensory cues in the regulation of smoke intake. *Pharmacol Biochem Behav* 1993; 44: 891-900.

203 Naqvi NH, Bechara A. The airway sensory impact of nicotine contributes to the conditioned reinforcing effects of individual puffs from cigarettes. *Pharmacol Biochem Behav* 2005; 81: 821-9.

204 Rose JE. The role of upper airway stimulation in smoking. In: Pomerleau, O, Pomerleau, CS, editors. Nicotine Replacement: A Critical Evaluation. New York: Alan R. Liss, Inc; 1987. pp. 95-106.

205 Rose JE, Behm FM, Westman EC, Johnson M. Dissociating nicotine and non-nicotine components of cigarette smoking. *Pharmacol Biochem Behav* 2000; 67: 71-81.

206 Brauer LH, Behm FM, Lane JD, Westman EC, Perkins C, Rose JE. Individual differences in smoking reward from de-nicotinised cigarettes. *Nicotine Tob Res* 2001; 3: 101-9.

207 Battig, 1998. pp. 87-111.

208 Rose JE, Tashkin DP, Ertle A, Zinser MC, Lafer R. Sensory blockade of smoking satisfaction. *Pharmacol Biochem Behav* 1985; 23: 289-93.

209 Rose JE, Zinser MC, Tashkin DP, Newcomb R, Ertle A. Subjective response to cigarette smoking following airway anesthetisation. *Addict Behav* 1984; 9: 211-5.

210 Russell et al., 1974. pp. 313-46.

211 Battig, 1998. pp. 111-2.

212 Leventhal H, Avis N. Pleasure, addiction, and habit: factors in verbal report of factors in smoking behaviour?. *J Abnorm Psychol* 1976; 85: 478-88.

213 Russell MAH, Peto J, Patel UA. The classification of smoking by factorial structure of motives. *J. R. Statist. Soc.* 1974; A 137: 313-46.

214 Berlin I, Singleton EG, Pedarriosse A-M, Lancrenon S, Rames A, Aubin H-J, Niaura R. The modified reasons for smoking scale: factorial structure, gender effects and relationship with nicotine dependence and smoking cessation in French smokers. *Addiction* 2003; 98: 1575-83.

215 Warburton DM, Mancuso G. Evaluation of the information processing and mood effects of a transdermal nicotine patch. *Psychopharmacology* 1998; 135: 305-10.

smoke to gain confidence in a social setting.[216] [217] One study examined the effects of smoking in a social interaction test. It found that smoking reduced anxiety during social interaction and that smokers had enhanced feelings of being successful in changing the opinions of others and in expressing their own views.[218]

It is also well known that smoking assists in regulating mood and emotion. Smokers often report they are more relaxed when they smoke[219, 220] and smoking is often seen to increase during times of stress. The sensory stimulation provided by cigarettes may play a role in relieving stress. One study found that subjects obtained reduction in stress from de-nicotinised smoke aerosol to the same extent as from cigarette smoke.[221]

Nicotine has been shown to have positive effects in terms of mood enhancement.[222] Nicotine has also been shown in laboratory studies to alleviate depressed mood. For example, it has been shown, both in animal studies[223] (using behavioural models of depression) and in human non-smokers[224] treated with a transdermal nicotine patch, that nicotine reduces depression. Smokers also report that smoking reduces anxiety and laboratory studies have confirmed this effect.[225] There is consistent evidence that nicotine, whether from smoking tobacco or chewing nicotine-impregnated

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216 Warburton DM. Situational determinants of smoking. *Pharmacopsychoecologia* 1988; 1: 67-77.

217 Berlin et al., 2003.

218 Gilbert DG, Spielberger CD. Effects of smoking on heart rate, anxiety, and feelings of success during social interaction. *J Behav Med* 1987; 10: 629-38.

219 McKennell AC, Thomas RK. Adults and adolescents smoking habits and attitudes. London: British Ministry of Health; 1967.

220 Warburton DM. Nicotine: an addictive substance or a therapeutic agent? *Progr Drug Res* 1989; 33: 9-41.

221 Levin ED, Rose JE, Behm F, Caskey NH. The effects of smoking-related sensory cues on psychological stress. *Pharmacol Biochem Behav* 1991; 39: 265-8.

222 Warburton DM. The puzzle of nicotine use. In: Lader M, editors. The Psychopharmacology of Addiction. Oxford: Oxford University Press; 1988. pp. 27-49.

223 Picciotto MR, Brunzell DH, Caldarone BJ. Effect of nicotine and nicotinic receptors on anxiety and depression. *Neuroreport* 2002; 13: 1097-106.

224 Salin-Pascual RJ, Rosas M, Jimenez-Genchi A, Rivera-Meza BL, DelgadoParra V. Antidepressant effect of transdermal nicotine patches in non-smoking patients with major depression. *J Clin Psychiatry* 1996; 57: 387-9.

225 Juliano LM, Brandon TH. Effects of nicotine dose, instructional set, and outcome expectancies on the subjective effects of smoking in the presence of a stressor. *J Abnorm Psychol* 2002; 111: 88-97.

gum, reduces aggressive behaviour in smokers.[226] Laboratory studies have shown that aggressive behaviour in rats can be reduced by the administration of nicotine.[227]

Smokers often report that smoking improves alertness[228] and laboratory studies have shown that nicotine improves performance and enhances cognitive functioning.[229, 230, 231] These effects include increased levels of arousal and alertness, improved capacity to maintain performance during long and boring tasks, improved capacity to attend to task-relevant information, improved capacity to maintain concentration of attention, faster learning and enhanced 'working' memory. As Prof. David Warburton, a widely published and renowned researcher in the field of smoking and nicotine, has said:

[a] large body of evidence shows that nicotine improves mood and enhances information processing capacity. These results can be interpreted in terms of a functional model of nicotine use. In this model, nicotine use can be seen as purposive, a behaviour to obtain psychological resources.232

The evidence shows that people choose to smoke because it is pleasurable and they derive many benefits from smoking.

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226 Cherek DR, Bennett RH, Grabowski J. Human aggressive responding during acute tobacco abstinence: effects of nicotine and placebo gum. *Psychopharmacology* 1991; 104: 317-22.

227 Driscoll P, Battig K. Selective inhibition by nicotine of shock-induced fighting in the rat. *Pharmacol Biochem Behav* 1981; 14: 175-9.

228 Berlin et al., 2003.

229 Bell SL, Taylor RC, Singleton EG, Henningfield JE, Heishman SJ. Smoking after nicotine deprivation enhances cognitive performance and decreases tobacco craving in drug abusers. *Nicotine Tob Res* 1999; 1: 45-52.

230 Gray JA, Mitchell SN, Joseph MH, Grigoryan GA, Dawe S, Hodges H. Neurochemical mechanisms mediating the behavioural and cognitive effects of nicotine. *Drug Dev Res* 1994; 31: 3-17.

231 Foulds J, Stapleton J, Swettenham J, Bell N, McSorley K, Russell MAH. Cognitive performance effects of subcutaneous nicotine in smokers and never-smokers. *Psychopharmacology* 1996; 127: 31-8.

232 Warburton DM. The functional conception of nicotine use. In: Clarke PBS, Quik M, Adlkofer F, Thurau K, editors. *Effects of Nicotine on Biological Systems II: Advances in Pharmacological Sciences - V. Nicotine and Smoking: Current Controversies*. Basel: Birkhauser Verlag; 1995. pp. 257-64.

6.5. HABIT VS. ADDICTION

6.5.1. HABIT

Historically, smoking was viewed as a settled practice or habit, similar to drinking coffee or to eating chocolate. It is, therefore, not surprising that when pharmacologists first established standards for distinguishing addictive substances from ordinary substances that people use, smoking fell into the category of habit and not addiction. The pharmacological definitions of addiction and habit were promulgated by the World Health Organization ("WHO") in 1957 and later used by the Advisory Committee to the US Surgeon General ("Advisory Committee"), in preparing its 1964 Report. The Advisory Committee included Maurice H. Seevers MD PhD, a leading pharmacologist of the era with an expertise in habit-forming drugs, who had been instrumental in developing the 1957 WHO definition. The 1964 Report concluded that smoking is a habit, not an addiction.[233]

The WHO criteria for characterising a habit were:

- absence of intoxication;
- a *"desire (but not a compulsion) to continue"* using the substance *"for the sense of improved well-being which it engenders";*
- *"little or no tendency to increase the dose"* (tolerance);
- *"some degree of psychic dependence but … absence of a physical dependence and hence of an abstinence syndrome"* (withdrawal); and
- lack of detrimental effect on society.[234]

This definition of habit, and the corresponding definition of addiction, was developed primarily by pharmacologists and focused on objectively verifiable or measurable physical effects of a substance.

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[233] U.S. Department of Health, Education and Welfare. Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service. Washington, DC: U.S. Department of Health, Education and Welfare; 1964.

[234] Id. at p. 351.

The Advisory Committee noted that smoking does not cause intoxication; smokers have a desire, but not a compulsion to smoke; there is little or no tendency for smokers to increase the "dose" of tobacco and thus tolerance does not develop; there is no characteristic physical withdrawal syndrome upon stopping smoking, and instead, *"a gamut of mild symptoms and signs is experienced and observed as in any emotional disturbance secondary to deprivation of a desired object or habitual experience;"*[235] and smoking involves no detrimental effects on society. Because smoking met the criteria of a habit but none of the criteria for addiction, the Advisory Committee concluded in the 1964 Report that cigarette smoking is properly characterised as a habit, to be distinguished from addiction to substances such as morphine, alcohol and barbiturates.[236] The Advisory Committee also recognised the *"significant beneficial effects of smoking primarily in the area of mental health."*[237]

6.5.2. ADDICTION

As the field of addiction, or more properly "dependence," fell under the provenance of psychiatrists and psychologists (behaviouralists) as opposed to pharmacologists, the definition of dependence expanded and became more flexible and less objective. Under the expanded definition, cigarette smoking, and later nicotine, could be characterised as dependence-producing. This expanded definition also resulted in the use of many common substances, as well as certain activities, being characterised as resulting in dependence. Unfortunately, as discussed below, the terms "dependence" and "addiction" are often used interchangeably; therefore, the term "addiction" is now sometimes used to describe consumption of substances such as coffee,[238] chocolate,[239] carrots[240, 241] and water,[242] as well as activities such as

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235 Id. at p. 352.
236 Id. at pp. 349-51.
237 Id. at p. 356.
238 Hughes JR, Higgins ST, Bickel WK, Hunt WK, Fenwick JW, Gulliver SB, Mireault GC. Caffeine self-administration, withdrawal, and adverse effects among coffee drinkers. *Arch Gen Psychiatry* 1991; 48: 611-7.
239 Hetherington MM, Macdiarmid JI. "Chocolate addiction": a preliminary study of its description and its relationship to problem eating. *Appetite* 1993; 21: 233-46.

gambling,[243] sex,[244] internet use,[245, 246, 247] exercise[248] and watching television.[249] The term "addiction" is even used today to refer to nations, as in the proposition that a country is *"addicted to oil."*[250]

Thus, there is a serious question as to whether the expanded definitions of "addiction" are appropriate, sufficiently objective, and of value in discussing behaviour. Many commentators are now of the view that there exists *"a state of conceptual chaos"*[251] *in which "the word addiction has too many meanings."*[252]

The view that smokers are "addicted" to smoking or nicotine has fostered an environment in which the term "addiction" and related concepts, such as "dependence," "hooked," "diminished autonomy," etc. are used without qualification. For example, Section 3.7 of the Consultation states:

first inhalation of tobacco is the most important tobacco-use milestone … some young people experienced the first symptoms of tobacco dependence within a day of smoking for the first time. Half of those who reported being 'hooked' were smoking as few as seven or eight cigarettes a month. (Section 3.7)

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240 Cerny L, Cerny K. Can carrots be addictive?: an extraordinary form of drug dependence. *Br J Addict* 1992; 87: 1195-7.

241 Kaplan R. Carrot addiction. *Aust NZ J Psychiatry* 1996; 30: 698-700.

242 Kaplan R. When a patient is addicted to tap water. Medical Observer 1998 June 12; 12.

243 Potenza MN, Fiellin DA, Heninger GR, Rounsaville BJ, Mazure CM. Gambling: an addictive behaviour with health and primary care implications. *J Gen Intern Med* 2002; 17: 721-32.

244 Griffin-Shelley E. Sex and love addiction: definition and overview. Outpatient treatment of sex and love addicts. Connecticut: Praeger; 1993. p. 5-19.

245 Griffiths M. Internet addiction - time to be taken seriously? *Addiction Res* 2000; 8: 413-8.

246 Block JJ. Issues for DSM-V: internet addiction [editorial]. *Am J Psychiatry* 2008; 165: 306-7.

247 Chou C. A review of the research on internet addiction. *Educational Psychology Review* 2005; 17: 363-88.

248 Adams J, Kirkby RJ. Excessive exercise as an addiction: a review. *Addict Res Theory* 2002; 10: 415-37.

249 Kubey R, Csikszentmihalyi M. Television addiction is no mere metaphor. *Sci Am* 2002; 286: 74-80.

250 Can the US break its oil addiction? BBC News 1 February 2006. Available from: URL: http://news.bbc.co.uk/2/hi/science/nature/4669260.stm.

251 Shaffer HJ. The most important unresolved issue in the addictions: conceptual chaos. *Subst Use Misuse* 1997; 32: 1573-80.

252 Alexander BK, Schweighofer ARF. Defining addiction. *Can Psychol* 1988; 29: 151- 62.

The reference for this statement is a study by a group of researchers[253] who have written a number of articles on the topic of youth smoking. These publications have inspired articles in the popular press with titles like:

"Report: One cigarette can make teen an addict"[254] and *"Inhaling from just one cigarette can lead to nicotine addiction: Kids show signs of addiction almost immediately."*[255]

Even a cursory review of the data reported by these researchers in their most recently published study (2008) reveals the weaknesses of their interpretations of these data.[256] For example, the authors offer the following:

Individuals have lost full autonomy over their smoking when quitting becomes unpleasant or difficult. … Diminished autonomy was reported by 46% of subjects who smoked less often than monthly and by 25%-30% of current smokers who had smoked only one cigarette in total. … These data suggest that smoking one cigarette in total can prompt a loss of autonomy.[257]

These statements are based on responses obtained from surveys using a questionnaire formulated by the researchers themselves, and not based on widely used diagnostic criteria such as the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders in the revised Fourth

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253 DiFranza JR, Savageau JA, Fletcher K, O'Loughlin J, Pbert L, Ockene JK, McNeill AD, Hazelton J, Friedman K, Dussault G, Wood C, Wellman RJ. Symptoms of tobacco dependence after brief intermittent use: the Development and Assessment of Nicotine Dependence in Youth–2 Study. *Arch Pediatr Adolesc Med* 2007; 161: 704-10.

254 DPA. Report: One cigarette can make teen an addict. *The Earth Times* 2008; Available from: URL: http://www.earthtimes.org/articles/show/187167,report-one-cigarette-can-make-teen-an-addict.html.

255 Inhaling from just one cigarette can lead to nicotine addiction: kids show signs of addiction almost immediately. *Science Daily* 2007; Available from: URL: http://www.sciencedaily.com/releases/2007/07/070703171843.htm.

256 Scragg R, Wellman RJ, Laugesen M, DiFranza JR. Diminished autonomy over tobacco can appear with the first cigarettes. *Addict Behav* 2008; 33: 689-98.

257 Id. at p. 689.

Version (Text Revision) (DSM-IV (TR) (2000)),[258] or the WHO's tenth version of the International Classification of Diseases (ICD-10 (1992)).[259]

An individual who smokes one cigarette in his lifetime, or who smokes less than once a month, cannot accurately be characterised as a "current smoker." It is equally difficult to make sense of the statement that *"25%-30% of current smokers who had smoked only one cigarette in total,"* or *"who smoked less often than monthly"* have *"diminished autonomy,"* or have somehow become "addicted," to smoking. An individual who has smoked one cigarette in his lifetime and never smoked again, or who smokes *"less often than monthly,"* clearly has control over his smoking. Even more perplexing is the claim in the UK DoH consultation document that 28% of smokers who have ever in their lives smoked only "1-2 puffs" and who have not smoked again, have lost "autonomy" over their smoking.[260] Recognising the peculiarity of these interpretations, the authors also point out that *"[i]t may seem logically impossible that, across all survey years, 14% of subjects who had smoked only one cigarette in their lifetimes reported a failed attempt at cessation."*[261]

It is unfortunate that the UK DoH consultation document has accepted the conclusions of this flawed research.

6.5.3. ICD-10 AND DSM-IV (TR)

Today, both ICD-10 and DSM-IV (TR) list criteria by which a diagnosis of "dependence" can be made. The criteria apply to all substances and are similar in both diagnostic schemes. In setting forth the criteria for a diagnosis of dependence, both ICD-10 and DSM-IV (TR) have abandoned any requirement that a set of objective characteristics, such as tolerance, physical withdrawal and intoxication, be fulfilled before a diagnosis of dependence may be made.

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258 American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders: DSM-IV-TR. 4th ed. Washington, DC: American Psychiatric Association; 2000.

259 World Health Organization. The ICD-10 classification of mental and behavioural disorders. Clinical descriptions and diagnostic guidelines. Geneva: World Health Organization; 1992.

260 Id. Table 4 at p. 694.

261 Id. at 696.

A major failing of the ICD-10 and DSM-IV (TR) criteria is that they do not distinguish intoxicating drugs such as heroin and barbiturates from pleasurable, non-intoxicating substances such as cigarettes, chocolate, sugar and coffee. The common experience of individuals who use these various substances would lead to the conclusion that there are vast differences in terms of their pharmacological effects. To point out one obvious distinction, smoking cigarettes does not have any mind-altering or intoxicating effect such as there is with heroin and barbiturates. The fact that the application of DSM-IV (TR) criteria to coffee could lead to the conclusion that caffeine causes dependence in certain individuals[262, 263] highlights how overly broad this definition is.

In contrast to alcohol and heroin, the general criteria for substance dependence set forth in DSM-IV (TR) and ICD-10 do not fit well with smoking. Tacit acknowledgment of this fact is made in DSM-IV (TR), for example, when the authors state that *"[s]ome of the generic dependence criteria do not appear to apply to nicotine, whereas others require further explanation."*[264] An examination of how DSM-IV (TR) deals with *"nicotine dependence"* in the context of what were previously the standard criteria for a diagnosis of "addiction" reveals the extent of this poor fit. (See Appendix 2 for an analysis of the DSM-IV (TR) criteria for "dependence" and its discussion of "nicotine dependence.")

The inclusion of smoking within the expanded definitions of "addiction" and even within ICD-10 and DSM-IV (TR) remains a controversial one. In fact, as one commentator recently observed, *"[m]any scientists implicitly recognise that nicotine dependence is different when they do not include nicotine dependence when studying drug 'dependence'."*[265]

Given that both ICD-10 and DSM-IV (TR) use the term "dependence" and not "addiction," it might strike one as odd that the term "addiction" is now so

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262 Bernstein GA, Carroll ME, Thuras PD, Cosgrove KP, Roth ME. Caffeine dependence in teenagers. *Drug Alcohol Depend* 2002; 66: 1-6.

263 Hughes JR, Oliveto AH, Liguori A, Carpenter J, Howard T. Endorsement of DSM-IV dependence criteria among caffeine users. *Drug Alcohol Depend* 1998; 52: 99-107.

264 American Psychiatric Association. 4th ed., 2000. p. 264.

265 Hughes JR. Should criteria for drug dependence differ across drugs? *Addiction* 2006; 101: 134-41.

frequently used in the context of smoking. The term "addiction" was never used in the various versions of the DSM classifications, and the term was replaced with "dependence" by the WHO in its ICD classifications as early as 1965. [266] The term "addiction" was reintroduced into the public discourse on smoking primarily by the US Surgeon General in its 1988 Report titled "Nicotine Addiction" ("1988 US SG Report.") [267] As one commentator has written:

the substitution of addiction for dependence was not accidental nor grounded in providing information, since the strongly negative associations of labelling smoking as an addiction were not lost on the Surgeon General, who could hardly have been unaware of the fact that 'A tobacco-smoking habit is bad enough, but it is even worse when one thinks of it as an addiction.' [268]

Indeed, the term "addiction" carries with it not only a sense of moral judgment, but also the convenient comparison to the abuse of illicit substances:

while not having a scientific meaning, addiction had a range of popular meanings that all tended to suggest a loss of control, of volition, of the power to choose. Indeed, to speak of someone being addicted was to conjure up images of heroin users inescapably in the grip of their compulsion. [269]

The use of the term "addiction" in connection with smoking has also become commonplace in the UK. For example, the Tobacco Advisory Group of the Royal College of Physicians published a report in 2000 entitled "Nicotine

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266 Luik JC. Science through the looking-glass: the manipulation of "addiction" & its influence over obesity policy. Washington, D.C., Washington Legal Foundation; 2007. p. 8.

267 U.S. Department of Health and Human Services. The health consequences of smoking: nicotine addiction: a report of the Surgeon General. Rockville, Maryland: U.S. Department of Health and Human Services; 1988.

268 Id. at pp. 26-7.

269 Id. at p. 23.

Addiction in Britain" ("RCP 2000 Report.")[270]

A view of smoking as the equivalent to "nicotine addiction," in which the smoker has no choice but to smoke, is also inconsistent with the way in which society views the ability of individuals to make informed decisions:

To claim that an individual is unable to choose is a very radical view -- it reduces this individual to something less than a full person. It implies that his or her behaviour is governed by causal mechanisms beyond volitional control, and reduces the individual to a consumption robot -- a helpless spectator to his own body's movements.[271]

As stated by one commentator in the context of alcohol consumption:

While the decision not to drink is called control, the decision to drink is called lack of control. This asymmetry is ill-founded. Sometimes the actor's motives for abstaining are stronger than the opposite motives, and he abstains. At other times the motives for drinking are stronger, and he drinks. In both cases the actor controls his behaviour.[272]

This statement applies with equal force to an individual's decision to smoke, or to stop smoking.

6.5.4. MILLIONS OF PEOPLE HAVE STOPPED SMOKING

Putting aside the competing definitions of the term "addiction," cigarette smoking is not an "addiction" if the use of that term is intended to mean that a person is unable to stop smoking. While some smokers might have difficulty

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270 Royal College of Physicians. Nicotine Addiction in Britain: A report of the Tobacco Advisory Group of The Royal College of Physicians. London: Royal College of Physicians of London; 2000.

271 Skog O-J. Addict's choice. *Addiction* 2000; 95: 1309-14, at p. 1309.

272 Id. at pp. 1309-10.

in stopping, anyone can stop if they choose to do so. Millions of people in the UK and elsewhere have stopped smoking. Recent data indicates that there are at least 11 million people in the UK who have stopped smoking.[273] Furthermore, the vast majority of people who stop smoking have done so without any assistance. In the US, for example, according to a 1988 report, there were approximately 40 million former regular smokers, 90% of whom had quit without assistance.[274] As of 2003, *"[f]orty-four million Americans - almost half of those who have ever smoked - have quit."*[275]

6.5.5. NICOTINE REPLACEMENT THERAPY

The consultation emphasises the view that "nicotine dependence is a major determinant of the ease of quitting" (Section 2.15) and suggests that an initiative *"could aim to make existing medicinal nicotine products more widely and easily available to smokers as alternatives to cigarettes."* (Section 5.6) Indeed, if nicotine is "addicting" and explains why people smoke, it would be expected that use of nicotine replacement therapy ("NRT") would be highly effective in assisting smokers in stopping smoking, an expectation endorsed by the RCP 2000 Report.[276] By providing nicotine through a route other than smoking, NRTs would be expected to minimise, if not eliminate, the withdrawal symptoms and cravings that are said to be so distressing to smokers attempting to stop. Contrary to this expectation, however, the Tobacco Advisory Group of the Royal College of Physicians in its 2007 Report ("RCP 2007 Report") noted that NRT *"is not as efficacious as would be anticipated if tobacco dependence reflected a 'simple' addiction to nicotine."*[277] This conclusion confirms that, *The most well-known anomaly to the nicotine*

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273 Office for National Statistics General Household Survey 2003. London: The Stationery Office.
274 U.S. Surgeon General Report, 1988. p. 466.
275 National Cancer Institute. Those who continue to smoke: is achieving abstinence harder and do we need to change our interventions. Smoking and Tobacco Control Monograph 15. Hyattsville: National Cancer Institute; 2003. p. 1.
276 Royal College of Physicians, 2000. pp. 143-4.
277 Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP; 2007. p. 54.

addiction thesis is the modest efficacy of nicotine replacement therapy (NRT) for smoking cessation.[278]

There appears to be a consensus among researchers in the field that no NRT has been found to eliminate "craving" and "withdrawal."[279, 280, 281]

Although it is sometimes claimed that *"NRTs increase the rate of quitting by 50-70%,"*[282] to make this claim requires selective use of the data. A recent meta-analysis of 111 NRT studies found that in almost 60% of those trials, NRT either had no effect or was less effective than placebo.[283] In studies claiming that NRT is effective, the actual differences between NRT and placebo are small and, in fact, a recent study found that after 48 weeks, only 10% of people using NRTs had stopped smoking, in contrast to 12% of people using placebo.[284] In view of such reports, one prominent commentator noted that:

standard nicotine replacement strategies have produced only modest progress toward achieving higher quit smoking rates.[285]

While some people report that feelings of craving and withdrawal are reduced by NRTs, this may well be the result of a placebo effect. In fact, a study investigated this issue and showed that *"regardless of actual treatment, smokers who believed they had received nicotine had significantly better*

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278 Dar R, Frenk H. Re-evaluating the nicotine delivery kinetics hypothesis. *Psychopharmacology (Berl)* 2007; 192: 1-7.

279 Rose JE. Nicotine Addiction and Treatment. *Annu Rev Med* 1996; 47: 493-507.

280 Hughes JR, Hatsukami DK, Pickens RW, Krahn D, Malin S, Luknic A. Effect of nicotine on the tobacco withdrawal syndrome. *Psychopharmacology* 1984; 83: 82-7.

281 Abelin T, Buehler A, Muller P, Vesanen K, Imhof PR. Controlled trial of transdermal nicotine patch in tobacco withdrawal. *Lancet* 1989; 1: 7-12.

282 Stead L, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Datab Syst Rev* 2008; CD000146, at p. 2.

283 Id. at p.7.

284 Id.

285 Rose JE. Denicotinised cigarettes: a new tool to combat cigarette addiction? [Commentary]. *Addiction* 2007; 102: 181-2.

outcome than those who believed they had received placebo."[286] Thus, the placebo effect might well explain even the modest success ascribed to NRT.

It has been claimed that the limited efficacy of NRT is explained by the idea that nicotine derived from smoking reaches the brain in as little as 7-10 seconds, with arterial nicotine levels *"peaking approximately 20 seconds after each puff,"*[287] whereas nicotine derived from an NRT reaches the brain *"much more slowly."*[288] The UK DoH consultation document refers to this claimed difference in Section 5.7. However, results of a recent study are inconsistent with the claim that it takes 7-10 seconds for nicotine derived from smoking to reach the brain.[289] In fact, the study found that it took more than 2 ½ minutes for 90% of the nicotine in puffed cigarette smoke to reach the brain in smokers described as being "highly dependent." It also found, contrary to expectations, that in infrequent smokers the mean time for similar levels of nicotine in puffed cigarette smoke to reach the brain was approximately one minute. This led these researchers to observe that *"these results imply that some nicotine delivery systems (e.g. nasal spray) could deliver nicotine as rapidly as cigarettes, and that factors other than pharmacokinetics (e.g. irritation) may be important in influencing their acceptability and efficacy."*[290] In addition, although the inhaler and nasal spray versions of NRT increase plasma nicotine concentrations at about the same rate as nicotine derived from puffed cigarette smoke, these fast acting NRTs are not preferred over slower acting NRTs and are not reported to be more effective than slower acting NRTs.[291, 292]

It might also be expected that if nicotine were "addicting," nicotine administered in an NRT would be abused like heroin and other drugs of

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286 Dar R, Stronguin F, Etter J-F. Assigned versus perceived placebo effects in nicotine replacement therapy for smoking reduction: a secondary analysis of a large randomised trial in Swiss heavy smokers who were unwilling to quit. *J Consult Clin Psychol* 2005; 73: 350-3.

287 Royal College of Physicians, 2007 p. 23.

288 Id. at p. 24.

289 Rose JE, Garg S, Lokitz SJ, Turkington TG, Minton RC, Smith HC, Herskovic JE, Behm FM, Wildrick S, Garg PK. Slower brain uptake of inhaled nicotine in dependent cigarette smokers than in non-dependent smokers.[abstract PA1-1]. Proceedings of 13th Annual Meeting of the Society for Research on Nicotine and Tobacco; February 21-24, 2007; Austin, Texas. 2007.

290 Rose et al., 2007.

291 Hajek P, West R, Foulds J, Nilsson F, Burrows S, Meadow A. Randomised comparative trial of nicotine polacrilex, a transdermal patch, nasal spray, and an inhaler. *Arch Intern Med* 1999; 159: 2033-8.

292 Dar and Frenk, 2007.

abuse. However, there is no convincing evidence to suggest that NRTs are abused. A leading commentator observed that:

evidence of nicotine replacement product abuse is essentially nonexistent.[293]

The lack of efficacy of NRTs and the fact that they are not abused like usual drugs of abuse, present major challenges to the claim that cigarette smoking can be explained as an addiction to nicotine.

6.5.6. HUMAN SELF-ADMINISTRATION STUDIES

In light of the evidence regarding NRTs, it is not surprising that laboratory studies do not show that humans self-administer nicotine, despite claims to the contrary. In the field of research on the use and abuse of drugs, self-administration experiments are considered important evidence as to whether addiction potential exists. If test subjects will not willingly administer the substance, then the substance cannot be addicting.

In this field of research, a "reinforcer" is defined as any event that, when contingent upon a given behaviour, increases the frequency of the behaviour. Thus, if nicotine is "addicting," it would be expected to be a reinforcer and it would be expected that humans would engage in behaviour to obtain nicotine.

The results of studies designed to determine if non-smokers like nicotine have been summarised as follows:

The consistent result of all studies, however, is that regardless of the mode of administration, people who never smoked dislike the effects of nicotine.[294]

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[293] Hughes JR. Part IV. Behavioural toxicity of nicotine: Dependence on and abuse of nicotine replacement medications: An update. In: Benowitz NL, editors. Nicotine Safety and Toxicity. New York: Oxford University Press; 1998. pp. 147-57.

[294] Frenk H, Dar R. A Critique of Nicotine Addiction. Boston: Kluwer Academic Publishers; 2000. p. 95 [citations omitted].

Thus, studies of non-smokers show that they do not like nicotine.

The 1988 US SG Report claimed that *"studies of i.v. [intravenous] nicotine self-administration demonstrated conclusively that nicotine itself can serve as an effective reinforcer in humans,"* based on studies of abstinent smokers.[295] More recently, two groups of researchers (Harvey et al. 2004[296] and Sofuoglu et al. 2008[297]) have claimed success in human self-administration of nicotine.

The 1988 US SG Report relied upon prior research conducted by Henningfield and Goldberg, both of whom collaborated with Harvey in the 2004 study. However, Harvey, Henningfield and Goldberg in their 2004 publication accepted that it had not previously been shown that humans (abstinent smokers) will self-administer nicotine. As to the claim that their subsequent work discussed in their 2004 paper showed that humans will self-administer nicotine, the subjects in this study were told that they would be receiving either placebo or nicotine, and were further told that nicotine is a psychoactive substance. These factors could well have led the subjects to press the lever to obtain nicotine due to the expectation that nicotine would be rewarding, *"especially when confined to an isolated room for 3 hours at a time."*[298]

In 2008, Sofuoglu et al. claimed to have demonstrated self-administration of nicotine. However, a group analysing both Sofuoglu et al. (2008) and Harvey et al. (2004), found as follows:

Unfortunately, the blinding procedures in the Sofuoglu study are not clearly reported. A priori knowledge by participants that they would be selecting between nicotine, a drug they may believe they are addicted to, and an inactive placebo would be expected to confound the results, especially if they are able to distinguish between the substances. … Interestingly, in the only

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295 U.S. Surgeon General Report, 1988. p. 192.

296 Harvey DM, Yasar S, Heishman SJ, Panlilio LV, Henningfield JE, Goldberg SR. Nicotine serves as an effective reinforcer of intravenous drug-taking behaviour in human cigarette smokers. *Psychopharmacology* 2004; 175: 134-42.

297 Sofuoglu M, Yoo S, Hill KP, Mooney M. Self-administration of intravenous nicotine in male and female cigarette smokers. *Neuropsychopharmacology* 2008; 33: 715-20.

298 Dar R, Frenk H. Nicotine may reinforce intravenous drug-taking behaviour in drug users: a comment on Harvey et al. (2004). *Psychopharmacology* 2005; 179: 516-7.

previous 'demonstration' of i.v. nicotine self-administration in humans, participants were explicitly informed that they would be responding for either nicotine or placebo (Harvey et al. 2004). Furthermore, numerous investigations that have failed to observe nicotine self-administration have used protocols that have either attempted to blind participants to the substance they would be receiving (e.g. Henningfield et al. 1983) or to mask the stimulus properties of the placebo.[299]

Therefore, the recent analysis by Fulton and Barrett leads to the conclusion that human self-administration of nicotine has not been shown. These investigators concluded that:

… until nicotine self-administration is demonstrated (and replicated) using paradigms that employ adequately blinded conditions, it is premature to conclude that nicotine has reinforcing properties in the absence of tobacco in humans.[300]

6.5.7. ANIMAL SELF-ADMINISTRATION STUDIES

The proponents of the nicotine addiction view frequently claim that laboratory research has shown that animals will press a lever in order to obtain nicotine[301] and that such behaviour is the hallmark of the addiction potential of nicotine. Neither of these claims can withstand critical analysis.

In a classic animal self-administration study, a rat confined in a chamber learns that if it presses an active lever (behaviour) it receives food (reinforcer). In this example, the food is a positive reinforcer and it increases the tendency of the rat to press the active lever. Food is, in fact, a primary reinforcer -- the rat finds food naturally rewarding without any prior conditioning.

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299 Fulton HG, Barrett SP. A demonstration of intravenous nicotine self-administration in humans? *Neuropsychopharmacology* 2008; 33: 2042-3.

300 Id.

301 Royal College of Physicians, 2000. pp. 46-7.

One theory of addiction proposes that addictive drugs can act as primary positive reinforcers - they increase the tendency of the user to administer the drug because the drug itself is rewarding. The 1988 US SG Report identified the capability *"of functioning as a reinforcer"* to be a criterion of substances characterised as "pharmacologically addicting,"[302] and stated as follows:

The primary bio behavioural mechanism by which dependence-producing drugs maintain drug seeking is by functioning as positive reinforcers … That is, drugs can serve as stimuli that strengthen behaviour leading to their own presentation.[303]

While it is claimed that animals will self-administer nicotine, the studies relied upon for this claim have serious flaws and none show that animals will press a lever in order to get nicotine. These flaws include: (1) failure to extinguish a prior behaviour; (2) failure to control for the effect of variables such as light cues; and (3) failure to control for the general activating effects of nicotine. Some experiments have also suffered from basic methodological flaws. For example, in some experiments animals that did not learn to self-administer nicotine were inexplicably eliminated from the study.[304]

a. EXTINCTION

In an animal nicotine self-administration study, rats are usually first trained to press a lever to receive a reward, such as food. The rats then should undergo a procedure called "extinction." During the process of extinction, when the rats press the lever, they receive no food. Extinction is successful when the rats no longer try to obtain food by pressing the lever. However, if the experimenter does not allow sufficient time for extinction to occur, then, when again presented with a lever, the rats will press the lever expecting to obtain food. In experiments with nicotine, if extinction has not taken place before the

302 U.S. Surgeon General Report, 1988. p. 149.
303 Id. at p. 181.
304 Frenk and Dar, 2000. pp. 66-7 [citations omitted].

experimenter has substituted nicotine for food, the experimenter may mistakenly report that rats are pressing the lever to obtain nicotine. The results of some experiments claiming to have demonstrated nicotine self-administration are invalid precisely for this reason. In these experiments, animals that were food-deprived were observed to lever-press for nicotine, but animals which had ad libitum access to food did not lever-press, thus showing that the animals were lever-pressing in an effort to obtain food, rather than for nicotine.[305]

b. LIGHT CUES

A well designed and executed self-administration study must ensure that no unaccounted for variables can explain the observed results. Thus, in a nicotine self-administration study, control groups of animals are necessary to confirm that any increase in the frequency of lever-pressing in the animals that receive nicotine is in fact due to the reinforcing effect of nicotine.

In nicotine self-administration studies, the controls are animals injected with saline or with nothing when they press a lever. The frequency with which those animals press a lever is compared to the frequency with which another group of animals presses a lever to obtain nicotine. However, most nicotine self-administration experiments have used more than one variable. Often, when animals press a lever, they receive an injection of nicotine, but the lever-press also lights a cue light. Previous studies have shown that an animal will press a lever just to turn on a light.[306, 307, 308] Therefore, in these studies, the experimenter cannot tell if the animal is pressing the lever for the nicotine or for the cue light unless he has done additional experiments to determine how often animals will lever-press to obtain the light cue alone compared to controls. One such experiment would be to turn on a light cue when the

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[305] Id. at p. 64-5 [citations omitted].

[306] Harrington GM. Strain differences in light-contingent bar press behaviour of the rat. *Bulletin of the Psychonomic Society* 1979; 13: 155-6.

[307] Myslobodsky M. Petit mal epilepsy: a search for the precursors of wave-spike activity. New York: Academic Press; 1976.

[308] Williams DI, Lowe G. Light reinforcement in the rat: the effects of continuous and discontinuous periods of apparatus familiarisation. *Q J Exp Psychol* 1972; 24: 98-101.

animal presses the inactive lever, but none of the studies have used this option. A majority of the experiments claiming to have demonstrated nicotine self-administration in animal models have failed to account for the possible confounding effect of a light cue.[309, 310] Indeed, recent experiments that did control for the confounding effect of a light cue have confirmed that a light cue acts as a positive primary reinforcer.[311, 312, 313] In one experiment, the authors reported the following:

In this paradigm, the VS [visual stimulus] served as a primary reinforcer; rats responded to the VS in the absence of any other scheduled outcome.[314]

These authors also reported that:

Nicotine alone was a weak reinforcer; the VS alone was slightly more reinforcing than nicotine.[315]

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309 Frenk and Dar, 2000. p. 62.

310 Frenk H, Dar R. Reward potentiation or behavioural activation? A comment on Donny et al. [Letter to the Editor]. *Psychopharmacology* 2004; 171: 472-3.

311 Donny EC, Chaudhri N, Caggiula AR, Evans-Martin FF, Booth S, Gharib MA, Clements LA, Sved AF. Operant responding for a visual reinforcer in rats is enhanced by noncontingent nicotine: implications for nicotine self-administration and reinforcement. *Psychopharmacology* 2003; 169: 68-76.

312 Palmatier MI, Liu X, Matteson GL, Donny EC, Caggiula AR, Sved AF. Conditioned reinforcement in rats established with self-administered nicotine and enhanced by noncontingent nicotine. *Psychopharmacology* 2007; 195: 235-43.

313 Chaudhri N, Caggiula AR, Donny EC, Booth S, Gharib M, Craven L, Palmatier MI, Liu X, Sved AF. Self-administered and noncontingent nicotine enhance reinforced operant responding in rats: impact of nicotine dose and reinforcement schedule. *Psychopharmacology (Berl)* 2007; 190: 353-62.

314 Palmatier MI, Evans-Martin FF, Hoffman A, Caggiula AR, Chaudhri N, Donny EC, Liu X, Booth S, Gharib M, Carven L, Sved AF. Dissociating the primary reinforcing and reinforcement-enhancing effects of nicotine using a rat self-administration paradigm with concurrently available drug and environmental reinforcers. *Psychopharmacology* 2006; 184: 391-400.

315 Id. at p. 391.

c. GENERAL ACTIVATING EFFECT OF NICOTINE

Another variable for which experimenters often fail to control is the general activating effect of nicotine, which leads to increased locomotor activity. If a rat receives nicotine, the general activating effect of the nicotine make it more likely that the rat will randomly press a lever. Therefore, the experimenter might report that the rat is pressing a lever to receive nicotine when it is generally performing certain activities more frequently because of a previous nicotine injection. Many experiments have failed to control for the general activating effect of nicotine,[316, 317] although at least one experiment that specifically did account for this factor demonstrated that nicotine has a general activating effect.[318]

In light of the problems encountered in the animal research with nicotine, some of the most prominent researchers in this field have now backed away from the belief that the role of nicotine in smoking is that of a primary reinforcer. In fact, even the RCP 2007 Report concluded that *"nicotine alone is a relatively weak reinforcer in a self-administration paradigm."*[319] Researchers are now conducting self-administration studies designed to investigate whether or not nicotine may make other rewards associated with nicotine more rewarding.[320, 321, 322] In the context of smoking, these researchers are suggesting that while *"primary reinforcement by nicotine is not a sufficient explanation"* for smoking, it may play a role in enhancing the rewarding properties of *"sensorimotor stimuli associated with tobacco consumption."*[323] The RCP 2007 Report concluded that this new line of

316 Frenk and Dar, 2000. pp. 52-3.
317 Dar R, Frenk H. Nicotine self-administration in animals: a re-evaluation. *Addict Res Theory* 2002; 10: 545-79.
318 Donny EC, Caggiula AR, Rose C, Jacobs KS, Mielke MM, Sved AF. Differential effects of response-contingent and response-independent nicotine in rats. *Eur J Pharmacol* 2000; 402: 231-40.
319 Royal College of Physicians, 2007. p. 56.
320 Palmatier et al., 2007, citing Donny EC, Chaudhri N, Caggiula AR, Evans-Martin FF, Booth S, Gharib MA, Clements LA, Sved AF. Operant responding for a visual reinforcer in rats is enhanced by noncontingent nicotine: implications for nicotine self-administration and reinforcement. *Psychopharmacology* 2003; 169: 68-76.
321 Chaudhri et al, 2007. p. 360.
322 Palmatier MI, Liu X, Caggiula AR, Donny EC, Sved AF. The role of nicotinic acetylcholine receptors in the primary reinforcing and reinforcement-enhancing effects of nicotine. *Neuropsychopharmacology* 2007; 32: 1098-108.
323 Palmatier et al., 2007. p. 235.

research, *may be profoundly significant because it suggests that, in the self-administration paradigms employing animal models, responding is reinforced to a significant extent by the conditioned stimulus rather than the drug directly [citations omitted]…. If this observation translates to tobacco smoke, it implies that people may smoke, predominantly, for conditioned stimuli associated with inhaling tobacco smoke, rather than a simple dependence on the boli of nicotine present in each puff.*[324]

Thus, current research provides additional support for the proposition that smokers smoke because they enjoy smoking, rather than because they are "addicted" to nicotine.

6.5.8. NEUROCHEMISTRY

Notwithstanding the shift of emphasis among the animal researchers, there are still those who try to explain smoking behaviour on the basis of nicotine and its effect on the release of neurotransmitters (e.g. dopamine) in the brain. In fact, the observation that nicotine leads to the release of neurotransmitters is unremarkable. Researchers have reported that virtually all substances and activities that give pleasure to humans, from foods such as chocolate,[325] coffee,[326] and sugar,[327] to activities such as exercise[328] and sex,[329] and even seeing one's baby's smile,[330] also cause the release of neurotransmitters in the brain. In addition, neutral actions or situations such as mobility or immobility, as well as aversive stimuli such as an electric shock and other

[324] Royal College of Physicians, 2007. pp. 56-7.

[325] Bassareo V, Di Chiara G. Modulation of feeding-induced activation of mesolimbic dopamine transmission by appetitive stimuli and its relation to motivational state. *Eur J Neurosci* 1999; 11: 4389-97.

[326] Solinas M, Ferre S, You Z-B, Karcz-Kubicha M, Popoli P, Goldberg SR. Caffeine induces dopamine and glutamate release in the shell of the nucleus accumbens. *J Neurosci* 2002; 22: 6321-4.

[327] Hajnal A, Norgren R. Accumbens dopamine mechanisms in sucrose intake. *Brain Res* 2001; 904: 76-84.

[328] Adams J, Kirkby RJ. Excessive exercise as an addiction: a review. *Addict Res Theory* 2002; 10: 415-37.

[329] Pfaus JG, Damsma G, Wenkstern D, Fibiger HC. Sexual activity increases dopamine transmission in the nucleus accumbens and striatum of female rats. *Brain Res* 1995; 693: 21-30.

[330] Strathearn L, Li J, Fonagy P, Montague PR. What's in a Smile? Maternal brain responses to infant facial cues. *Paediatrics* 2008; 122: 40-51.

stressors (e.g., warnings of foot-shock),[331, 332] can also result in the release of dopamine. Therefore, the fact that a substance causes the release of dopamine in the brain is not a hallmark of anything definitive, much less that of "addictive" substances.

In recent years, the flaws in the simplistic view that dopamine release explains "addiction" to smoking have been further exposed through the increasing knowledge of nicotine neurochemistry. For example, the number of nicotinic receptors (which bind with nicotine molecules leading to the release of dopamine in the brain) are increased with regular smoking and it had been claimed that this was physical evidence of "addiction" to nicotine.[333, 334, 335] However, it has now been shown that the increase in the number of nicotinic receptors is not permanent and that their numbers return to baseline levels after smoking cessation.[336] Moreover, recent evidence suggests that nicotinic receptors are desensitised in regular smokers, so that some of the existing nicotinic receptors are incapable of triggering the release of dopamine.[337]

This evidence led to the statement in the RCP 2007 Report that *"this finding [regarding desensitisation of nicotinic receptors] may be highly significant, given the importance currently attributed to the mesolimbic dopamine system in mediating the reinforcing effects of nicotine …."*[338] The same publication concluded that, *"although cigarette smoking in humans promotes dopamine*

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331 Atrens DM. Nicotine as an addictive substance: a critical examination of the basic concepts and empirical evidence. *J Drug Issues* 2001; 31: 325-94.

332 Young AMJ, Ahier RG, Upton RL, Joseph MH, Gray JA. Increased extracellular dopamine in the nucleus accumbens of the rat during associative learning of neutral stimuli. *Neuroscience* 1998; 83: 1175-83.

333 Benwell ME, Balfour DJ, Anderson JM. Evidence that tobacco smoking increases the density of (-)-[3H] nicotine binding sites in human brain. *J Neurochem* 1988; 50: 1243-7.

334 Court JA, Lloyd S, Thomas N, Piggott MA, Marshall EF, Morris CM, Lamb H, Perry RH, Johnson M, Perry EK. Dopamine and nicotinic receptor binding and the levels of dopamine and homovanillic acid in human brain related to tobacco use. *Neuroscience* 1998; 87: 63-78.

335 Gentry CL, Lukas RJ. Regulation of nicotinic acetylcholine receptor numbers and function by chronic nicotine exposure. *Current Drug Targets - CNS & Neurological Disorders* 2002; 1: 359-85.

336 Breese CR, Marks MJ, Logel J, Adams CE, Sullivan B, Collins AC, Leonard S. Effect of smoking history on [3H] nicotine binding in human post-mortem brain. *J Pharmacol Exp Ther* 1997; 282: 7-13.

337 Watkins SS, Koob GF, Markou A. Neural mechanisms underlying nicotine addiction: acute positive reinforcement and withdrawal. *Nicotine Tob Res* 2000; 2: 19-37.

338 Royal College of Physicians, 2007. p. 33.

release, the contribution of this effect to sustained smoking behaviour in humans is still not fully understood."[339]

Clearly, there is new thinking afoot about nicotine and the role it might play in smoking behaviour, even among those who espouse the addiction view of smoking. It would be most unfortunate if the current UK DoH consultation led to new regulations based on outmoded and outdated science.

6.5.9. SMOKING CESSATION

The consultation states that *"most smokers ["seven smokers in ten"] want to quit, and in the course of a year just under half make a quit attempt, but only 2–3% succeed in quitting for good each year."* (Section 4.4) This statement echoes a similar statement appearing under the heading "Difficulty in controlling use" in the RCP 2000 Report which stated:

In the UK, about 80% of smokers have made at least one attempt to quit, and some 30% make at least one attempt each year. Only a tiny proportion of quit attempts succeed, so that only approximately 1% of smokers in the UK become long-term ex-smokers each year.[340]

Although these figures are used to suggest that individuals find stopping smoking to be prohibitively difficult, they are, in fact, misleading and do not bear at all on the ability of a smoker to stop smoking. To begin with, expressions of a desire to quit are meaningless without further context or elaboration. By way of example:

… almost half of Los Angeles residents say they'd like to live elsewhere and … nearly a third of blue-collar workers say they'd like to leave their jobs. The fact that these people stay where they are does not mean they are powerless

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339 Id. at p. 39.
340 Royal College of Physicians, 2000. p. 86.

to change their situations. Rather, it indicates that they are not prepared to bear the costs of making a change, including the benefits they would have to give up.[341]

Indeed, a stated desire to stop smoking may amount to nothing more than a vague and unspecific expression of future intent. According to data published by the NHS from 2005, for example, 72% of smokers interviewed said they *"would like to give up".* However, when broken down into further categories, as many as 31% said they wanted to give it up only *"a fair amount"* or *"a little".*[342]

Furthermore, frequently the expression of a desire to do something does not translate into action. Someone who reports wanting to stop smoking may in fact make no effort to do so. For example, in a study involving 11,709 current smokers, 4,775 said *"they would be interested in stopping smoking if a smoker's clinic were arranged."* [343] However, when it came to following through on their stated desire, *"257 (5%) attended a preliminary meeting about the clinic, and only 150 (3%) made use of the clinic."*[344]

Another study evaluating this concept described its findings as follows:

In the most recent United States survey, 68% of smokers stated that they were 'interested' in quitting. … However, if the question is asked in a more concrete way: 'Are you planning on quitting in the next month?', less than 20% agree.[345]

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341 Viscusi WK. Smoking: making the risky decision. New York: Oxford University Press; 1992.

342 The Information Centre. Statistics on NHS stop smoking services in England, April 2005 to March 2006. London: The Information Centre; 2006. p. 58.

343 Kozlowski LT, Herman CP, Frecker RC. What researchers make of what cigarette smokers say: filtering smokers' hot air. *Lancet* 1980; 1: 699-700, at p. 699.

344 Id.

345 Hughes JR. Four beliefs that may impede progress in the treatment of smoking. *Tob Control* 1999; 8: 323-6, at p. 323.

Data from yet another recent (2006) study also bears on this issue:

Two thirds of American smokers are not presently planning to quit, meaning that more than 30 million smokers are not thinking about changing their smoking status any time soon.[346]

Thus, irrespective of the reported figures for people stating a desire to stop smoking, in fact few may have any plans to take any positive steps towards doing so.

People may report a desire to stop smoking for a number of reasons, including simply responding to a questioner in the manner they feel appropriate for the situation:

How better for a smoker to avoid the pesterings of a physician or other interviewer than to say (whether believing it or not) that he wants to and has even tried to give up cigarettes?[347]

This point is illustrated in a well-known experiment involving heroin users. When asked questions about their substance use by a "suit-wearing interviewer" on one occasion, and by a known heroin user on another, the subjects conformed their answers to what they thought the different interviewers wanted to hear. Thus, they *"portrayed a stronger version of the 'helpless addict'" to the formally dressed interviewers in comparison to the answers they provided to the known heroin user".*[348]

Likewise, the percentages of "attempts" at smoking cessation indicated in the above statements from the Department of Health and elsewhere have to be

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346 McCaul KD, Hockemeyer JR, Johnson RJ, Zetocha K, Quinlan K, Glasgow RE. Motivation to quit using cigarettes: A review. *Addict Behav* 2006; 31: 42-56, at p. 43.

347 Kozlowski et al., 1980. p. 699.

348 Davies JB. Reasons and causes: understanding substance user's explanation for their behaviour. *Hum Psychopharmacol* 1996; 11: s39-s48, at p. S42, citing Davies JB, Baker R. The impact of self-presentation and interviewer bias effects on self-reported heroin use. *Br J Addict* 1987; 82: 907-12.

viewed with caution. Absent independent and objective measures, it is not possible to verify individuals' claimed quit attempts. In the statistics reported above, for example, what qualifies as an attempt to stop smoking is not defined. For example, if an individual wakes up in the morning and decides to stop smoking, but lights up a cigarette several hours later, it is difficult to see how that qualifies as an attempt to stop smoking. A legitimate attempt should involve serious efforts to change a daily smoking routine. None of this detail is addressed in sweeping statements about self-reported quit attempts.

Thus, the percentages of people who claim a desire to stop smoking, as well as the self-reported percentage of unsuccessful attempts to stop, are not informative or useful in quantifying the number of people who are having difficulty in stopping smoking, or how seriously "addicting" smoking or nicotine may be. Indeed, if the lack of success in smoking cessation were attributable to severity of the "addiction," it would be expected that severity of reported "withdrawal" symptoms and "craving" for smoking would accurately predict likelihood of success of smoking cessation. In fact, this is not the case. As the RCP 2000 Report has stated, *"severity of withdrawal is only a weak predictor in stopping smoking."*[349, 350] Severity of "craving" for cigarettes is also not an accurate predictor of success at smoking cessation.[351]

Numerous studies have also reported that satisfaction of DSM-IV (TR) criteria for a diagnosis of "nicotine dependence" is a weak predictor of success in smoking cessation.[352] Moreover, the resumption of smoking does not follow the time-course that would be expected if it were due to "withdrawal" severity, as most resumption of smoking takes place well after the first few weeks of abstinence, the period when "withdrawal" symptoms and "craving" are reported to be at their greatest.[353, 354, 355]

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349 Royal College of Physicians, 2000. p. 143.

350 Patten CA, Martin JE. Does nicotine withdrawal affect smoking cessation? Clinical and theoretical issues. *Ann Behav Med* 1996; 18: 190-200.

351 Gossop M. Compulsion, craving and conflict. In: Warburton DM, editors. Addiction Controversies. Chur: Harwood Academic Publishers; 1990. p. 236-49.

352 Hendricks PS, Prochaska JJ, Humfleet GL, Hall SM. Evaluating the validities of different DSM-IV-based conceptual constructs of tobacco dependence. *Addiction* 2008; 103: 1215-23.

353 Patten et al., 1996.

354 West R, Hajek P, Belcher M. Severity of withdrawal symptoms as a predictor of outcome of an attempt to quit smoking. *Psychol Med* 1989; 19: 981-5.

What studies uniformly do report, however, is that motivation is *"a critical factor in whether or not [one is] likely to quit."*[356] Motivation is also significantly associated with success in smoking cessation.[357, 358, 359, 360, 361, 362, 363, 364, 365] In other words, and not surprisingly, anyone who is motivated to stop smoking can do so, and the more motivated one is, the more likely they are to be successful in a quit attempt.

The simple fact that motivation is crucial to smoking cessation is not surprising and, as stated in Section 4.4 of the Consultation, is consistent with the data demonstrating that individuals seeking help in smoking cessation (through either use of NRTs and/or other help) are more likely to succeed than those who do not. As discussed above, this cannot be explained by the efficacy of NRTs. Rather, individuals who take steps like purchasing NRTs and seeking advice in stopping smoking demonstrate a level of motivation that is not necessarily reflected in those who claim to want to stop smoking but do not take such steps. In addition, as discussed above, using an NRT that one expects will help in smoking cessation can result in a placebo effect.[366]

This is not to deny that some people experience difficulty in stopping smoking, or that some people have tried to give up smoking several times, only to resume smoking at a later time. However, to attempt to explain an individual's

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355 Hall SM, Havassy BE, Wasserman DA. Commitment to abstinence and acute stress in relapse to alcohol, opiates, and nicotine. *J Consult Clin Psychol* 1990; 58: 175-81.

356 Foulds J. Strategies for smoking cessation. *Br Med Bull* 1996; 52: 157-73, at p. 158.

357 Dale LC, Olsen DA, Patten CA, Schroeder DR, Croghan IT, Hurt RD, Offord KP, Wolter TD. Predictors of smoking cessation among elderly smokers treated for nicotine dependence. *Tob Control* 1997; 6: 181-7, p. 183.

358 Foulds, 1996. p. 158.

359 Osler M, Prescott E. Psychosocial, behavioural, and health determinants of successful smoking cessation: a longitudinal study of Danish adults. *Tob Control* 1998; 7: 262-7.

360 Sciamanna CN, Hoch JS, Duke GC, Fogle MN, Ford DE. Comparison of five measures of motivation to quit smoking among a sample of hospitalised smokers. *J Gen Intern Med* 2000; 15: 16-23.

361 Marlatt GA, Curry S, Gordon JR. A longitudinal analysis of unaided smoking cessation. *J Consult Clin Psychol* 1988; 56: 715-20.

362 Boardman T, Catley D, Mayo MS, Ahluwalia JS. Self-efficacy and motivation to quit during participation in a smoking cessation program. *Int J Behav Med* 2005; 12: 266-72.

363 McCuller WJ, Sussman S, Wapner M, Dent C, Weiss DJ. Motivation to quit as a mediator of tobacco cessation among at-risk youth. *Addict Behav* 2006; 31: 880-8.

364 Peters EN, Hughes JR, Callas PW, Solomon LJ. Goals indicate motivation to quit smoking. *Addiction* 2007; 102: 1158-63.

365 Nezami E, Sussman S, Pentz MA. Motivation in tobacco use cessation research. *Subst Use Misuse* 2003; 38: 25-50.

366 Dar and Frenk, 2005. pp. 516-7.

lack of success in smoking cessation as the result of "addiction" lacks explanatory power. It is merely a convenient way to try to explain a behaviour ("smoking") by attributing a reason for the behaviour (*"people smoke because they are addicted"*). As explained in detail above, the terms "addiction" and "dependence" today are used so ubiquitously and to refer to so many different activities, use of substances, and behaviours as to render the terms devoid of real and useful meaning.

Instead, it is more useful to analyse why people may find it difficult to stop smoking in the context of why people generally may find it difficult to alter other habits. As one observer has noted:

… smoking can be considered an automatic behaviour in the sense that, when it is well practiced, it can be performed with minimal use of attentional resources. … many repetitive behaviours that have been labelled 'addictive,' such as smoking, gambling, and eating, may be particularly difficult to control because they require very little attention to perform but considerable attention to alter or inhibit.[367]

The same authors noted that *"the idea that smoking behaviour … occurs automatically does not imply that the behaviour is uncontrolled or uncontrollable …."*[368] When coupled with the fact that smoking confers many and different benefits to smokers in different times and situations, as discussed in detail above, it is understandable that altering this habit and stopping smoking might be difficult for some people.

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[367] Baxter BW, Hinson RE. Is smoking automatic? Demands of smoking behaviour on attentional resources. *J Abnorm Psychol* 2001; 110: 59-66.

[368] Id.

6.6. CONCLUSION

Cigarette smoking is a settled practice or habit from which smokers derive benefits. Cigarette smoking is not an addiction if by that term it is meant that smokers are unable to stop smoking. Millions of smokers have stopped smoking in the UK and elsewhere, and the vast majority have done so without assistance. This is not to deny that some people might have difficulty in stopping, but any smoker can stop if he or she chooses to do so.

7. POTENTIALLY REDUCED EXPOSURE AND POTENTIALLY REDUCED RISK PRODUCTS FOR THOSE WHO CHOOSE TO SMOKE

7. POTENTIALLY REDUCED EXPOSURE AND POTENTIALLY REDUCED RISK PRODUCTS FOR THOSE WHO CHOOSE TO SMOKE

7.1. SUMMARY

Imperial Tobacco has long requested the UK Government to develop criteria by which tobacco products can be judged on the basis of their relative risks. These would serve to provide adult consumers with the means by which they can manage their own health by choosing recognisable tobacco products that may offer reduced risk. There has been little progress on this.

Successive UK governments appear to have been ambivalent with regard to the concept of so-called "reduced harm" or "reduced risk" tobacco products. Our experience in developing and marketing a concept called New Smoking Material in the 1970s highlighted the importance of collaboration and the establishment of common goals between the tobacco industry and the Government.

Specific Government aims should be made clear if there is to be progress on this issue. However, the debate is overly politicised by the emotional intervention of many single issue pressure groups which do not seem to understand the relevant science.

Imperial Tobacco continues to conduct research into tobacco products which may come to be regarded as potentially offering reduced risk to consumers. We have submitted data on such products to the DoH but, as yet, have received no considered expert review.

In the consultation document the Department of Health notes the significant effort by the tobacco industry in the research and development of Potentially Reduced Exposure Products but that the "[e]vidence on the *relative safety of these products is not conclusive*[369]".The lack of evidence on the relative risks

[369] Department of Health (2008). Consultation on the future of tobacco control. p.54, para.5.18.

of these products is in part due to a lack of consensus on objective criteria and predictive tests required to make such a comparative analysis.

If the Department of Health is serious in exercising its obligations to people who choose to continue smoking, the best way forward is to pursue a policy of constructive dialogue with Imperial Tobacco and other tobacco manufacturers with the aim of developing the objective criteria and predictive tests that are essential to make progress in this area.

7.2. INTRODUCTION

Imperial Tobacco welcomes the opportunity to discuss ways in which the products that smokers continue to smoke can be comparatively evaluated on an objective, scientific basis and thereby improved for their benefit. We have for some time called upon the UK Government to develop criteria by which tobacco products can be judged on the basis of their relative risks (summarised in our annual Corporate Responsibility ("CR") Reviews 2004, 2005, 2006 and 2007). These criteria would serve to provide adult consumers with further means by which they can manage this aspect of their own health by choosing recognisable tobacco products that may offer reduced risk. There has been little progress on this issue, and the debate has centred more recently on smoking tobacco compared with smokeless tobacco or snus. However, this type of tobacco may only be of interest to a small minority of adult smokers who may wish to exercise their choice for what they see as a reduced risk product.

Imperial Tobacco acknowledges the considered work of the Committees on Carcinogenicity, Mutagenicity and Toxicology in their dispassionate reviews of the relevant science. This is an ideal approach that we fully support. Their conclusions coincide directly with our own, as stated in our CR Review 2005:

> "*The Committees commented that tobacco smoke was a highly complex chemical mixture and that the causative agents for smoke induced diseases (such as cardiovascular disease, cancer, effects on reproduction and on offspring) were unknown. The mechanisms by which tobacco induced adverse effects were not established.*"

> *"The Committees therefore agreed that, on the basis of current knowledge, it would be very difficult to identify a toxicological testing strategy or a bio monitoring approach for use in volunteer studies with smokers where the end-points determined or biomarkers measured were predictive of the overall burden of tobacco-induced disease*[370]*."*

This should spur on the government to work with the tobacco manufacturers to develop meaningful, proportionate and soundly-based testing regimes, rather than seeking to impose ill-advised and ill-thought through regulation.

7.3. HISTORICAL DEVELOPMENTS

In the early 1950s, very little was known about the chemical constituents of either tobacco or tobacco smoke and, after consulting independent scientists, we concentrated our research in this area.

In 1960, the UK tobacco manufacturers decided to set up a purpose-built facility to conduct research relating to smoking and health. The broad objectives of this research were to develop reliable tests for measuring any biological activity of tobacco smoke; to identify any potentially harmful constituents and, if possible, to remove them. As explained later, this may still be relevant today. Tobacco smoke was found to be a highly complex mixture and by the late 1960s hundreds of compounds had been identified in the smoke of a typical cigarette.

Scientific advisers to the UK Government at the time believed that one way to reduce potentially harmful constituents would be by lowering tar yields. Values obtained using tar yield measurements appear on the packs of many cigarettes today. However, despite the continued imposition and reduction of tar yield ceilings, further reductions are unjustified since the benefits of such reductions are no longer endorsed by the UK and other governments. Some public health authorities now believe that new approaches are necessary.

[370] Committees on Toxicity, Carcinogenicity, Mutagenicity of Chemicals in Food, Consumer Products and the Environment (2004). Joint Statement on Re-assessment of the Toxicological Testing of Tobacco Products. Department of Health, London. ttp://cot.food.gov.uk/pdfs/cotstatementtobacco0409

Successive UK governments appear to have been ambivalent with regard to the concept of so-called "reduced harm" or "reduced risk" tobacco products. In the 1970s, in close collaboration with Imperial Chemical Industries and the Independent Scientific Committee on Smoking & Health (the Hunter Committee), Imperial Tobacco developed a concept called New Smoking Material (NSM) and then placed it on the market. During the development of NSM, Imperial provided vast amounts of data to the Hunter Committee. In April 1977, the Hunter Committee gave its limited endorsement to such products, stating that they *"are certainly no worse than tobacco and there is some evidence that they will make smoking cigarettes containing them safer*[371]*"*. Unfortunately, these efforts at reducing smokers' risks were actively campaigned against and undermined by the UK government funded by the Health Education Authority.

7.4. RECENT DEVELOPMENTS

An approach to reduce the potential risks associated with smoking that is still relevant today is thought to be by the removal of certain selected smoke constituents. The resulting products have been called "potentially reduced exposure products" (PREPs). Issues associated with their development have been reviewed by the Institute of Medicine in the USA which in its 2001 report *"Clearing the Smoke"* concluded that *"for many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible*[372]*."*

In its 2007 report, entitled *"Scientific Methods to Evaluate Potential Reduced-Risk Tobacco Products"*, the Life Sciences Research Office concluded that *"reliable testing and assessment methods for individual risk reduction are currently available for premarket evaluation of potentially reduced risk tobacco products*[373]*"*.

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[371] The Tobacco Industry and the Health Risks of Smoking, House of Commons Health Select Committee, Session 1999-2000, volume II, p.213.1

[372] Institute of Medicine (2001). Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction. National Academy Press, Washington DC.

[373] LSRO (2007). Scientific Methods to Evaluate Potential Reduced-Risk Tobacco Products. ISBN: 0-9753167-7-X

7.5. CONCLUSIONS

Our experience illustrates that PREPs are best developed in collaboration with Government Competent Authorities, recognising that potentially reduced exposure to certain smoke constituents does not necessarily mean that the risks associated with smoking will be reduced for all smokers. To our knowledge no regulatory authority in the world has agreed to a testing strategy by which such products could be assessed.

Specific Government aims should be made clear if there is to be progress on this issue. However, the debate is overly politicised by the emotional intervention of many single issue pressure groups which do not seem to understand the relevant science.

For our part, we continue to conduct research into tobacco products which may come to be regarded as potentially offering reduced risk to consumers. We have submitted data on such products to the UK Department of Health, but as yet we have received no considered expert review and in one instance, we did not even receive an acknowledgement of our submission.

In the consultation document the Department of Health notes the significant effort by the tobacco industry in the research and development of PREPs but that the "*evidence on* the *relative safety of these products is not conclusive*[374]".

The lack of evidence on the relative risks of these products is in part due to a lack of consensus on objective criteria and predictive tests required to make such a comparative analysis.

If the Department of Health is serious in exercising its obligations to people who choose to continue smoking, the best way forward is to pursue a policy of constructive dialogue with Imperial Tobacco and other tobacco manufacturers with the aim of developing the objective criteria and predictive tests that are essential to make progress in this area.

[374] Department of Health (2008). Consultation on the future of tobacco control. p.54, para.5.18.

8. MINIMISING EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE (ETS)

8. MINIMISING EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE (ETS)

8.1. SUMMARY

Imperial Tobacco believes that the decision to use tobacco products is a choice for adults. In as much as smokers should show courtesy to other adults, this courtesy should especially be extended to children, who are often unable to exercise a choice in their environment and surroundings in the way that adults can.

However, Imperial Tobacco completely rejects the notion that further restrictions on smoking in private premises or in private vehicles in isolation are in any way justified. It is our view that Government has no role in regulating the private lives of adults in the UK who have chosen to smoke.

Imperial Tobacco's view on Environmental Tobacco Smoke (ETS) concurs largely with the opinion expressed by the Economic Affairs Committee of the House of Lords in 2006 that: *"the decision to ban smoking in public places [in the UK] may represent a disproportionate response to a relatively minor health concern."*

Rather than encouraging smoking cessation, the smoking ban has instead had a well-documented negative impact on many other UK businesses, especially in the hospitality sector.

The UK Department of Health should stand aside from the emotion of vested interests and critically re-examine the impact of the existing ban, accepting that there have been negative impacts both in financial and in social terms. These areas need to be addressed in the forthcoming review of the smoking ban which is scheduled for 2010.

Imperial Tobacco believes that adults who choose to smoke and non-smokers who choose to accompany them should be able to do so in primarily adult venues in which they work and socialise.

In reassessing this balance, the Government should give consideration to the proven potential of ventilation to achieve exceptional indoor-air quality, even in venues where smoking may be permitted. To focus entirely on the elimination of smoking ignores other substances that affect indoor-air quality, and smoke free policies have removed the incentive for many owners to provide effective ventilation in their premises. We therefore believe that indoor-air standards for workplaces and hospitality venues would provide a more comprehensive and holistic approach to achieving beneficial indoor-air quality.

8.2. INTRODUCTION

In its consultation paper, the Department of Health contends that *'Exposure to second-hand smoke is a serious health hazard, and there is no safe level of exposure*[375]*.*

Although many people in the UK now believe that environmental tobacco smoke (ETS) is harmful, this belief has been fostered over the past thirty years by individuals and organisations such as the tobacco control pressure group Action on Smoking & Health (ASH). ASH describes its methods as including *"Advocacy and lobbying of all relevant stakeholders for practical public policy measures to control tobacco ...."*[376] In deploying that methodology, ASH asserts that exposure to ETS causes death and disability from diseases ranging from cervical cancer to stroke and claims that its assertions are scientifically based.

However, while public health organisations continue to publish documents claiming that ETS is hazardous to health and that there is *"no safe level"* of exposure to ETS, governmental bodies and others, including scientists, who are not influenced or controlled by these organisations or by the anti-tobacco lobbies, continue to reject these claims. For example, in 2001, after an investigation that lasted more than six years, the United States' Occupational Safety and Health Administration (OSHA) stated that the *"original risk and*

[375] Department of Health, Consultation on the Future of Tobacco Control, para 3.96
[376] Action on Smoking and Health – aims and methods, from its website http://www.ash.org.uk/ on 14/02/2006

exposure estimates [of ETS] are not valid"[377] and withdrew its Notice of Proposed Rulemaking to protect workers in the workplace from ETS. In 2006, the Economic Affairs Committee of the House of Lords in the United Kingdom examined the issues of ETS and health and concluded that *"the decision to ban smoking in public places [in the UK] may represent a disproportionate response to a relatively minor health concern…* [and that] *lessons learned from the progress of this legislation should be used to ensure that future policy responses are transparent, evidence-based, and proportionate."*[378]

Moreover, any researcher publishing data that do not support the claimed health danger of ETS is attacked by the public health advocates as not acting in the interests of public health. Thus, when the British Medical Journal published data from the American Cancer Society (CPS I) study in 2003[379], showing no association between ETS exposure and disease, the author, Dr. J. Enstrom, was widely criticised. The crux of the criticism had less to do with his data than the fact that his study was funded in part by tobacco manufacturers. The Editor of the BMJ was subjected to the same criticism. In a reasoned rebuttal to that criticism, the Editor concluded with these words *"… I found it disturbing that so many people and organisations referred to the flaws in the study without specifying what they were. Indeed, this debate was much more remarkable for its passion than its precision."*

More recently, Professor James E Enstrom was moved to publish a detailed response to the many criticisms of his research findings[380]. This was done to defend the honesty and scientific integrity of his research and to *"… respond to my most powerful critics, who have attempted to suppress and discredit findings that do not support their ideological and political agendas".*

In summary, Enstrom said *"It is very disturbing that a major health organization like the ACS has made false and misleading statements about*

[377] The U.S. Secretary of Labor's response to US Action on Smoking and Health Petition for Writ of Mandamus, In re Action on Smoking and Health (ASH), No. 01-1199 (D.C. Cir. Aug. 10, 2001), at p. 9.
[378] House of Lords Select Committee on Economic Affairs: Government Policy on the Management of Risk. Volume 1: Report, 7 June 2006, at p. 26.
[379] Enstrom J E & Kabat G C, Environmental tobacco Smoke and tobacco related mortality in a prospective study of Californians 1960-1998, BMJ 2003;326: 1057-1061.
[380] Enstrom J E, Defending legitimate epidemiologic research: combating Lysenko Pseudoscience, Epidemiologic Perspectives & Innovations 2007, 4:11

me and my May 17, 2003 BMJ paper for over four years. It is further disturbing that prominent individuals like Thun, Samet, and Glantz have continued to attack the findings in the BMJ paper, even though I have presented extensive evidence that supports the validity of these findings. In addition, it is reprehensible that the BMJ paper was inserted in the USDOJ RICO lawsuit and omitted from the 2006 Surgeon General's Report. These actions must be kept in mind when evaluating the honesty, integrity, and objectivity of those responsible."

8.3. CHEMICALS IN INDOOR AIR FROM SMOKING

No real-life environment is free from chemicals and particles. Any consideration of tobacco smoke and ETS must take proper account of the complex chemical nature of the background environment.

"Mainstream smoke" is the smoke that is inhaled directly by a smoker. "Sidestream smoke" emanates from the lit end of a tobacco product or is exhaled smoke.

ETS is not a single entity, but rather is indoor air in general to which chemicals derived from tobacco smoke (either sidestream or mainstream) are added. These chemicals are immediately and highly diluted by the indoor air.

Commenting on ETS, the International Agency for Research on Cancer (IARC) recognised this *"considerable air dilution,"* stating that: *"…it must be kept in mind that exposure to SS [sidestream smoke] occurs under considerable air dilution, while the MS [mainstream smoke] of cigarettes is inhaled without major dilution".*[381]

Thus, smoking in an indoor environment contributes chemicals to indoor air which immediately become part of the complex chemical mixture that is indoor air. Moreover, the vast majority of cigarette smoke constituents that have been measured in indoor air are already present in indoor air from sources other than smoking. The IARC Report quoted above accepts that indoor air is

[381] International Agency for Research on Cancer. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans: tobacco smoking. Volume 38. Lyon, France: World Health Organization - International Agency for Research on Cancer; 1986. at p. 121

also affected by building materials and other building properties; ventilation; the many products in daily use in households; and activities such as cooking, exercising, sleeping and smoking.

All the chemicals in indoor air that are attributed to smoking are immediately and highly diluted by the indoor air itself and most of the chemicals present in ETS are present in very small amounts. The vast majority of the tobacco smoke constituents that have been measured in indoor air are already present in indoor air from sources other than smoking.

Occupational or workplace exposure levels (WELs) have been set in relation to many of the tobacco smoke constituents that have drawn the attention of public health bodies. While most of the chemicals present in tobacco smoke have not been measured in indoor air in real life, the indoor air concentration of tobacco smoke constituents that have drawn the attention of public health bodies can be calculated with reference to nicotine, which is unlikely to be present from other sources. The quantity of these chemicals in tobacco smoke has been calculated in the laboratory[382] and the quantity is related to the concentration of nicotine.

Therefore, from a given indoor air concentration of nicotine, the concentration of other chemicals contributed by tobacco smoke to indoor air and of interest to public health bodies can be calculated. Performing that calculation, even assuming an exaggerated air/nicotine concentration of 100 µg /m3, shows that the other smoke derived chemicals are present only in very small amounts.[383]

For each tobacco smoke constituent for which an occupational exposure limit (WEL) has been set the predicted concentration, even under exaggerated exposure conditions, is far below the 8-hour workplace exposure limit.

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[382] Gregg E, Hill C, Hollywood M, Kearney M, McAdam K, McLaughlin D, Purkis S, Williams M. The UK Smoke Constituents Testing Study. Summary of results and comparison with other studies. Beitr Tabakforsch Intl 2004; 21: 117-38.

[383] That 100 µg /m3 is an exaggerated air nicotine concentration is validated by real-life indoor air nicotine data. In fact, a comprehensive review identified 243 published values for mean indoor air nicotine and more than 85% of them were less than 20 µg/m3 with only two exceeding 100 µg/m3, in what were very unusual circumstances. Jenkins RA, Guerin MR, Tomkins BA In: Eisenberg M, editors. The chemistry of environmental tobacco smoke: composition and measurement. Second ed. Boca Raton: CRC Press LLC; 2000.

8.4. THE NEGATIVE IMPACT OF THE 2007 SMOKEFREE REGULATIONS

The smoking ban has had a negative impact on many UK businesses. Adults who choose to smoke should be able to do so in primarily adult venues in which they work and socialise.

Although the current consultation does not address the 2007 Smokefree Regulations, it is inappropriate to comment on smoking in the home or in private vehicles in isolation without also acknowledging the detrimental consequences of limiting the opportunities for adults to smoke in social settings and in workplaces.

In 2006 an independent study confirmed that the Scottish ban on smoking had led to a 10% decrease in sales of food and alcohol in hospitality venues and a 14% decrease in customers in Scottish public houses within the first three months of the ban.[384] Since these are average figures, the statistics hide the true extent of the negative impact in some sectors of the hospitality trade.

Imperial Tobacco regrets the negative impact that the smoking ban in the UK has had on many UK businesses and on the quality of life of many adults (smokers and non smokers) who wish either to enjoy smoking or the company of smokers in social settings and believes that adults who choose to smoke should be able to do so in primarily adult venues. This includes those places in which people both work and socialise.

In the UK hospitality trade - pubs, nightclubs, casinos, betting shops and bingo halls - it is British bingo (an adult pursuit) that is suffering the most following the smoking ban. Club revenues in Scotland reportedly declined by between 17 and 27 per cent during the first six months of the ban. Market research provided by Mintel estimates that overall the club market in the rest of the UK is set to shrink by 12%. This is in sharp contrast to the 24%

[384] Short-run economic effects of the Scottish smoking ban, Adda J, Berlinski S, Machin S,; International Journal of Epidemiology, December 2006.

increase in club trade seen between 2004 and 2005 the industry's most recent growth peak.[385]

Drinking pubs have also been badly hit, especially if they have no means to create an outdoor space for smokers and those that are not positioned to focus on food sales. Pubs have been closing at a rate of 27 per week - nearly four every day - over the past year, according to figures released in March 2008 by the British Beer & Pub Association.[386] The current closure rate is seven times faster than in 2006 and 14 times faster than in 2005; 1,409 pubs closed during 2007.

In 2007 Imperial Tobacco made its response to the European Commission Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level' through the Confederation of European Community Cigarette Manufacturers (CECCM).[387]

The CECCM paper advocated the adoption of an EU-wide smoking ban with exemptions for adults in enclosed public places and workplaces. Our view is that any employer or responsible person, including owners or managers within the hospitality sector (e.g. restaurants, pubs and bars), should be able to elect to set aside physically separate, ventilated and designated parts of their premises where adults who choose to smoke may continue to do so, and where non-smokers who choose to accompany adult smokers may join them.

Without challenging the evidence provided in the consultation paper from Ireland and Scotland, it remains the case that the impact of recent smoking bans across the UK on overall consumption of tobacco products has been smaller than anticipated. Imperial Tobacco currently estimates the negative impact of the comprehensive ban on smoking in public places in the UK on our overall cigarette volumes to be around 4 per cent and, as with our experiences in other markets such as Ireland and Italy, we expect this impact to diminish over time.

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[385] The Impact of the Smoking Ban - UK - December 2007 http://www.mintel.com
[386] BBPA 'Pub closures accelerate towards 30 per week', 05 March 2008
[387] Confederation of European Community Cigarette Manufacturers (CECCM) Response to European Commission Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level' - 4th April 2007

It is clear from this that adults who choose to smoke will continue to do so, and that owners and managers of facilities who value smokers as customers will make every effort to accommodate them. It makes sense therefore within an overall tobacco control strategy to acknowledge this and to make appropriate provision for smokers in primarily adult venues.

Imperial Tobacco believes that smoking must be viewed as an adult activity. Adults who choose to smoke should be able to do so in primarily adult venues and non-smokers who choose to accompany them should be able to do so. This must include the places in which people work and socialise.

8.5. THE CASE FOR VENTILATION

One important aspect that has not been addressed in the UK's smokefree regulations is the efficacy of ventilation. Imperial Tobacco acknowledges that ETS can be annoying to both smokers and non-smokers in some situations and believes that ventilation is an important tool in producing a comfortable environment in social settings where smoking occurs.

Many studies of ventilation have been performed in environments where the highest concentrations of constituents of tobacco smoke can be expected, such as pubs, restaurants and casinos (see field studies below). These studies show that through proper ventilation it is possible to reduce the concentrations of these constituents in the indoor air to a level which is comparable to that found in the outdoor air.

The role of ventilation in improved Indoor Air Quality should be recognised and addressed. Ventilation can produce indoor air quality equivalent to the outdoor ambient air even in venues where smoking occurs.

Field studies have been conducted in the UK and the US on the effect of ventilation on indoor air quality in spaces where smoking takes place. The field studies measured ventilation and indoor air quality in two pubs and a restaurant in the UK[388] and in a casino in the US[389].

[388] Indoor Air Quality and Ventilation Case Study of Hospitality Venues in the United Kingdom. Source: Theodor Sterling Associates. (2007)
[389] Indoor Air Quality Monitoring, Bellagio Casino, Las Vegas. Source: Theodor Sterling Associates. (1999)

The UK study (see below) was commissioned by Imperial Tobacco. It reported that levels of respirable suspended particles (RSP), carbon monoxide and nitrogen oxide measured indoors were comparable to results measured outdoors.

Table 1 – UK Study: Indoor and Outdoor Measurements

	Mosaico, London December 7, 2006 Italian restaurant/ wine bar	Three Horseshoes, Cardiff December 4, 2006 Small one-room pub	The Yard, Cardiff December 5, 2006 Large restaurant/pub	Range of Outdoor Air Measurements (all venues)
CO (ppm)	2.9	3.1	2.9	2.5 -3.0
NO_2 (ppm)	< 0.1	< 0.1	< 0.1	<0.1
RSP – instantaneous ($\mu g/m^3$)	29	49.4	33.9	21 - 42
$PM_{2.5}$ ($\mu g/m^3$)	27.6	46.3	33.7	18 - 41.3
PM_{10} ($\mu g/m^3$)	34	49.4	34.9	24.3 - 48.7

Similarly, a US study (see below) reported RSP, carbon monoxide and carbon dioxide levels indoors that were comparable to the outdoor air quality measurements. Furthermore, the indoor air quality measurements in the well-ventilated spaces were better than the target values for outdoor air quality set by the EU, UK and US.

Table 2 – US Study: Indoor Air Quality inside Bellagio Casino compared with outdoor environment

	Airborne Concentration in Bellagio Casino	Airborne Concentration in Outdoor air	UK outdoor air quality standards
RSP	25 µg/m3	15 µg/m3	50 µg/m3 (PM 10 – 24h)
Carbon monoxide	1.4 µg/m3	2.4 µg/m3	10 µg/m3 (8 hour)
Carbon Dioxide	596 ppm	374 ppm	n/a

The indoor air quality in an effectively ventilated indoor environment, even in one where smoking occurs, can be comparable to the air quality in the outdoor environment.

Ventilation is an important aspect of ETS which was not addressed in the UK's 2007 smokefree regulations. The empirical evidence provided here shows that ventilation, where properly designed and maintained, is effective in providing indoor air quality equivalent to the outdoor ambient air in venues where smoking occurs.

We urge the UK authorities to examine this evidence carefully with a view to allowing employers and business owners with the option to provide segregated ventilated areas within their premises for adults who choose to smoke and for non-smokers who choose to accompany them.

8.6. CONCLUSION

Imperial Tobacco completely rejects the notion that further restrictions on smoking in private premises or in private vehicles in isolation are in any way justified. It is our view that Government has no role in regulating the private lives of adults in the UK who have chosen to smoke. In as much as smokers should show courtesy to other adults, this courtesy should especially be extended to children, who are often unable to exercise a choice in their environment and surroundings in the way that adults can.

The UK Department of Health should stand aside from the emotion of vested interests and critically re-examine the impact of the existing ban, accepting that there have been negative impacts both in financial and in social terms.

In reassessing this balance, the Government should give consideration to the proven potential of ventilation to achieve exceptional indoor-air quality, even in venues where smoking may be permitted.

APPENDIX 1

ANSWERS TO DOH CONSULTATION QUESTIONS

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ANSWERS TO DOH CONSULTATION QUESTIONS

Question 1: What smoking prevalence rates for all groups (children, pregnant women, routine and manual workers and all adults) could we aspire to reach in England by 2015, 2020, and 2030, and on what basis do you make these suggestions?

It is for the Government to determine all public service targets. Imperial Tobacco suggests that any proposals that the Government brings forward that are designed to reduce smoking prevalence should be evidence-based, proportionate and should comply with the established principles of good regulation. Even so, smokers should retain the freedom to choose to smoke without being harangued or coerced to support artificial and overly optimistic targets set by Government.

What else should the Government and public services do to deliver these rates?

It is our view that many adults in the UK will continue to choose to smoke for the foreseeable future, albeit that the overall proportion of smokers in the UK is likely to continue to decrease.

Question 2: What more do you think could be done to reduce inequalities caused by tobacco use?

Chapters 4 (*Youth Smoking*) and 5 (*Illicit Trade)* should be taken into consideration in answering this question.

Imperial Tobacco believes that health inequalities are a direct result of inequalities in socio/economic circumstances. Smoking is not a cause of these inequalities which should be addressed by an appropriate range of interventions designed to address poverty, poor educational performance etc. Excessive and regressive taxation of tobacco products puts an unfair and disproportionate tax burden on the lower income groups. The level and structure of excise taxation of tobacco products should take into account the income of its consumers who tend to turn to the illegal market once they are unable to afford legitimate tobacco products, rather than stop smoking.

Question 3: Do you think the six-strand strategy should continue to form the basis of the Government's approach to tobacco control into the future? Are there other areas that you believe should be added?

The answers to this question are complex and for a true understanding of our views on these complex matters our submission must be read in its entirety. As explained in our submission, further tobacco regulation is unnecessary and the Government's proposals are not justified on the evidence. If introduced

they are likely to be ineffective in dealing with the Government's concerns and possibly even counterproductive.

Rather than introduce further measures aimed at reducing smoking, Government should concentrate on enforcing the numerous existing measures including the recent raising of the age of sale and tackling illegal selling. Government should also ensure that adequate resources are allocated to the enforcement authorities to carry out their duties.

Government should also acknowledge that there is a substantial proportion of the adult population who enjoy smoking and who will continue to choose to smoke.

Imperial notes that further tobacco control regulatory measures such as the Criminal, Justice and Immigration Act are already set to be introduced later in 2008/2009. The effectiveness of these measures, both individually and collectively, has yet to be assessed.

Question 4: How can collaboration between agencies be enhanced to contribute to the inland enforcement against illicit tobacco?

Chapter 5 (*Illicit Trade*) answers this question in detail.

A key priority is to ensure full implementation of the Tobacco Protocol that has been agreed between Trading Standards and the Department of Health. Without adequate funding or resourcing, Trading Standards cannot fulfil its remit in tackling illegal selling or preventing under age sales to children.

Other agencies such as SOCA, HM Revenue & Customs and the Police Services have a role to play and seek to do so wherever they have resources available. Notwithstanding border controls, much greater emphasis should be placed on inland enforcement supported by prosecutions – disruption in the illicit supply chain can only be a partial deterrent if no prosecutions follow.

Thus a wider remit to all agencies on illicit tobacco offences supported by a more effective enforcement strategy would in itself promote better co-ordination and allocation of resource – this could be managed using SOCA as the model or indeed as the lead agency.

Question 5: What more can the Government do to increase understanding about the wider risks to our communities from smuggled tobacco products?

Chapter 5 (*Illicit Trade*) answers this question in detail.

Legally produced cigarettes that are manufactured to the strictest regulatory standards are fundamentally different to counterfeit and smuggled products that are of uncertain origin and which will have been made without conforming to UK standards of materials, manufacture, processing or distribution. Unfortunately, the DoH consultation document states (Section 2.32) that "…there is no conclusive evidence that smoking smuggled tobacco is any more harmful to health than smoking legal, duty-paid tobacco …" This assessment could be counter-productive, and may even be construed as

promoting smuggled tobacco products to be of equal quality to our own products, which are made to the highest standards.

The general population sees the purchase of illicit or counterfeit tobacco as a "victimless crime". This is unlikely to be the case as tobacco smuggling is known to fund other more serious criminal activities such as drug smuggling and people smuggling.

In order to increase understanding of the wider risks to communities from purchasing smuggled tobacco products, the Government should intensify and improve its communications and educational campaigns. These need to highlight and target the activities of smugglers and criminals on a consistent basis. It should also ensure that Trading Standards Officers and other related enforcement agencies are sufficiently educated, resourced and targeted.

Question 6 (a): What more do you think the Government could do to reduce demand for tobacco products among young people?

Chapters 2 (*Retail Display of Tobacco Products and Plain Tobacco Packaging*), 3 (*Tobacco Accessories, Vending Machines and Minimum Pack Size*) and 4 (*Youth Smoking*) address this issue.

The reasons young people smoke are complex, but the main causes are well documented in the literature as:

- parental smoking
- peer influence (friends and siblings)
- low socio-economic status
- poor coping skills
- poor academic performance

Imperial Tobacco believes Government policies designed to tackle these key determinants, such as improved educational performance and social circumstances, combined with early education on the health risks associated with smoking, would be the most effective way to reduce demand for tobacco products amongst young people.

Question 6 (b): What more do you think the Government could do to reduce the availability of tobacco products to young people?

Chapters 2 (*Retail Display of Tobacco Products and Plain Tobacco Packaging*), 3 (*Tobacco Accessories, Vending Machines and Minimum Pack Size*) 4 (*Youth Smoking*) and 5 (*Illicit Trade*) should be considered in answering this question.

As long as the illicit trade constitutes a substantial amount of the UK tobacco market, tobacco products will remain available to children despite the best efforts of legitimate retailers and Trading Standards officers in ensuring that only over 18s are sold tobacco products.

Smugglers and counterfeiters, and those who distribute and sell illicit tobacco products, do not comply with age sale restrictions nor do they discriminate to whom they sell tobacco products. Substantially greater efforts should be made to eliminate illicit trade in tobacco.

Government should concentrate on enforcing the numerous existing measures including the recent raising of the age of sale to 18 and tackling illegal selling. Government should ensure that adequate resources are allocated to the enforcement authorities to carry out their duties in this regard. We would not oppose legislation which would make it an offence for an adult to purchase tobacco on behalf of a minor (proxy purchasing) should the UK Government wish to reconsider complementing existing age of sale laws, although this may be very difficult to enforce

Question 7: Do you believe that there should be restrictions on the advertising and promotion of tobacco accessories, such as cigarette papers?

No. Chapter 3 (*Tobacco Accessories, Vending Machines and Minimum Pack Size*) answers this question in detail.

The evidence given in the consultation document does not support the contention that the advertising of tobacco accessories has the effect of encouraging young people to smoke, stopping those who wish to give up from quitting, or causing smokers who have stopped smoking to return to smoking. Please refer to our detailed submission on this proposal.

Question 8: Do you believe that there should be further controls on the display of tobacco products in retail environments? If so, what is your preferred option?

No. Chapter 2 (*Retail Display of Tobacco Products and Plain Tobacco Packaging*) answers this question in detail.

The evidence given in the consultation document simply does not support the contention that the display of tobacco products in retail environments has the effect of encouraging young people to smoke. Please refer to our detailed submission on this proposal.

Retailers are already well regulated with regard to their obligations not to sell tobacco products to young people.

Imperial Tobacco supports Option 1, together with early and comprehensive education about the risks associated with smoking coupled with increased resources for Trading Standards to tackle illegal selling where it exists.

Question 9: Do you believe that there should be further controls on the sale of tobacco from vending machines to restrict access by young people?

Chapter 3 (*Tobacco Accessories, Vending Machines and Minimum Pack Size*) answers this question in detail.

Imperial Tobacco supports reasonable solutions to reduce the illegal access by minors to cigarettes through vending machines. With this in mind, we support Option 2 - restricted access mechanisms - as a proportionate measure.

If so, what is your preferred option?

Option 2. Please refer to our detailed submission on this issue

Question 10: Do you believe that plain packaging of tobacco products has merit as an initiative to reduce smoking uptake by young people?

No. Chapter 2 (*Retail Display of Tobacco Products and Plain Tobacco packaging*) answers this question in detail.

The evidence given in the consultation document simply does not support the contention that tobacco packaging has the effect of encouraging young people to smoke.

We believe that we are entitled to use our packaging to enable our adult consumers to distinguish our high quality products from those of our competitors. The erosion or expropriation of our intellectual property rights is of serious concern to us and to our shareholders.

Please refer to our detailed submission on this issue.

Question 11: Do you believe that increasing the minimum size of cigarette packs has merit as an initiative to reduce smoking uptake by young people?

No. Chapter 3 (*Tobacco Accessories, Vending Machines and Minimum Pack Size*) answers this question in detail.

Imperial Tobacco does not believe that this proposal has any merit. We believe it may in fact be counterproductive to Government's objectives as it may encourage increased consumption or transfer legal purchasing into the illicit trade. Please refer to our detailed submission on this proposal.

Question 12: Do you believe that more should be done by the Government to reduce exposure to second-hand smoke within private dwellings or in vehicles used primarily for private purposes? If so, what do you think could be done? Where possible, please provide reference to any relevant information or evidence to accompany your response.

Chapter 8 (*Minimising Exposure to Environmental Tobacco Smoke)* answers this question in detail.

We disagree that the Government should seek to regulate private dwellings and private vehicles. It is our view that Government has no role in regulating the private lives of adults in the UK who have chosen to smoke.

Instead, when reviewing the Health Bill in 2010 the UK Department of Health should critically re-examine the existing rules, accepting that within some sectors there have been major negative effects both economically and socially, and should address these areas fully and carefully in the review.

Question 13: What do you believe the Government's priorities for research into smoking should be?

Chapter 7 (*Potentially Reduced Exposure and Potentially Reduced Risk Products for Those Who Choose to Smoke*) answers this question in detail.

Imperial Tobacco acknowledges the work of the Committees on Carcinogenicity, Mutagenicity and Toxicology in their considered review of the science. This dispassionate approach is one that we fully support. Their conclusions coincide directly with our own[390]: that proof of reduced risk may be difficult to achieve.

Government and the tobacco industry should work together to develop meaningful, proportionate and soundly-based product testing regimes, rather than risking an uninformed and ill-thought-through approach to regulation.

Question 14 (a): What can be done to provide more effective NHS Stop Smoking Services for: smokers who try to quit but do not access NHS Support; and, routine and manual workers, young people and pregnant women – all groups that require tailored quitting support in appropriate settings?

Chapter 6 (*Nicotine and Smoking Cessation*) answers this question in detail.

Smoking is a complex behaviour and different people smoke for different reasons. Fundamentally however people smoke cigarettes because they enjoy smoking. It brings them pleasure and they derive a variety of benefits from smoking.

Some people may find it difficult to stop smoking, but we believe it is important for them to understand that they are able to stop if they choose to do so. Millions of people have stopped smoking, the vast majority without assistance. There are more ex-smokers than smokers in the UK today.

Question 15: How can communication and referral be improved between nationally provided quit support (such as the website and helplines) and local services?

Chapter 6 (*Nicotine and Smoking Cessation*) contains our detailed views on smoking cessation.

[390] Imperial Tobacco Limited, Corporate Responsibility Review, 2005

Question 16: How else can we support smoking cessation, particularly among high-prevalence or hard-to-reach groups?

Chapter 6 (*Nicotine and Smoking Cessation*) contains our detailed views on smoking cessation.

Question 17: Do you support a harm reduction approach and if so can you suggest how it should be developed and implemented?

Chapter 7 (*Potentially Reduced Exposure and Potentially Reduced Risk Products for Those Who Choose to Smoke*) answers this question in detail.

If the Government is serious in exercising its obligations to adults who choose to smoke they should thoroughly examine potential modifications to existing product types. The objective should be to provide smokers with a choice of products which may be of reduced exposure and potentially reduced risk, then the best way forward is to pursue a policy of constructive dialogue with the industry, combined with defining objective criteria and predictive tests by which such products may be evaluated.

APPENDIX 2: NICOTINE AND SMOKING CESSATION

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DSM-IV (TR), like ICD-10, approaches "dependence" by laying out a general framework that applies to all substances and requires only that three or more criteria be met, not necessarily simultaneously, at any time within the same twelve month period. The following are the general "substance dependence" criteria:

(a) tolerance;

(b) withdrawal;

(c) substance taken in larger amounts or over longer period than intended;

(d) persistent desire or unsuccessful efforts to cut down or control use;

(e) great deal of time spent to obtain or use substance or recover from its effects;

(f) important activities given up or reduced because of substance use; and

(g) continued use despite problems from use of substance.

To support a diagnosis, the cluster of three or more of the above must lead to *"clinically significant impairment or distress"* in the user of the substance, which implies a disruption to the normal functioning of an individual to such an extent and of such a magnitude as to warrant possible medical intervention. No single criterion is essential to a diagnosis.

DSM-IV (TR) provides a more detailed analysis of how the substance dependence criteria apply to different substances than ICD-10, by referring diagnosing clinicians to sections that deal specifically with different substances, including nicotine. Thus, DSM-IV (TR) includes a section that addresses application of the dependence criteria to "nicotine dependence."

The DSM-IV (TR) and ICD-10 criteria for "nicotine dependence" have major shortcomings. First, they are subjective and depend primarily upon self-reporting by smokers. Self-reports about the use of substances are widely regarded as not reliable without objective verification.[391, 392, 393] In addition, smoking fits poorly within the diagnostic criteria.

1. TOLERANCE

DSM-IV (TR) defines tolerance in the general substance dependence section as either one of two phenomena:

(a) need for markedly increased amounts of the substance to achieve intoxication, or

(b) markedly diminished effect with continued use of the same amount of the substance.[394]

Thus, tolerance refers to the response to the desired effect of the drug. The fact is that, apart from an initial increase in amount smoked early in a smoker's history, dose escalation does not occur with smoking. Rather, patterns of smoking are maintained for years and even decades at very stable and consistent levels.[395] Thus, in considering "nicotine dependence," the authors of DSM-IV (TR) redefine "tolerance" as the absence of *"nausea, dizziness or other characteristic symptoms despite use of very substantial amounts of nicotine".* However, this describes acclimation to aversive effects, not "tolerance" to the desired effects, of smoking. As the US Surgeon General's 1964 Report concluded, this phenomenon *"might be better termed*

391 Davies, 1996.

392 Lee PN, Forey BA. Misclassification of smoking habits as determined by cotinine or by repeated self-report: a summary of evidence from 42 studies. *J Smoking-Related Diseases* 1995; 6: 109-29.

393 Mair M, Barlow A, Woods SE, Kierans C, Milton B, Porcellato L. Lies, damned lies and statistics? Reliability and personal accounts of smoking among young people. *Soc Sci Med* 2006; 62: 1009-21.

394 DSM-IV-TR, 2000 at p. 192. ICD-10 likewise defines tolerance in this way: "evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses." ICD-10 at pp. 75-76.

395 Janson H. Longitudinal patterns of tobacco smoking from childhood to middle age. *Addict Behav* 1999; 24: 239-49, at p. 239 ("Tobacco smoking has been shown to be remarkably stable over long periods of individual's lives").

toleration than tolerance; the user 'puts up with' symptoms of irritation and nicotine toxicity that might be unacceptable to the novice."[396] In fact, the concept of tolerance does not apply to smoking generally and does not apply to the smoking patterns of individuals.

2. WITHDRAWAL

Withdrawal describes behavioural and/or physiological changes observed for a short period after use of a drug is discontinued which disappear as the period of abstinence grows longer. DSM-IV (TR) describes the criterion of withdrawal from stopping smoking as being met when there is abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four or more of the following symptoms, the cluster of which must lead to *"clinically significant distress or impairment"* in the life of the individual:

(a) dysphoric or depressed mood;

(b) insomnia;

(c) irritability, frustration or anger;

(d) anxiety;

(e) difficulty concentrating;

(f) restlessness or impatience;

(g) decreased heart rate; or

(h) increased appetite or weight gain.

Most of these symptoms are subjective and depend primarily upon self-reporting by smokers. As noted above, self reports of symptoms are generally not considered reliable without verification.

Moreover, all of the above symptoms, other than the last two, could be characterised as relatively mild, psychological symptoms. They can be

[396] U.S. Surgeon General Report, 1964. p. 353.

contrasted with the often severe physical symptoms of withdrawal from drugs such as heroin. As described in the US Surgeon General's 1964 Report, what smokers who quit may experience is a *"gamut of mild symptoms and signs … as in any emotional disturbance secondary to deprivation of a desired object or habitual experience. … In contrast to drugs of addiction,"* the mild symptoms one may experience following stopping smoking "never constitute[ ] a threat to life."[397] It was further noted that *"no characteristic abstinence syndrome occurs,"* meaning that reported symptoms can vary across individuals, in contrast to the characteristic symptoms of withdrawal from drugs such as heroin.[398]

The last two symptoms contained in the withdrawal symptoms list, "decreased heart rate" and "increased appetite or weight gain," might arguably be classified as "physical" symptoms. However, according to DSM-IV (TR)'s definition, they must occur within 24 hours of cessation or reduction of nicotine use to be considered relevant to a diagnosis. Decreased heart rate, increased appetite and weight gain are not necessarily pathological conditions. Moreover, there is no indication that any of these symptoms causes "clinically significant distress or impairment" within twenty-four hours of cessation.

In fact, even if an individual were to receive a diagnosis of "nicotine dependence," that determination would not mean that the individual was unable to stop smoking. DSM-IV (TR) itself states that a diagnosis under its scheme, *does not carry any necessary implication regarding the individual's degree of control over the behaviours that may be associated with the disorder.*[399]

DSM-IV (TR) goes on to caution that a diagnosis, *does not demonstrate that a particular individual is (or was) unable to control his or her behaviour at a particular time.*[400]

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397 U.S. Surgeon General Report, 1964. p. 352.
398 Id.
399 DSM-IV-TR, 2000. p. xxxiii.
400 Id.