



Selecting the Evidence to Fit the Policy

*An Evaluation of the Department of Health's Consultation on
Standardised Tobacco Packaging*

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Executive Summary

There is a high risk that a policy adopted on the basis of a flawed consultation will end up doing more harm than good. The Department of Health's (DH) 2012 consultation on standardised packaging for tobacco products is seriously flawed in four critical areas:

1) The structure of the consultation is framed to obtain political support for standardised packaging

Contrary to guidance on good practice, the consultation fails to establish a clear baseline for what would happen without the proposed intervention. Furthermore it fails to present a credible range of policy options, presenting policymakers with the false choice of standardised packaging or doing nothing (there is an intermediate but unspecified middle option). Thus policy-makers are confronted with a loaded question: Are you in favour of standardised packaging or do you want teens and young people to start smoking?

2) The questionable nature of the evidence adduced in support of the policy and the misleading inference drawn from it

As a matter of logic, for standardised packaging to work, there must exist a causal relationship between tobacco packaging and smoking. The DH has not demonstrated that such a relationship exists. What is described as evidence in the consultation is based mainly on surveys of smokers' views and intentions – not what they actually do (a crucial distinction recognised elsewhere by the DH, but not for the purposes of this consultation) – which a US Court described as 'mere speculation and conjecture.' Although the Labour government rejected standardised packaging in 2009, the DH does not point to new evidence that would justify a change in policy. Indeed the DH describes the impact of standardised packaging on smoking behaviour as one of 'the main uncertainties' of the policy.

3) The DH admits that the consultation is prone to bias, yet has decided to do nothing to correct it

In addition to the skewed framing of the consultation discussed above, bias enters the consultation through the DH's reliance for its evidence base on a 'narrative synthesis' of research papers (the Stirling University review) selected and commented on by researchers, two of whom are self-declared advocates of plain packaging; the studies underlying the Stirling University review; and the DH's subjective elicitation exercise, in which selected experts are asked their opinions on the quantified effect of what the policy might be. Even though the DH considered impartiality impractical with respect to the last, it refuses to disclose each individual expert's name, what they said and what their interests are.

4) Failure to quantify the downside risks of the policy

The price mechanism is known to be the most effective tobacco control tool, yet the DH does not analyse the effect of de-branding cigarettes on prices, instead parking the impact on cigarette prices as a 'risk' of the policy. Similarly the DH does not examine the potential impact on the consumption of illicit tobacco of homogenising packaging, thereby reducing barriers to illicit tobacco. This too is treated as a risk of the policy and not subjected to thorough analysis.

The overall effect of the consultation is to create the misleading impression that standardised packaging is a low cost / low risk option to cut smoking. In reality, the DH has not produced evidence of a causal relationship between packaging and smoking uptake, consumption or cessation. On the other hand, it minimises possible negative impacts to public health objectives of the policy on pricing and on illicit tobacco consumption by not examining them, leaving aside the wider impacts on Exchequer revenues and the social and criminal justice problems caused by the trade in illicit tobacco.

1. Purpose and scope

1. This paper analyses the Department of Health's (DH) 2012 consultation on standardised (plain) packaging of tobacco products against the Government's own criteria, as well as those used by the European Commission, for consultations and regulatory impact assessments. These requirements were designed to ensure that the putative benefits of proposed regulatory interventions outweigh the costs and that unintended consequences are identified and, as far as possible, incorporated into the evaluation.
2. If a consultation does not meet these standards, it is unlikely that ministers and parliamentarians will have sufficient information on which to make a balanced judgment of the proposed intervention. They need to be provided with the information to enable them to decide whether the proposed policy is likely to do more good than harm. If they are not, the consultation is flawed and it becomes more likely that the policy will be harmful.
3. In analysing the DH's performance against these criteria, the paper's principal focus is on evaluating it in terms of public health benefits and disbenefits. To provide some perspective, it does this in the context of tobacco control policy since the 1998 White Paper. It focuses particularly on the Labour government's handling of plain packaging in its last two years in office, when it rejected plain packaging. The paper asks whether there has been a fundamental change in the evidence since then to justify a change in policy, given that public health policy objectives remain the same.
4. Additionally there are risk exposures to the DH's budget in the form of possible compensation payable to tobacco companies for the loss of intellectual property (mentioned in this paper) and wider economic impacts include possible revenue losses to the Exchequer and negative impacts on retailers. Social impacts are most likely to occur through the mechanism of stimulating trade in illicit tobacco and reducing barriers to it, with implications for policy towards young people, the border authorities and the criminal justice system – impacts which are not analysed in this paper.

2. Background

5. In April 2012, the DH began a consultation on whether tobacco companies should be forced to remove all branding and sell cigarettes in standardised or plain packs. The deadline for responses was in August 2012 and the DH is currently considering its response and is expected to make an announcement shortly.
6. The 2012 consultation took place three years after the previous Labour government had examined standardised packaging as part of the updating of the tobacco control strategy previously set out in the 1998 White Paper *Tobacco Kills*. On 9th November 2009 the Secretary of State, Andy Burnham, wrote to Tessa Jowell rejecting plain packaging. Although there was some

evidence that packaging might increase brand awareness among young people,

‘as yet, no studies have shown that introducing plain packaging of tobacco would cut the number of young people smoking or enable people who want to quit to do so. Given the impact plain packaging would have on intellectual property rights, we would need strong and convincing evidence showing the health benefits of this policy before it would be acceptable at an international level.’¹

7. The requirement for strong and convincing evidence sets an evidentiary and analytical threshold for the current consultation for the DH to proceed with a policy of standardised packaging. It implies that three years ago, there was insufficiently robust evidence to justify plain packaging. It also implies that the intellectual property represented by tobacco companies’ branding is a material factor in any policy evaluation of plain packaging.

3. Generic consultation objectives and standards

8. The purpose of a policy consultation is to give policy makers the best possible evaluation of the benefits and costs of policy options, informed by responses from stakeholders and civil society. These standards are designed to ensure that regulation achieves its stated objectives and that policy makers and legislators are properly informed as to the likely costs and possible negative impacts.
9. In assessing how well the DH consultation on standardised packaging measures up against this objective, five standard-setters are of particular relevance:
 - The Coalition Government’s regulatory principles
 - HM Treasury’s *Green Book* guidance
 - The Government’s Impact Assessment Toolkit
 - The European Commission’s *Impact Assessment Guidance*
 - The Courts

3.1 The Coalition Government’s regulatory principles

10. In implementing the Coalition Agreement commitment to reduce regulation, the Coalition Government set out its approach in a December 2010 policy statement, *Reducing Regulation Made Simple*. The reality is that regulation is never cost-free, it stated, ‘it can be ineffective in achieving its intended outcomes if its effects on the system as a whole have not been properly considered.’²
11. The statement put in place a new framework designed to ensure that ‘alternative approaches to regulation are thoroughly explored, and that traditional “command and control” regulation is seen as the last, not the first resort.’³ It enjoined ministers to ensure that the government only intervened where necessary and that they should focus on identifying the most effective

ways to achieve desired policy outcomes. Civil servants were asked to review more frequently whether policies are delivering intended outcomes.⁴

3.2 Treasury Green Book

12. In addition to setting out guidance on the evaluation of spending programmes, the *Green Book* covers regulatory interventions.⁵ It outlines the process for appraising policy interventions, the first step of which is to produce an analysis justifying action:

‘This overview must include an analysis of the negative consequences of intervention, as well as the results of not intervening, both of which must be outweighed to justify action.’⁶

13. Option appraisal is a key step in the process. A wide range of options should be created and reviewed and appraised by establishing a base.⁷ The list should include a minimum amount of action necessary (the ‘do minimum option’) so that the reasons for more interventionist actions can be judged.⁸
14. The *Green Book* states when a policy or programme has advanced to a pre-determined degree, ‘it should undergo a comprehensive evaluation.’ Its purpose is to assess the outturn of the policy against expectations, so that

‘the lessons learned are fed back into the decision-making process. This ensures government action is continually refined to reflect what best achieves objectives and promotes the public interest.’⁹

3.3 Impact Assessment Toolkit

15. The Government’s 2011 *IA Toolkit* is tailored to complement the *Green Book*.¹⁰ It specifies that formal consultations should quantify the effect of the proposals and scale the impacts by monetising their effect, even if at that stage the monetisation numbers are indicative.¹¹ In these cases, the information required to enable full monetisation should be identified.¹²
16. Careful consideration should be given to possible unintended consequences, such as how things could go wrong, the *IA Toolkit* cautions. It also requires assessments to include the financial and resource impacts on other departments (specifically identifying the justice system) and asks whether the proposals will affect the rate of crime or impact crime prevention.¹³
17. The *IA Toolkit* emphasises the importance of forward planning. ‘Lack of forward planning is not a justification for limited analysis,’ it states.¹⁴ This admonition, together with the need to identify unintended negative consequences, should be borne in mind in assessing the standardised packaging consultation’s handling of the downside risks it identifies.

3.4 European Commission

18. The European dimension needs to be considered as well. In its 2009 rejection of plain packaging, the previous government stated that it would not support the policy at an international level because of its impact on intellectual property rights.

19. An objective set by the Coalition in *Reducing Regulation Made Simple* is to work with EU member states to encourage 'smarter regulation by applying more rigorous use of evidence in the EU.'¹⁵ Examining the DH consultation against consultation standards required by the European Commission for European regulation is relevant and politically prudent.
20. In fact, the Commission's approach to consultation is more rigorous and structured, requiring much higher evidentiary standards and testing of alternative policy options than the more generalised standards common in Whitehall. In its 50-page *Impact Assessment Guidelines* published in January 2009, the Commission set out the logical steps that should be followed in preparing an impact assessment and the questions it must answer. These include:
- The nature and scale of the problem
 - The objectives that should be set
 - The main policy options for reaching them
 - The likely economic, social and environmental impacts of those options
 - A comparison of the main options in terms of effectiveness, efficiency and coherence in solving the problems¹⁶

3.5 The Courts

21. In undertaking consultations, the Courts have set standards which public bodies should meet:
- The information in the consultation must not be incorrect or misleading
 - The consultation should give the true reasons for putting forward the relevant proposals
 - The product of the consultation exercise must be taken into account in finalising any proposals
 - The public body must embark on the consultation process prepared to change course if persuaded by that consultation process to do so¹⁷

Although the Courts do not readily grant leave to apply for Judicial Review and successful applications constitute the minority of cases, they provide a back-stop to public bodies' conduct and standards.

4. Tobacco control and the UK tobacco market

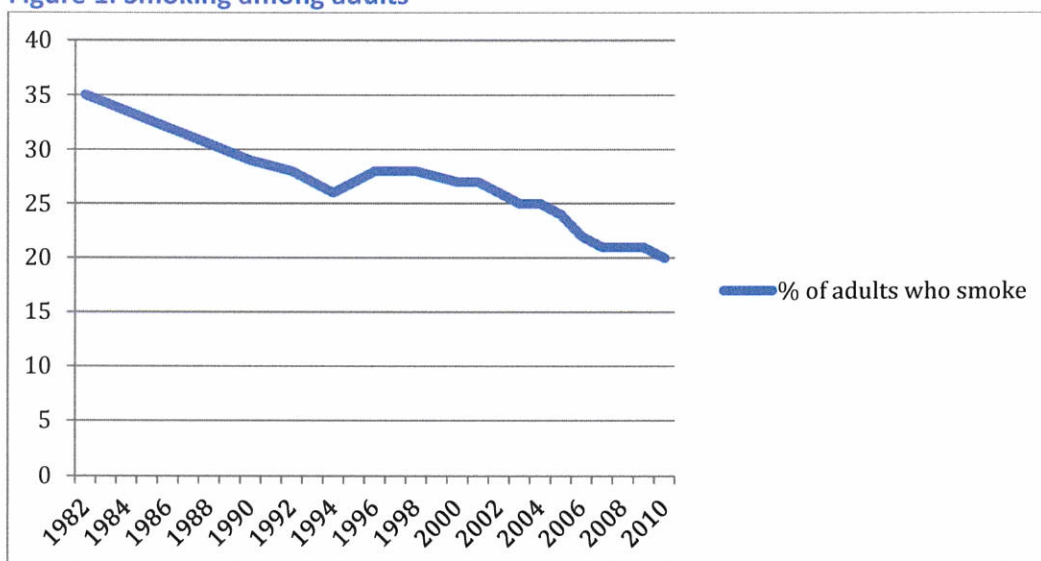
22. Governments' efforts to discourage tobacco smoking have arguably been the single most valuable public health policy in saving lives and reducing illness. They span a broad range of policies:
- Educating the public on the dangers of smoking
 - Taxation to raise the price of tobacco, reduce affordability and discourage consumption
 - Direct regulatory interventions

- Preventing youth access to tobacco products
- Cessation support to help smokers quit

23. The DH noted in its March 2011 Tobacco Control Plan, research in social and behavioural economics suggest that reducing the uptake of smoking is best achieved by influencing the adult world in which young people grow up.¹⁸ Despite hardening social attitudes towards smoking in recent years, the decline in smoking since the 1950s appears to have stalled, as had also happened in the mid-1990s:

- In 1999 54% of non-smokers objected to people smoking near them, a figure that rose to 69% in 2008/09¹⁹
- In 1998, 28% of adults were smokers, falling to 22% in 2006, since when the percentage of adult smokers has been stuck in the low twenties²⁰

Figure 1: Smoking among adults



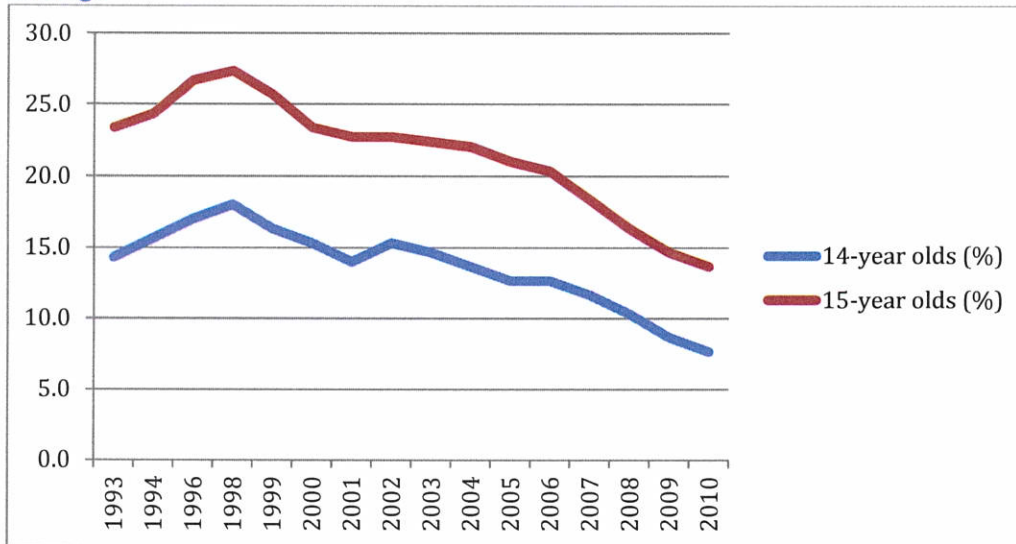
Source: ONS, General Lifestyle Survey in NHS Information Centre, *Statistics on Smoking - England, 2012*, Table 2.2

Notes:

- (1) Figures for 1983-1989, 1993, 1995, 1997 & 1998 interpolated
- (2) From 1998, samples changed from an unweighted to a weighted basis

24. On the other hand, DH survey data on school smoking show steady declines among 14- and 15-year olds from the late 1990s, when it had risen.

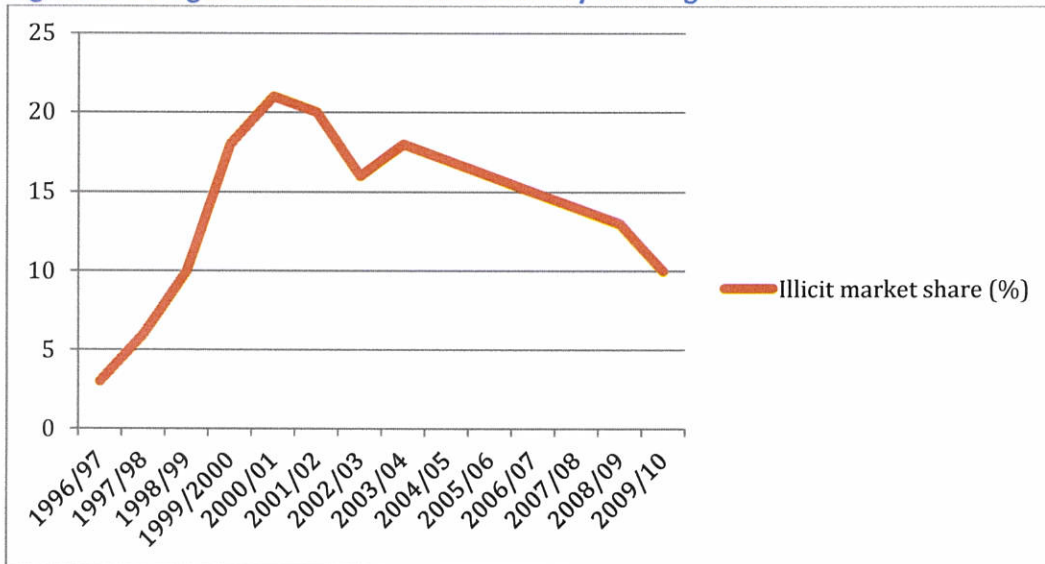
Figure 2: Prevalence of smoking among 14- and 15-year olds – trailing 3-year average



Source: NHS, 'Smoking, drinking and drug use among young people in England in 2010'

25. Like smoking among school children, the share of the UK tobacco market taken by illicit trade rose in the second half of the 1990s and then declined, falling from 21% in 2000/01 to 10% in 2009/10.

Figure 3: UK cigarette market – share taken by illicit cigarettes



Source: HMRC

This reflects the success of Her Majesty's Revenue and Customs' (HMRC) 'Tackling Tobacco Smuggling' Strategy. Since it was first introduced in 2000, more than 20 billion cigarettes have been seized.²¹

4.1 Key issues for the consultation

26. Whilst it is always difficult to demonstrate cast-iron causality between HMRC's success at curbing illicit cigarettes and the decline in smoking among teens of school age, there are clear linkages. In the Coalition's 2011 Tobacco Control Plan, the DH acknowledged that making tobacco less affordable is 'proven to be an effective way of reducing the prevalence of smoking. Young people, pregnant women and people from lower socio-economic groups are particularly sensitive to price. The health gain from high-priced tobacco, however, can be undermined if the illicit market in tobacco products is allowed to thrive at the expense of legal, duty-paid products.'²²
27. Thus a proper examination of plain or standardised packaging should, as The *Green Book* requires, analyse the negative consequences of the proposed intervention. Clearly its potential impact on the consumption of illicit tobacco is one such.
28. A second is the potential impact of standardised packaging on cigarette pricing structure. Would de-branding encourage a further shift to lower priced cigarettes by eroding the pricing premium smokers currently pay for premium brands?
29. On the other hand, to have any benefit, it would need to be demonstrated that cigarette packaging is a causal factor – in a similar way that affordability is – in the consumption of cigarettes. If not, such a policy would have no public health benefits but most likely incur public health disbenefits, before taking account of the wider economic and social costs of driving tobacco sales away from regulated channels (potential revenue losses to the Exchequer, the impact on small retailers, the additional flow of cash going to criminal gangs and the association of school children with them by buying illicit tobacco and drugs from them).

5. Public policy context

30. Smoking rates fell steadily through the 1970s and 1980s. However, the long downward trend stopped in the mid-1990s. In 1996, adult smoking rates rose for the first time since 1972.²³ Furthermore there was an increase in teen smoking, particularly among girls.²⁴

5.1 The 1998 White Paper

31. This was the backdrop that led the new Labour government in 1998 to announce a comprehensive public health strategy to tackle smoking. Key measures were:
- **Tax.** The price of cigarettes relative to incomes had fallen in the first half of the 1990s.²⁵ The cigarette duty escalator was therefore set to rise by at least 5% a year in real terms to outpace the growth of incomes. As the 1998 White Paper explained, 'Research shows that the demand for tobacco products is related to their price. As prices rise, demand falls. So high tax levels are one important means of reducing tobacco

consumption. High tobacco prices are also a deterrent to children tempted to take up smoking.²⁶

- **Crackdown on smuggling.** The White Paper recognised the threat posed by illicit cigarettes to public health objectives of higher tobacco taxation and increased resources to tackle it. ‘The Government’s policy of increasing tobacco duty by on average 5 per cent a year in real terms will help to encourage smokers to cut down or quit, and will help to discourage other children and adults from starting. But the effectiveness of continued tax increases is being undermined by tobacco smuggling.’²⁷
- **Enhanced health education.** Public education programmes, the White Paper said, were the most direct way of changing attitudes and behaviour. It emphasised the importance of integrated mass media campaigns and in particular the effectiveness of television advertising.²⁸
- **Curbing passive smoking.** The White Paper argued that completely smoke-free places were the ideal, but stopped short of the ban on smoking in public places that would be enacted eight years later.²⁹
- **Action to protect young people.** Youngsters started smoking for a variety of reasons, the White Paper observed.

‘Some smoke to show their independence, others because their friends do. Some smoke because adults tell them not to, others to follow the example of role models. There is no single cause. Parents, brothers and sisters who smoke are a powerful influence. So is advertising. So too is sport which is often sponsored by tobacco companies.’³⁰

The White Paper led to tougher enforcement against under-age cigarette sales, proof-of-age requirements, restrictions on point-of-sale displays and bans on tobacco advertising, promotion and sponsorship.

32. Altogether, the White Paper’s thirteen measures constituted a coherent package. On paper at any rate, one measure did not undermine the effectiveness of another. In the language of the day, the White Paper was evidence of joined-up government. If there was any tension or conflict in the overall approach, it was that the tobacco duty escalator increased the profitability of trade in illicit cigarettes, overwhelming the government’s anti-smuggling measures. As a result, the escalator was switched off in 2001.

5.2 Labour’s Tobacco Control Review

33. The effectiveness of the measures in the 1998 White Paper was to be assessed against progress in meeting national targets, principally to halt the rise in child smoking and to re-establish the downward trend in adult smoking.³¹ By and large, it succeeded.
34. However the aggregated approach to assessing the effectiveness of the White Paper against overall prevalence benchmarks meant that it is hard to tell which measures worked and which didn’t. The contribution of each component to the downward trend was not assessed and quantified.

35. In 2008, the Labour government embarked on a process to develop a new tobacco control strategy with a consultation that concluded with the 2010 policy statement *A Smokefree Future*. It had three over-arching aims:

- Stopping the inflow of young smokers
- Assisting smokers to quit
- Protecting families and communities by encouraging a rise in the proportion of smokefree homes

36. Maintenance of high cigarette prices was central to reducing smoking. According to the 2008 consultation paper:

‘Cigarette consumption and smoking cessation are both responsive to changes in the price of tobacco products. The price mechanism is generally accepted to be the most effective, population-level policy lever available to government to combat smoking ... Evidence from the World Bank shows that price has a greater impact on consumption of tobacco than any other factor, suggesting that a 10% rise in price can lead to a 4% fall in prevalence.’³²

For this reason, illicit tobacco threatened public health objectives. In the words of *A Smokefree Future*:

‘Reductions in affordability can be driven by taxation on tobacco products or profit on tobacco products. The availability of cheaper illicit tobacco products undermines the effectiveness of high prices and increases affordability, especially for more disadvantaged groups who are more likely to buy illicit tobacco.

‘Maintaining or increasing the real value of tobacco duty will reduce the affordability of tobacco products, provided parallel action is taken to reduce the illicit tobacco share.’³³

37. The 2008 consultation paper highlighted evidence presented by the anti-smoking campaign ASH, on how tobacco smuggling exacerbated health inequalities and might also discourage younger smokers from quitting. ASH’s research found that one in three of the youngest smokers in the sample reported buying cigarettes from illicit sources.³⁴

5.2.1 Plain packaging and the 2008-2010 review

38. The 2008 consultation paper invited feedback on the potential for plain packaging to reduce smoking among young people.³⁵ However, *A Smokefree Future* parked the issue, presumably for the reasons given by Andy Burnham in November 2009 (para 6 above). The evidence base regarding plain packaging needed to be ‘carefully examined,’ it said, and the Government would encourage research into the links between packaging and consumption.

‘The Government will also seek views on, and give weight to, the legal implications of restrictions on packaging for intellectual property rights and freedom of trade.’³⁶

5.3 Recent tobacco control measures

39. As a result of these policies, from the mid-2000s, there has been a significant and continuing tightening of tobacco control measures. (Table 1).

Table 1 Timeline of recent tobacco control measures – England

	Measure	Legislation
2004	▪ Restrictions on point of sale promotion	▪ Tobacco Advertising and Promotion Act 2002
2007	▪ Prohibition of smoking in public places and the work place ▪ Illegal to sell tobacco to children – minimum age raised from 16 to 18	▪ Health Act 2006 ▪ Protection of Children (Tobacco) Act
2008	▪ Pictorial health warnings on cigarette packets	▪ Implementation of the EU Tobacco Products Directive 2001 with the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007
2011	▪ Ban on cigarette vending machines	▪ Health Act 2010
2012	▪ Phased implementation of ban on point-of-sale displays in supermarkets and large stores	▪ Health Act 2010
2015	▪ Extension of point-of-sale bans to all retail outlets	▪ Health Act 2010

5.4 Tobacco control policy under the Coalition

40. Within seven months of taking office, the Coalition set out what it described as a ‘radical new approach’ to public health in the White Paper *Healthy Lives, Healthy People: Our strategy for public health in England*. Its focus is on empowering local communities.³⁷ The White Paper set out a set of principles which include:

- A focus on key outcomes, ‘with transparency of outcomes to enable accountability through a proposed new public health outcome framework’³⁸
- The Government’s ‘core values of freedom, fairness and responsibility’³⁹
- Balancing ‘the freedoms of individuals and organisations with the need to avoid harm to others’⁴⁰
- Using a ladder of interventions to ‘determine the least intrusive approach necessary to achieve the desired effect and aim to make voluntary approaches work before resorting to regulation’⁴¹

41. In March 2011, the DH published a new tobacco control plan setting out what the then Secretary of State, Andrew Lansley, called ‘a comprehensive package of evidence-based action.’⁴² At its heart was a new approach to

improving public health – tackling the wider social determinants of health ‘to build people’s self-esteem, confidence and resilience right from infancy.’⁴³

42. The starting point for the 2011 Tobacco Control Plan was that ‘smoking prevalence has fallen little since 2007 and we need to take new action to drive prevalence down further.’⁴⁴
43. What additional action is likely to be most effective? The apparent stalling in the decline of smoking occurred during a period of increasingly tight tobacco controls. Like the 1998 White Paper, the 2011 Tobacco Control Plan does not analyse the effectiveness of individual measures, even though after more than a decade, the evidence is clearer now than it was then: Not all public health initiatives designed to curb smoking work.
44. In the 2011 Plan, the Government announced it would look at whether plain packaging could be effective in reducing the number of young people who take up smoking and help those trying to quit. As part of its examination of the case for plain packaging, the Government said it would also ‘explore the competition, trade and legal implications, and the likely impact on the illicit tobacco market of options around tobacco packaging.’⁴⁵
45. The 2011 Plan also noted that smokers were increasingly down-trading to cheaper, lower-end cigarettes. Levels of consumption of tobacco products at various prices will vary between individuals and social groups, the Government said. ‘To explore the scope for new policy interventions in this area, we will encourage research to examine the evidence on the average price that different groups usually pay for tobacco products and the pack size,’ the Plan stated.⁴⁶ Although it did not make an explicit connection between plain packaging and down-trading, there is a clear risk that the effect of de-branding premium cigarette brands would be to devalue them in the eyes of smokers and thus encourage further downtrading and possibly more smoking.

6. Standardised packaging: Consultation objective

46. The 2012 DH Impact Statement on the standardised packaging consultation states:

‘A policy to introduce standardised packaging would need to be justified and be based on expected benefits over and above existing tobacco control measures.’⁴⁷
47. This statement is in accordance with the *Green Book*’s requirement to establish a clear base against which to assess the results of not intervening (see para 12 above). For EU legislation, the European Commission also requires that the relevant Impact Assessment include a clear baseline scenario as the basis for comparing policy options:

‘The aim of the baseline scenario is to explain how the current situation would evolve without additional public intervention – it is the “no policy change” scenario.’⁴⁸
48. The Commission guidelines go on to state that a good baseline should have a strong factual basis and, ‘as far as possible, be expressed in quantitative

terms.⁴⁹ Sensitivity tests and risk assessments should be undertaken to explore whether an undesired development may – or may not – happen. Where legislation is already in place, ‘less can be more,’ the guidelines state. ‘If existing measures do not produce the desired effects, creating a new instrument may not be the best remedy.’⁵⁰

49. The DH recognises the need to improve evaluation of its public health interventions. In the 2010 public health White Paper *Healthy Lives, Healthy People* remarked on the ‘patchy’ use of what works. Further progress was needed to build and apply the evidence base for ‘what works.’ It promised a more rigorous approach with

‘a culture of using the evidence to prioritise what we do and test out innovative ideas needs to be developed, while ensuring that new approaches are rigorously evaluated and that the learning is applied in practice.’⁵¹

50. Despite this, the DH consultation on standardised packaging contains no analysis of the benefits of existing measures and presents no evidence on the anti-smoking policies which work and the ones that don’t. Given the apparent stalling in the long term fall in adult smoking, this omission undermines the foundation of the consultation. Furthermore some measures have only just been implemented and others are in the pipeline, so their effectiveness is unknown.
51. By the criterion adopted by the DH for the consultation, the lack of a solid baseline for the effectiveness of existing measures creates a flimsy basis on which to assess the potential benefits of standardised packaging. Moreover it conflicts with the DH’s approach in the 2010 public health White Paper and does not meet the standards set by the *Green Book* in establishing a base case (the results of not intervening) and evaluating the effectiveness of previous interventions (paras 12-14 above).

7. A flawed approach

52. The consultation is geared to finding reasons to justify its preferred policy measure. As a result, the consultation is structurally flawed.

7.1 Untested premise

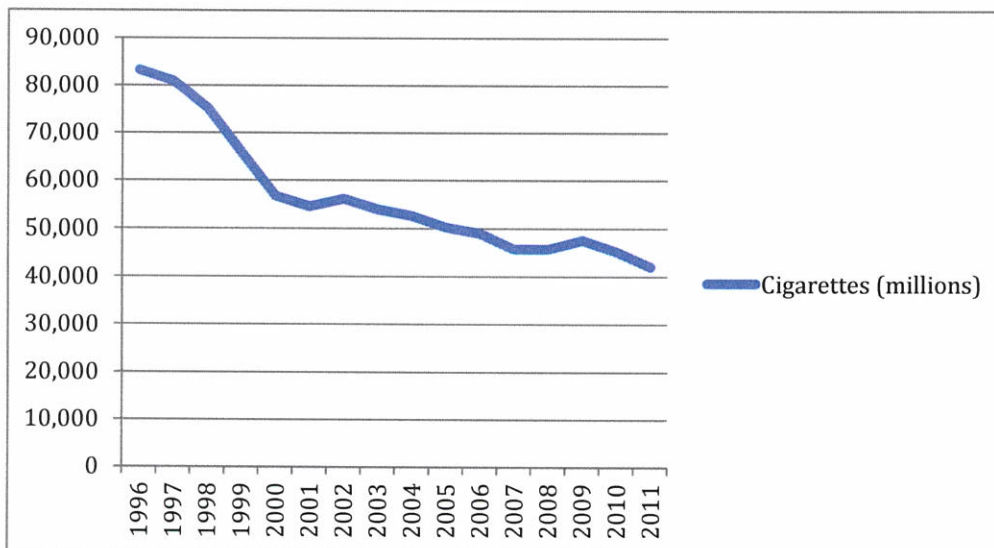
53. The consultation exercise rests on the unstated assumption that branded cigarette packaging is a factor that turns non-smokers into smokers and prevents smokers from trying to quit. Whether the assumption is valid is critical to the efficacy of the proposed policy. If it is not, the policy will not cut smoking.
54. A 116-page review commissioned by the DH from the University of Stirling (the Stirling University review) came to the trivially true conclusion that tobacco companies try to make their packaging attractive, but presented no evidence as to whether packaging was a factor in people starting smoking or is an obstacle to them quitting.
55. The consultation does not ask the critical question:

- Is branded cigarette packaging a means of attracting new smokers and dissuading existing ones from giving up?

Or

- Is it a competitive tool used by tobacco companies to win market share and enable them to charge premium prices?
56. Evidence that tobacco companies make significant investments in packaging and branding cannot answer the question because it doesn't tell us anything about the effect on the purchaser's decision to buy and smoke cigarettes. Instead the evidence is grounded in the nature of the product (nicotine is a highly addictive drug) and the reasons why teens and young people start smoking in the first place.
57. If branded packaging is a market share and /or premium pricing tool, then the premise of standardised packaging is not valid and the policy will fail to achieve its objective of cutting smoking. An economic analysis of the industry would help the DH answer this critical question on which the whole policy turns (examined further in Section 7.9 below).
58. Since 1996, the number of cigarettes released for domestic consumption has almost halved - from 83.3 billion cigarettes in 1996 to 42.0 billion in 2011 (Fig. 4). Thus the empirical evidence suggests that branding has not attracted new smokers or reversed the overall decline in cigarette consumption.

Figure 4. Quantity of cigarettes released for home consumption



Note: 1999 is an interpolated average to exclude the impact of forestalling as result of the November 1999 budget

Source: NHS Information Centre, 'Statistics on Smoking - England, 2012,' Table 2.11

59. The causes as to why teens and young people start smoking is a subject of extensive research and should constitute the natural starting point for an objective policy analysis. The 1998 White Paper noted that young people start smoking for a variety of reasons (it did not, however, mention cigarette packaging as one of them). In a response to the 2012 consultation

commissioned by tobacco company PMI, economist and Nobel Laureate James Heckman wrote of the literature on the economics and public health of youth risky behaviours, including smoking:

‘These literatures have identified multiple causal factors affecting youth smoking behaviour, such as prices, parental and peer smoking, early family environments and investment in children.’⁵²

7.2 Lack of evidence

60. In 2009, the DH concluded there was insufficiently robust evidence to support a move to plain packaging. The 2012 consultation does not spell out how the evidence might have changed since 2009.

61. There are two criticisms to make of the DH’s handling of evidence in the 2012 consultation:

- The evidence that the DH could have analysed but chose not to; and
- The questionable nature of what the DH construes as evidence

Each are analysed in turn.

7.2.1 Evidence not analysed

62. Until Australia introduced plain packaging in December 2012, there was no jurisdiction that required standardised cigarette packaging as a tobacco control measure. As yet, there is no direct evidence as to its effect. However there is a wealth of evidence both from the UK and internationally on the effectiveness or otherwise of precursor policies, notably on point-of-sale display bans and pictorial health warnings that shrink the branded area of cigarette packs.

63. Analysing existing evidence would have enabled the DH to see whether there is a statistically significant relationship between the size of health warnings on packets and smoking. The DH’s standardised packaging consultation does not include or even mention any such analysis. Indeed, the DH fails to ask the crucial evidentiary questions required of a genuinely objective policy appraisal:

- Despite the tighter controls on cigarette promotion and packaging that have come into force since 2004, why has the long-term reduction in smoking rates stalled in recent years?
- Why is it that the UK has nearly double the rate of young smokers compared to the US (23% vs.12%) despite having much more prominent health warnings – the US only requires textual health warnings on one side of the packet?^{*53}

* The data on young smokers is drawn from the 2011 ESPAD Report on Substance Use among Students in 36 European Countries. The report also includes survey data from the United States. The ESPAD survey targets slightly older students (average age = 15.8 years) while the average age for US respondents is 16.2 years, whereas the NHS surveys are for 11-15 year olds. A further difference is that ESPAD is surveying cigarette use in the past 30 days

7.2.2 Nature of evidence

64. The nature of the evidence adduced by the Food and Drug Administration (FDA) in favour of requiring pictorial warnings on cigarette packs was a matter deliberated by the United States Court of Appeals for the District of Columbia Circuit in 2012. In *RJ Reynolds et al v. Food and Drug Administration et al*, the FDA conceded that survey evidence on the effect of the proposed warnings did not permit it to reach 'firm' conclusions about the 'long-term, real-world effects' of the proposed warnings. Instead the FDA claimed the existing scientific literature 'provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation.'⁵⁴
65. However the Court found that the FDA had
'not provided a shred of evidence—much less the “substantial evidence” required by the APA [Administrative Procedure Act]—showing that the graphic warnings will “directly advance” its interest in reducing the number of Americans who smoke.'⁵⁵
66. Whilst the FDA made much of the 'international consensus' surrounding the effectiveness of large graphic warnings, the Court found that it offered no evidence showing that such warnings had directly caused a material decrease in smoking rates in any of the countries requiring them.
67. The FDA's reliance on what the Court described as 'questionable social science' was 'unsurprising' in view of the raw data regarding smoking rates in countries that have enacted graphic warnings.⁵⁶ Although the FDA maintained the data 'is suggestive' that large graphic warnings 'may' reduce smoking consumption, citing a 1995 United States Supreme Court case, the Court decided that it could not meet the required legal standard with 'mere speculation and conjecture.'⁵⁷
68. *RJ Reynolds et al v. Food and Drug Administration et al* is relevant to examining the strength of the public health benefits of standardised packaging. Whilst the Court was presented with inconclusive evidence on the effectiveness of pictorial health warnings from countries which require them, in the case of standardised packaging, there is no evidence at all. Instead the DH has opted to rely on reviews of surveys on smokers' intentions compiled by Stirling University (7.3 below) and asking experts their opinions – in an exercise the DH calls an 'Elicitation of Subjective Judgments' (7.5 below).

7.3 The Stirling University review

69. To inform policy development and responses to the 2012 consultation, the DH commissioned a systematic review of the evidence on plain tobacco

whereas the NHS survey is for regular smokers. However there is a high statistical correlation between having smoked in the last 30 days and lifetime use. It is therefore possible that the NHS surveys under-report the prevalence of mid-teen smoking.

packaging from Stirling University, which had been asked in 2009 to produce a similar piece of work.

70. The 2009 Stirling University report made two statements that are particularly relevant to the 2012 consultation:
- 1) The first highlights the differences between what is viewed as evidence by a court and by the social scientists at Stirling University. Based on essentially the same material as that reviewed by the United States Court of Appeals three years later, which it characterized as speculation and conjecture, the 2009 Stirling University review claimed: ‘There is solid research evidence to show that health warnings do deliver real health benefits.’⁵⁸
 - 2) The 2009 Report acknowledged ‘significant weaknesses’ in the research base on standardised packaging. ‘No ecological or “real world” research has been conducted to see what actually happens, when for instance, smokers use generic packs over a period of time.’⁵⁹ It also highlighted the absence of longitudinal studies to disentangle cause and effect (a weakness in the research on health warnings highlighted by the Court in *RJ Reynolds et al v. Food and Drug Administration et al*).
71. Nonetheless, the 2012 Stirling University review for the standardised packaging consultation claimed to have found ‘evidence’ in favour of standardised packaging.⁶⁰ Had the nature of the evidence changed since the 2009 Stirling University report?
72. The 2012 Stirling University review makes no distinction between papers dated 2009 and before (i.e., ones which were deemed to provide insufficient evidence) and later ones. The review tabulates 37 papers that it analyses (some are listed more than once and some have two components) separately scoring their relevance and quality as high, medium and low. As shown in Table 2, there is little to distinguish the ones from 2009 and earlier and the post-2009 papers and very little basis for claiming that the post-2009 papers provide stronger evidence than the earlier ones.

Table 2: Analysis of quality of studies reviewed in the 2012 Stirling University review by date

	2009 or earlier studies	Post-2009 studies	Difference
Total	18	19	+1
High / high	1	2	+1
High / medium	10	12	+2
Medium / medium	5	5	0
Low / medium	4	1	-3
Low / high	1	1	0

Source: Moodie C, Stead M, Bauld L, McNeill A, Angus K, Hinds K, Kwan I, Thomas J, Hastings G, O'Mara-Eves A (2012) *Plain tobacco packaging: a systematic review*, Table 4.1

73. The 2012 review contains only one more post-2009 study (19 compared to 18). Of these, the post-2009 batch contains only one more study with a combined rating of high relevance and high quality – making a grand total of 2 in the post-2009 set.
74. To test the DH's claim that the research base had found that plain packaging would cut smoking rates, one of the post-2009 papers used in the Stirling University review was analysed. Thrasher, Rousu, Hammond, Navarro & Corrigan, 'Estimating the impact of pictorial health warnings and 'plain' cigarette packaging: Evidence from experimental auctions among adult smokers in the United States' (Thrasher *et al* (2011)) is one of 21 quantitative studies assessing the attractiveness of branded vs. plain packaging.
75. Thrasher *et al* (2011) used a format in which smokers placed bids for branded and plain cigarette packs, the results indicating 'statistically lower bids for the plain, unbranded pack.'⁶¹ However, Thrasher *et al* (2011) did not find any evidence that de-branded packaging would cut smoking rates, which is the ostensible policy objective of plain packaging and the claim made by the DH. Indeed, Thrasher *et al* (2011) did not test the effect of plain packaging on smoking rates
76. Thus there is no evidence in Thrasher *et al* (2011) to support the claim made in the Stirling University review of there being 'strong evidence' that plain packaging would help reducing smoking rates – a claim repeated by the DH in its Impact Assessment (See Box 1).⁶² What is described as evidence is inference – the authors infer, and the DH implicitly follows them, that less attractive packaging will cause people to smoke less.

Box 1: Thrasher et al (2011)

Summary

The study involved 402 smokers (participants had smoked at least one cigarette in the last month and more than 100 cigarettes in their lifetimes) at four sites in the US in which participants bid money in an auction for cigarettes in different packaging and different health warnings. The mean bid for the control condition packs with current health warnings (i.e., standard branded packs) was \$3.52 and for the plain, unbranded packs with pictorial health warnings was \$2.93.

The authors noted that many health policy researchers and tobacco control advocates were calling for plain packaging because it could eliminate colours and branding that can support false beliefs and increase the salience of pictorial health warnings. On the basis of the auction results, the authors wrote:

‘Our results are consistent with this research, indicating that plain packaging further reduces demand for cigarettes above and beyond the impact of pictorial health warnings.’

The paper concludes:

‘Prominent health warnings with graphic pictures will reduce demand for cigarettes. Pictorial warnings on plain packaging produced the greatest decrease in demand.’

Comment

All the study shows is that smokers are willing to pay more for branded cigarettes compared to de-branded packs with pictorial health warnings. The results say nothing about how many cigarettes they might smoke from branded compared to plain packs with pictorial health warnings. The authors’ conclusion about a reduction in demand for cigarettes reflects a fundamental misconception, confusing the perceived value of the branded pack compared to a plain pack and smokers’ demand for cigarettes. It is therefore misleading insofar as lower demand caused by de-branding implies fewer cigarettes will be smoked.

It is plausible to hypothesise the opposite occurring – because de-branded packs are perceived to have lower value, the price premium over cheaper brands is eroded and the smoker finds they can afford to smoke more to satisfy their nicotine addiction.

Source: Thrasher et al, ‘Estimating the impact of pictorial health warnings and ‘plain’ cigarette packaging: Evidence from experimental auctions among adult smokers in the United States’ in *Health Policy* 102 (2011), pp.41-48

77. Reliance on studies similar to those covered in the Stirling University review was also a feature of the case made by the FDA in *RJ Reynolds et al v. Food and Drug Administration et al*. In reality, what such evidence amounts to is supposition based, for the most part, on asking what people think and what they say they might do, rather than observing what smokers actually do.

78. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, and while the FDA might be correct that intentions are a ‘necessary precursor’ to behaviour change, the Court declared it

‘mere speculation to suggest that respondents who report increased thoughts about quitting smoking will actually follow through on their

intentions. And at no point did these studies attempt to evaluate whether the increased thoughts about smoking cessation led participants to actually quit.’⁶³

79. The Court went on to comment that an Australian study had reported increased quit attempts by survey participants after that country enacted large graphic warnings, but found ‘no association with short-term quit success.’⁶⁴ The authors of the 2012 Stirling University review were also aware of the limitations of such surveys. Towards the end of their review, there is an important disclaimer:

‘Findings regarding smoking-related attitudes, beliefs and behaviour from both the surveys and qualitative studies in the review are reliant on self-report. Without any form of validation (such as validating reported changes in cigarette consumption) these have quite weak predictive validity.’⁶⁵

80. The DH is well aware that surveys based on what people say they will do are unreliable predictors of what they will actually do. An example is a study by the DH which compared smokers’ stated intentions prior to the July 2007 implementation of smoke-free legislation to what smokers actually did after it came into force:

‘Although many participants felt the smokefree legislation would be likely to encourage them to cut back on the number of cigarettes they smoked, there was a disparity between intentions and actions.’⁶⁶

Yet the 2012 DH Impact Statement ignores its own findings, as well as the disclaimer in the Stirling University report.

81. Instead it states that the Stirling University review found ‘consistent evidence’ to support the claim that standardised packaging would cut smoking rates.⁶⁷ This is an intrinsically weak statement. Scientific knowledge advances by finding evidence that contradicts, modifies and refines existing theories or that establishes causal relationships, and where possible quantifies them. Asserting consistency can verge on the meaningless: the moon orbiting around the Earth is consistent with heliocentrism. It is also consistent with a Ptolemaic view of the Earth.

7.4 Absence of quantification and measurement

82. Quantification is a key step in enabling policymakers and stakeholders to assess the robustness of the policy options put forward for consultation. The *Green Book* states that wherever feasible, monetary values should be attributed to all impacts of any proposed policy.⁶⁸ As noted in para 15 above, the Government’s *IA Toolkit* states that assessments should monetize the effects of the proposals under consideration and indicate the information required to enable full monetisation.
83. The European Commission takes a still more rigorous approach. ‘Good quality data – facts as well as figures – are any essential part of any IA [Impact Assessment],’ the European Commission states in its 2009 guidance.⁶⁹ As far as possible, a good baseline for the Impact Assessment should be expressed in quantitative terms.⁷⁰ Impacts should be estimated using quantitative

techniques, ranging from simple extrapolation to fully fledged quantitative modeling, with the aim of understanding the extent of the impacts and estimate the costs and benefits in monetary form where possible. If such an approach is not possible, the reasons should be given.⁷¹

84. In the US, the FDA attempted to quantify the impact of the size of health warnings and tobacco consumption. However the relevant Regulatory Impact Analysis estimated a reduction in smoking that the FDA conceded was ‘in general not statistically distinguishable from zero.’⁷²
85. Here, unlike the FDA, the DH in its Impact Assessment completely eschews quantification of objective data. In doing so, it ignores the best practice guidance set out in the *Green Book* and the regulatory guidance in the *IA Toolkit*. Should plain packaging be proposed at a European level, proper quantification would be essential.

7.5 Elicitation of Subjective Judgments

86. Relying on experts’ subjective opinions about a hypothetical situation cannot substitute for analysis of objective data. Experts’ opinions do not constitute data to be analysed. Instead the role of experts is to collect, analyse and comment on empirical data.
87. Yet the DH is seeking to derive a quantified estimate of the impact of standardised packaging by asking experts for an ‘estimate of best guess.’⁷³ Deriving an estimate of the number of smokers likely to be dissuaded from smoking risks creating a misleading impression of objectivity.
88. This is worsened because cherry-picking, or selectivity, is built into the Elicitation of Subjective Judgments in at least three ways:
- Selection of the experts and which disciplines they are chosen from, to exclude those with an economics and econometrics background (who might be expected to test the claims of previous packaging restrictions against hard data)
 - The briefing given to them by the DH before the phone interviews as to what is expected of the experts
 - The assumptions which they must base their opinions on, notably that cigarette prices are unchanged (see 7.6 below)⁷⁴
89. Thus the design of the Subjective Elicitation builds in confirmation bias towards the DH’s preferred outcome of the consultation at the same time as potentially conferring a spurious sense of objectivity on the numbers derived from it. Whilst the DH concedes this, it does not question the objectivity of the resulting analysis and the question mark it places over its credibility (discussed further in Section 7.8.4 below). As the European Commission states in its Impact Assessment guidance, ‘the credibility of an IA depends to a large extent on providing results that are based on reliable and robust analysis, and which are transparent and understandable to non-specialists.’⁷⁵

7.6 Effect on cigarette prices

90. Price is a critical issue to the success or failure of the policy. Not only might it render the policy ineffective, it could lead to more smoking, as the price of cigarettes is known to be a factor influencing smoking. As noted in para 36 above, the DH had previously recognised in its 2008 consultation on the future of tobacco control that the relationship between changes in prices and consumption and acknowledged that price was generally accepted as the most effective mechanism to cut smoking.
91. Heckman notes that many studies have examined the responsiveness of consumer demand for smoking to changes in the 'full cost' of smoking, which includes not only the money price, but also restrictions on access, restrictions on use and the impact of future consequences, including health effects.⁷⁶ Heckman concludes:
- 'The relationship between price and quantity demanded of cigarettes has been studied extensively and estimated in numerous ways (e.g. over time, for youth and adults, for various brands, in many countries). Given the robustness of the findings, price may be considered a causal factor influencing youth smoking behaviour.'⁷⁷
92. Both the 'Elicitation of Subjective Judgment' exercise and the Stirling University review completely ignore the possible downward impact on price of de-branding cigarettes and thus the possibility that smoking might increase as a result of the policy.
93. The DH recognises that standardised packaging would reinforce the trend of downtrading to lower priced cigarette brands.⁷⁸ Cheaper cigarettes 'might threaten' the effectiveness of the policy and the possibility that standardised packaging would lead to lower prices is described by the DH as a policy risk and not analysed any further.⁷⁹
94. This is a cop out. Not only, as the *Green Book* states, should the negative consequences of a proposal be examined. In the case of standardised packaging, if prices fell as a result, it would destroy the rationale of the policy. The 2008 consultation listed price as a potential disadvantage, as it could force tobacco companies to compete on price alone.*⁸⁰

* The consultation paper went on to suggest that the effect of higher prices could be countered by higher tobacco taxes. However an unintended consequence of such a response might be to stimulate sales of illicit tobacco – the smoker of a premium brand is no longer buying the perceived brand value of the premium brand for the premium price, reducing the switching costs to cheaper brands or those purchased from non-regulated channels. As the 2012 Impact Assessment recognises, de-branding 'may weaken attachment of a smoker to their preferred brand' (DH (2012), para 21). Because the higher tax would apply to all cigarettes (not just de-branded premium ones), a significant tax increase would likely constitute a major boost to the illicit trade.

7.7 Impact on the illicit trade

95. A crucial aspect of the policy choice on standardised packaging is its potentially adverse impact on the supply of illicit cigarettes. If standardised packaging were to facilitate illicit supply, it could undermine the policy of making tobacco less affordable, a measure of proven effectiveness.
96. In 2010, the Coalition government re-introduced the tobacco duty escalator. This increases the attractiveness of the UK market to illicit suppliers. In the context of standardized packaging, a key issue therefore is its likely impact on the ability of HMRC and other public bodies to constrain the illicit market for fiscal and public health reasons.
97. The impact on the illicit trade is seen by the DH as one of the three main uncertainties of standardised packaging, along with price and on smoking rates (!).

Box 2: Excerpt from 2012 DH Impact Assessment on Standardised Packaging

‘The main uncertainties associated with the policy explored herein (beyond the impact upon smoking behavior itself) relate to impacts upon price and the illicit tobacco trade.’

Source: DH (2012), para 45

98. However the consultation’s treatment of the impact of standardised packaging on illicit tobacco is limited solely to the potential duty lost to the Exchequer.⁸¹ It ignores the impact on price from any growth in the share of the market taken by illicit cigarettes. This would undermine public health objectives in two ways:
- It would make cigarettes and tobacco more affordable
 - It would make tobacco more available, particularly to young people and school children, through unregulated channels
99. The DH states that the impact of standardised packaging on the sale of illicit cigarettes is ‘hard to predict.’⁸² Again, this is a cop out. As with the potential impact on price, the DH describes this as a risk of the policy, without examining what the consequences might be.⁸³
100. Whilst it is hard to predict the quantity of the effect, its direction isn’t hard to predict. No rational person contends that standardised packaging, by itself, would reduce sales of illicit products. The issue, therefore, is by how much it would increase them and the scale of extra criminal justice and border enforcement resources needed to constrain its growth.
101. By contrast, in a 2008 tobacco control consultation paper, the DH explicitly set out the threat to public health from illicit channels:
- ‘Illicit tobacco products are available at a number of locations in communities across the UK ... This creates a completely unregulated distribution network, and makes tobacco far more accessible to children and young people. Illicit tobacco is linked to organised crime and smuggling of other illicit goods such as drugs, alcohol and weapons.’⁸⁴

102. By facilitating the sale of illicit cigarettes, the policy could end up undermining the effectiveness of a tried-and-tested policy – higher cigarette duties. Such an outcome would not only cannibalise tobacco duties, but lower the price of cigarettes and boost consumption – a scenario that is not examined by the DH in the 2012 consultation. The potential impact of standardised packaging on the supply and consumption of illicit cigarettes is not a question that the DH is asking the experts in the Subjective Elicitation.

7.8 Susceptibility to bias

103. According to the *Green Book*, ‘optimism bias is the demonstrated systematic tendency for appraisers to be over-optimistic about key project parameters.’⁸⁵ It requires that optimism bias must be accounted for explicitly in all appraisals.

104. For cases in which no obvious empirical evidence is available (and the case for standardised packaging falls into that category, in that the DH ignored evidence on the effectiveness of precursor policies), the *Green Book* cautions that this ‘may indicate the project is unique or unusual, in which case optimism bias is likely to be high.’⁸⁶ In its guidance to public officials responsible for managing policy consultations, the European Commission states, ‘when carrying out the consultation and using the information it produces, you should be aware of a number of pitfalls that may introduce bias into the results.’⁸⁷

105. In the field of public health and tobacco control, British policy makers have a particular responsibility if they are to live up to the standards of their predecessors, as it was British epidemiologists who set unimpeachable standards of objectivity when they first discovered the link between tobacco smoking and lung cancer. In 1967, Sir Richard Doll, one of the two original researchers, illustrated the susceptibility of epidemiological evidence to distortion when he wrote: ‘The only safeguard is always to suspect the influence of bias, consider every way it could have entered the study and then test to see if it has.’⁸⁸

106. Bias has the potential to enter the DH consultation at four levels:

- The structure and focus of the consultation
- The Stirling University review
- The studies underlying the review
- The subjective elicitation exercise

7.8.1 Narrow focus

107. The consultation is focused solely on tobacco packaging. The three options being considered are standardised packaging; unspecified other packaging options; and ‘do nothing.’ The first two options depend on the unexamined premise that packaging is a causal factor in smoking, whilst a policy of ‘do nothing’ in an area, where no one disputes the need to cut smoking, creates a false choice.

108. This approach conflicts with best regulatory practice, as set out, for example, in the European Commission's 2009 Impact Assessment Guidelines. These state that a 'wide but credible range of options' should be considered.⁸⁹ Presenting only the status quo, the 'extreme' option and the preferred option should be avoided, as should only presenting complementary actions.
109. Options which might have greater benefit and lower risk than standardised packaging are excluded from the DH analysis. Because the potential impacts on price and the illicit trade of standardised packaging are not examined, the misleading impression is created that it is a low-cost, low-risk policy option.

7.8.2 Stirling University review

110. The Stirling University review is described as a 'narrative synthesis,' dependent on the reviewers' choice of papers and their decision on what to highlight from them.⁹⁰ Indeed the review states that it adopted an approach 'to review evidence to support these three proposed benefits' of standardised packaging, namely reducing pack and product appeal, increased salience of health warnings and reduced confusion about product harm.⁹¹ This approach to the selection of evidence implies that the Stirling University review excluded evidence that might question the policy's ability to deliver these benefits.
111. This raises the question of the respective roles of being an expert in a particular field and being a policy advocate. Sir Richard Doll took the view that the risk of bias was best safeguarded by clearly separating them. Doll's scientific philosophy precluded him from becoming emotionally attached to evidence, while at the same time providing a safeguard against accusations that his epidemiological conclusions were politically motivated, telling his biographer:
- 'I regarded my job as being to find out what the facts were. If you once get involved in deciding what attitude to take on the basis of the facts there's a danger your inquiry becomes biased.'⁹²
112. Based on a December 2009 article, 'Plain Packaging: a time for action,' it would be fair to describe that two out of the 2012 Stirling University review's ten authors as campaigners for plain packaging (Box 3). Moreover their assertion that it is an imperative for the tobacco industry to recruit new smokers is false and demonstrates the experts' ignorance of the economics of the tobacco industry as evidenced by the industry's performance in growing profits at the same time as smoking has declined (Section 7.9 below).

Box 3 Excerpts from Crawford Moodie, Gerard Hastings 'Plain Packaging: a time for action'

- 'The industry contend, as it did for years with advertising, that packaging only stimulates adult brand-switching ... [S]uch protestations of innocence have, as always, to be set against the industry's imperative to recruit and retain youth if it is to survive.'
- 'Plain packaging then cannot come too soon.'
- Plain packaging 'is the industry's Armageddon. Bring it on.'

Source: *European Journal of Public Health* (Dec 9, 2009), pp.1-2

7.8.3 The studies selected by the Stirling University Review

113. The studies selected by the Stirling University team might also be susceptible to bias. Of the 37 studies covered by the review, one third are written by one or more of the Stirling team and its collaborators, i.e., the reviewers reviewed themselves.

7.8.4 Subjective Elicitation exercise

114. The DH candidly admits that the Subjective Elicitation exercise is likely to be biased, but makes no attempt to correct for it. In choosing experts on whose views it will rely, the DH considers that 'impartiality and lack of an economic or personal stake in potential findings' are considered 'impractical in this area.'⁹³ It then refuses to disclose the identity of these experts together with their interests.

115. This lack of transparency makes it impossible for MPs and the public to assess for themselves the presence of bias and the nature and extent of the economic interests of the experts on whom the DH – and ultimately Parliament – is relying.

116. It is highly unusual for a public body to concede that bias is endemic; for it then to do nothing about it and for it to be unperturbed that public policy might be captured by outside advocates and those with economic interests. It is also contrary to the *Green Book* which states that to redress the tendency towards optimism, 'appraisers should make explicit adjustments for bias.'⁹⁴

7.9 Absence of economic analysis of the tobacco industry

117. A feature common to tobacco control policy papers and consultation documents from the 1998 White Paper onwards is the virtual absence of any analysis on the economics of the tobacco industry. Such analysis, focusing particularly on revenues, margins and profitability, would help answer the question posed in Section 7.1 above, that is: Do tobacco companies invest in cigarette brands and in packaging to attract new smokers or is branding a competitive tool to win market share and used to enable them to charge premium prices?

118. However there are a very limited number of references to such issues in the DH tobacco control policy papers and consultations. Where there is such discussion, it tends to be wrong, misleading or irrelevant (Table 3).

Table 3: DH Statements on Industry Economics

Document	Statement	Para	Comment
<ul style="list-style-type: none"> 2008 Consultation 2010 A <i>Smokefree Future</i> 	'We do know that the tobacco industry needs to recruit over a hundred thousand new smokers every year in England to replace those that die or quit'	3.5 1.44	Tobacco companies have increased revenues and profits even though cigarette volumes fell
<ul style="list-style-type: none"> 2010 A <i>Smokefree Future</i> 	'The UK tobacco industry has shown a capacity to evolve in order to meet the challenges that tougher tobacco control has brought ... The past decade has seen a proliferation of brands that are popular among poorer smokers, as well as increasing use of "roll your own" tobacco'	1.50	Customers, not companies drive demand for lower margin products (including illicit tobacco) in response to high tobacco taxes
<ul style="list-style-type: none"> 2008 Consultation 	'Tobacco manufacturers claim that the purpose of tobacco gantries [in shops] is merely to inform adult smokers of the price and availability of the price and availability of different brands. However, tobacco industry marketing strategy documents have suggested that a more important aim to attract new smokers'	3.43	The reference to documents alleging tobacco companies' attracting new smokers is to a 2003 study of the Australian retail environment. However the paper does not make any mention of what the DH asserted

119. The 2012 DH Impact Assessment contains a section on downtrading in the UK tobacco market. It notes that the erosion of premium brands' market share, falling from 35% in 2001 to 25% in 2009 and concluded that the extent of downtrading in response to standardised packaging was

'currently unknown and a variable on which evidence needs to be collected as part of the consultation.'⁹⁵

120. In fact, the Coalition's 2011 Tobacco Control Plan for England had already said it would encourage research into downtrading and the different prices paid by individuals and social groups.⁹⁶ Furthermore, the 2012 Impact Assessment did not examine the economic function of brands in the tobacco market in encouraging consumers to trade up to higher price points and what this might explain about the economic incentives and behaviours of tobacco companies.

121. Research into the relationship between advertising and consumption in the alcoholic beverages sector found that historical French alcohol consumption shifted from consumption of large amounts of table wine to smaller quantities of advertised beer and wine brands. According to the 1996

study, 'the main impact of advertising is to persuade consumers to trade up to more expensive, higher quality brands.'⁹⁷

122. If the parallel with the drinks industry holds, then the de-branding of cigarette packets might cause a shift in the opposite direction with an associated volume effect. Analysis of the economics of the tobacco industry is therefore critical to an assessment of standardised packaging as an effective tobacco control policy. Nonetheless, the Impact Assessment makes no reference to such analysis.

123. The co-existence of declining cigarette consumption and the tobacco industry's strong stockmarket performance is evidence that the DH has completely ignored and should have analysed. Since 1998, the share price for Imperial Tobacco Group PLC (Imperial), the largest tobacco group in the UK by market share, and the onset of the Labour government's tobacco control policies rose from 278p to £24.85 on 7th December 2012 – a nine-fold rise. Over the same period, the FTSE-100 index rose by 14%.

124. In a response to the 2008 DH consultation, Mr Adam Spielman, an investment analyst at Citigroup specialising in the tobacco sector, made a personal submission. Mr Spielman, the top-rated sell-side analyst in the tobacco sector, wrote:

'Probably, the most surprising (and important) point is that [the] tobacco industry can grow in a market like the UK, even in the face of a successful effort to reduce tobacco use. In fact, in some ways, the industry's objectives are aligned with those of tobacco control.

'This is because tobacco companies are interested in growing profit; this is quite compatible with simultaneous reductions in consumption and prevalence.'⁹⁸

125. The mechanics of how this works can be seen from numbers provided in Mr Spielman's submission on the breakdown of the retail price for a premium and a discounted brand summarised in Appendix I. Although the discount manufacturer's take per pack rose faster than that for the premium brand (+58.1% vs. 31.5%), the premium manufacturer's take at 84p per pack in July 2008 is nearly double that of the discount pack at 49p

126. The next step is to estimate the impact of the increases in price faced by smokers on tobacco company revenues. Ignoring the effect of inflation and applying the HMRC's central estimate for the relationship of changes in cigarette prices to volume (-0.72) implies that revenues of the discount cigarettes would increase by 35.5% and by 28.8% for the premium brand.^{*99} Tobacco companies would only lose revenue if the fall in the number of smokers caused by non-price reasons exceeded these percentage increases. Mr Spielman comments in his submission

* Although revenues for discount brands grow faster in response to tax increases than those for the premium brand, this is merely a function of the manufacturer's take being a smaller percentage of the retail price than (10.3% vs. 17.0% for the premium pack in July 2008). The absolute increase per pack is lower.

‘with rising sales and falling costs [because tobacco companies are making fewer cigarettes], profits will inevitably grow. No wonder the shares have been so strong.’¹⁰⁰

According to Mr Spielman, the costs are similar to make a premium pack of cigarettes as for a discount pack. This implies that the profit differential between premium and discount cigarettes is even greater.

127. The 96% net revenue per pack premium over discount cigarettes is sufficient to explain tobacco companies’ investment in premium brands in terms of the substantial revenue losses if the brand perception were eroded. It is not necessary to postulate that premium brands turn non-smokers into smokers for tobacco companies to have a strong profit rationale to invest heavily in branded packaging.

128. High tobacco duties thus support high and growing (net of tax) profit margins. According to Mr Spielman’s 2008 submission,

‘From an economic perspective the rapid increase in manufacturers’ prices holds the key to the entire industry: as long as prices rise faster than volumes fall, then net sales will rise ... From a tobacco-control perspective this mechanism to grow profits is perfectly acceptable because increasing prices decreases consumption and prevalence.’¹⁰¹

If the logic of Mr Spielman’s analysis is accepted, there is a contradiction between a policy of making cigarette packs less attractive (which is the objective of standardised packaging) and maintaining the high pricing structure of the UK tobacco market and its associated public health benefits.

7.10 Legal risks

129. The Labour government’s 2010 *A Smokefree Future* said it would seek views on and give weight to the legal implications of restrictions on packaging for intellectual property rights.¹⁰² However the 2012 Impact Assessment contained no evaluation of the potential legal risks created by standardised packaging to intellectual property rights. The consultation merely asks whether the policy would have legal implications.¹⁰³

130. In an opinion submitted on behalf of the tobacco company PMI, the former law lord Lord Hoffmann, asked whether the prohibition of branding required by standardised packaging would be contrary to Article I of the First Protocol to the European Convention on Human Rights. ‘Although this point is controversial,’ Lord Hoffmann wrote

‘Parliament may be entitled to take the view that there is a public interest justification in extinguishing the use of the marks on the ground that their use encourages people to smoke. But that is not enough to justify extinguishment of the marks *without compensation*’ (emphasis in the original).¹⁰⁴

8. Conclusions

131. The flaws in the consultation are sufficiently extensive as to cast doubt on whether it is anything more than an exercise in going through the motions to justify a pre-determined conclusion:
- Failure to establish the benefits of existing tobacco control measures to provide a yardstick to assess the effectiveness of standardised packaging, contrary to domestic and EU impact assessment standards
 - Reliance on the unstated and untested assumption that cigarette packaging is a factor causing people to smoke and one preventing them from stopping
 - Not carrying out any analysis of the economics of the tobacco industry to find out why its profitability and shareholder returns have been so strong during a period of tightening tobacco controls and the role of brands in supporting high prices in a declining volume market, findings which would contradict the premise of the policy
 - Ignoring core evidence on the causes of smoking and on the efficacy of precursor policies, whilst relying on what might be termed pseudo-evidence which the DH has good reason to know is a poor predictor of smokers' behaviour
 - Selectivity in choosing favourable findings and experts and ignoring others which might question the preferred policy option
 - Failing to examine the likely impact of standardised packaging on cigarette prices and the illicit trade and the consequent effect on smoking
 - The admission that the process is prone to bias and not attempting to remedy its effects
132. Overall the consultation is framed as a false choice between doing nothing and additional restrictions of cigarette packaging. It risks creating the misleading impression of standardised packaging as a policy with limited downside in terms of meeting public health objectives because the potential adverse impacts on price and the illicit trade are not analysed.
133. Although the standards set by government for domestic consultations can be described as fairly elastic, the 2012 standardised packaging consultation does not reflect the aims and intent of the Coalition's 2010 regulatory policy statement *Reducing Regulation Made Simple*. Neither does it met the standards set out in the *Green Book* and the *IA Toolkit*.
134. As a consequence, policy makers and parliamentarians are not being given the information they need to make a sound judgment on the merits of the proposal. It is arguable that the consultation falls below the standards set by the Courts in presenting information which is potentially misleading and its tolerance of bias, which might be construed as evidence of failing to set out the true reasons for putting forward the relevant proposals.
135. High quality public health outcomes will not be obtained with policies based on poor quality analysis and a category of evidence that a US court characterised as 'mere speculation and conjecture' (para 66 above).

Table 4 Benchmarking DH Standardised Packaging Consultation against Regulatory Guidance Standards

Consultation standard / principle	Set out by / in	End Ref	DH Shortfall against Standard
<i>'Command and control' regulation should be a last, not first resort</i>	<ul style="list-style-type: none"> The Coalition / <i>Reducing Regulation Made Simple</i> 	3	<ul style="list-style-type: none"> Standardised packaging is a last resort, command and control measure
<i>A wide range of options should be evaluated and tested</i>	<ul style="list-style-type: none"> HM Treasury / <i>Green Book</i> European Commission / <i>Impact Assessment Guidelines</i> 	9 16	<ul style="list-style-type: none"> DH only consulting on standardised packaging and an unspecified intermediate option
<i>Demonstrate what would happen without further regulatory intervention</i>	<ul style="list-style-type: none"> HM Treasury / <i>Green Book</i> 	6	<ul style="list-style-type: none"> DH has not provided forecasts of what would happen without standardised packaging DH has not established a baseline for the effectiveness of existing tobacco control measures DH did not analyse which tobacco control measures have worked and which ones are ineffective
<i>Analyse negative consequences of the proposed intervention</i>	<ul style="list-style-type: none"> HM Treasury / <i>Green Book</i> 	6	<ul style="list-style-type: none"> The DH has not analysed the negative consequences for public health policy of a possible reduction in cigarette prices caused by de-branding tobacco packaging The DH has not analysed the impact on public health objectives of the possible stimulation of consumption of illicit tobacco by standardised packaging or its wider economic and social impacts

Consultation standard / principle	Set out by / in	End Ref	DH Shortfall against Standard
<i>Quantify the effects of the proposals and scale the impacts by monetising their effect</i>	<ul style="list-style-type: none"> The Coalition / IA Toolkit 	11	<ul style="list-style-type: none"> There is no empirical evidence of a causal relationship between cigarette packaging and smoking rates, so the DH cannot provide objective estimates of the monetised value of longer life expectancy, instead the DH is relying on a Subjective Elicitation exercise which lacks transparency that the DH acknowledges is prone to bias The DH made no attempt to monetise the negative impacts of standardised packaging on any boost to the illicit on the grounds that the effect is hard to predict¹⁰⁵
<i>Include the financial and resource impacts on other government departments, including on the criminal justice system and the likely impact on the rate of crime or impact on crime prevention</i>	<ul style="list-style-type: none"> The Coalition / IA Toolkit 	13	<ul style="list-style-type: none"> The DH has not provided estimates of the likely financial cost to the criminal justice system, the impact on crime rates and crime prevention – or even acknowledged the need to do so
<i>Information in the consultation must not be incorrect or misleading</i>	<ul style="list-style-type: none"> The Courts 	17	<ul style="list-style-type: none"> The DH's repetition of the conclusion of the Stirling Review that there is strong evidence that plain packaging would reduce smoking is misleading The DH ignores the disclaimer buried in the Stirling Review that, in the absence of validation, surveys on attitudes have 'quite weak predictive validity' – which negates the review's assertion of there being strong evidence In endorsing the conclusions of Stirling Review, the DH also ignored its own findings of a disparity between smokers' intentions and their subsequent actions

Consultation standard / principle	Set out by / in	End Ref	DH Shortfall against Standard
<i>Consultations must give true reasons for putting forward the relevant proposals and should be willing to change course</i>	<ul style="list-style-type: none"> The Courts 	17	<ul style="list-style-type: none"> DH admission of the susceptibility of bias; its unwillingness to correct for bias and the lack of transparency surrounding its selection of experts and their interests to enable Parliamentarians and third parties to correct for bias taken together might be construed to imply the existence of an unstated reason for the proposal and that the consultation has been designed to achieve a pre-determined outcome

Appendix I

Change in breakdown of cigarette retail prices Nov 2004 – July 2008

	Premium brand (Marlboro)					Discount (Mayfair)			
	Nov 2004	July 2008	Change			Nov 2004	July 2008	Change	
	£	£	£	%		£	£	£	%
Tax	3.77	4.32	0.55	+14.6		3.47	3.96	0.49	+14.1
Trade margin	0.32	0.38	0.06	+18.8		0.21	0.25	0.04	+19.0
Manufacturer's take	0.73	0.96	0.23	+31.5		0.31	0.49	0.18	+58.1
Retail price	4.82	5.66	0.84	+17.4		3.99	4.77	0.78	+19.5
As % of retail price									
Tax	78.2%	76.3%				87.0%	83.0%		
Manufacturer's take	15.1%	17.0%				7.8%	10.3%		

Source: Adam Spielman, *Submission on the Future of Tobacco Control* (2008), Fig. 3

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