

W. KIP VISCUSI

**AN ASSESSMENT OF THE LIKELY EFFECT OF PLAIN PACKAGING ON
WARNINGS EFFICACY**

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I. EXECUTIVE SUMMARY

1. I have been engaged by British American Tobacco Norway to review the literature that claims that plain or standardized packaging (hereafter “plain packaging”) will contribute to reducing smoking initiation and more generally to reducing smoking prevalence, generally by making health warnings more effective and by preventing people from being misled by packaging features that draw attention away from the health warnings or suggest that the product is less harmful.
2. I conclude that the adoption of a plain packs policy will not make warnings more effective, increase risk awareness, or reduce smoking initiation. Although my reasons are readily apparent from the material that follows, I would like to highlight the following primary ones:
 - Public awareness about the health risks of smoking cigarettes is effectively universal. The hazards of smoking are known to the public in Norway including youth. The evidence demonstrates that new cigarette policies will be operating in an informational environment in which the health risks of smoking are well known.
 - The criteria for judging whether there is a productive role for warnings policies include whether they provide new information in a convincing manner and will lead to more accurate risk beliefs. To be of value, from the standpoint of promoting public health, information must influence decisions.
 - Given that consumers are adequately informed, there is no beneficial role for general additional warning efforts, which is essentially what it is contended that plain packaging would do given that plain packs do not provide any new information to consumers.
 - The experimental literature on plain packs provides no evidence to support the claim that a plain packs policy will make warnings more effective, increase risk awareness, or alter smoking behaviors. Many studies of plain packs do not even set out to address any of these fundamental concerns but instead focus on third person opinions of how plain packs will affect the attractiveness of cigarettes to others.

- The cigarette warnings in Norway have achieved a high level of noticeability. Increasing the prominence of a health warning which is already very large will not have an influence on smoking behaviors.
- If specific information gaps with respect to the knowledge of the risks of smoking are identified then targeted warnings focusing on those specific risks can be successful in increasing awareness of those risks. However, this does not require the implementation of Plain Packaging.
- There is no evidence demonstrating the link of any color to undermining the efficacy of the warnings or misleading consumers as to the risks of smoking. However, if there are specific colors that are misleading, such specific colors could be restricted. Again, this does not require the implementation of Plain Packaging.
- The recognized drivers of smoking initiation are peer effects, family environment, access to cigarettes, and socioeconomic status, not cigarette packaging.
- Studies of plain packs do not examine the influence of these recognized drivers of smoking initiation or show that plain packs foster more accurate risk beliefs or decrease rates of smoking initiation.
- Based on my analysis of the evidence and my many years of research on the use of hazard warnings and consumer behaviors, I am of the view that there is no sound basis to conclude that plain packaging would be effective in increasing risk awareness or reducing smoking behavior.

II. EDUCATIONAL BACKGROUND AND PROFESSIONAL EXPERIENCE

3. I am the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University, where I hold tenured appointments in the Vanderbilt University Law School, the Department of Economics, and the Owen Graduate School of Management. Throughout my career, my main research interest has been on societal and individual responses to risk and uncertainty, with primary focus on risks to health and safety. I currently focus on how consumers make decisions involving both the precisely understood risks and the less well understood hazards

of particular products, including cigarettes and drinking water. Much of my research has analyzed regulatory responses to risk—such as hazard warnings, government regulation, and the role of other social institutions—and how they affect consumer behavior. I also have extensive experience in the theory and practice of benefit-cost analysis.

4. I received a Bachelor's degree in Economics from Harvard University. While at Harvard, I was inducted into Phi Beta Kappa, graduated *summa cum laude*, and won the Allyn A. Young Prize for the best undergraduate thesis in economics. I also received a Master's degree in Public Policy, a Master's degree in Economics, and a Ph.D. in Economics, all from Harvard University. My graduate dissertation focused on how workers learn and assess employment risks, and how risk beliefs affect quitting behavior. I won the David A. Wells award for the best Ph.D. dissertation in economics.
5. Since obtaining my Ph.D., I have taught at several universities and held the following tenured faculty positions: University Distinguished Professor of Law, Economics, and Management, Vanderbilt University; John F. Cogan Jr. Professor of Law and Economics and Director of the Program on Empirical Legal Studies, Harvard Law School; Allen Professor of Economics, Duke University; Professor of Economics, Northwestern University; and Professor of Business Administration, Fuqua School of Business, Duke University. I have also been the Olin Visiting Professor at the University of Chicago.
6. My professional engagements have also included work with the U.S. federal government. In 1979, I was appointed to be the Deputy Director of President Carter's Council on Wage and Price Stability, a Senior Executive Service position within the Executive Office of the President. The primary purpose of the Council was to provide Executive Branch oversight for all major new federal regulations and to bring inflation under control; it was a major problem at the time. The Council on Wage and Price Stability also had responsibility for the White House oversight of all new federal regulations.¹ We also had input on all major economic policies, since we were a member of the Economic Policy Group, which was

¹ President Reagan transferred that authority to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget.

President Carter's cabinet-level group dealing with economic policy. I left that position in 1981.

7. The Reagan Administration subsequently asked me to become involved in a significant policy controversy as an expert on benefit-cost analysis. In 1982, the Occupational Safety and Health Administration performed a benefit-cost analysis of new regulations requiring that dangerous chemicals in the workplace be labeled, and it proposed what was known as the hazard communication regulation. The Office of Management and Budget (OMB) rejected that proposal, claiming that the costs were in excess of the benefits. Then-Vice-President Bush concluded that an expert should be brought in to resolve the dispute between the agencies, and both OMB and the Secretary of Labor nominated me. Prior to this time, there was no requirement that dangerous chemicals in the workplace be labeled; and this was the most expensive regulation that the Reagan Administration had considered up to that point. My report showed that the benefits did in fact exceed the costs and recommended issuing the new regulations. The regulation was issued soon after my report in support of it reached the White House. Among the items that came out of this regulation are the Material Safety Data Sheets now found in workplaces across the U.S.
8. I have worked extensively with the U.S. Environmental Protection Agency (EPA) on a continuous basis from 1983 to 2012 serving in several different roles. From 2002 to 2003, I was a full-time employee of that agency while on sabbatical from teaching. I have also been a member of numerous committees of EPA's Scientific Advisory Board, including the Environmental Economics Advisory Committee, the Clean Air Act Compliance Analysis Council, and the Homeland Security Advisory Committee. I have served as a consultant to EPA on public smoking restrictions. I have directed studies for EPA regarding risk communication, morbidity risk valuation, environmental regulation enforcement, hazardous waste cleanup, drinking water safety, and other matters.
9. I have conducted numerous studies for EPA that are closely related to the evaluation and design of hazard warnings. Much of my work for EPA has focused on the development of guidelines for the Agency for hazard warnings for dangerous

pesticides and chemicals. These studies involved an experimental structure in which consumers reviewed different warnings, assessed the implied risks, and indicated the precautions that they would take in using the product. This work has appeared in numerous articles, and much of it is summarized in two books: W. Kip Viscusi and Wesley Magat, *Learning about Risk: Consumer and Worker Responses to Hazard Information* (Cambridge: Harvard University Press, 1987), and Wesley Magat and W. Kip Viscusi, *Informational Approaches to Regulation* (Cambridge: MIT Press, 1992). These peer reviewed studies can be viewed as the academic precursors to much of the recent experimental work on cigarette warnings and plain packs.

10. In addition to my extensive work for EPA, I have consulted for several other governmental entities on a variety of issues, including the U.S. Department of Transportation, the U.S. Department of Labor, the U.S. Department of Justice, the U.S. General Accounting Office, the U.S. Department of Health and Human Services, the U.S. Office of Management and Budget, and the National Oceanic and Atmospheric Administration. I have also taught courses about risk, uncertainty, risk analysis, and hazard warnings to hundreds of Food and Drug Administration officials, congressional staff, and federal and state judges. I served as the Associate Reporter on The American Law Institute Study on Enterprise Responsibility for Personal Injury and co-wrote the chapter on Product Defects and Warnings. And I have testified before the U.S. Congress on nine occasions as an expert in economics and risk analysis. This testimony addressed such topics as, for example, alcoholic beverage warnings.
11. Apart from my academic and governmental work, I have consulted on matters such as risk perception, hazard warnings design, and safety devices for large companies, including Bic, DuPont, Becton Dickinson, R.J. Reynolds, Bristol-Meyers Squibb, Anheuser-Busch, Black & Decker, and Medline Industries. I have also served as a consultant/expert witness for the U.S. Department of Justice in a variety of cases. These include an analysis of natural resource damages issues in connection with the Exxon Valdez oil spill. I have also testified on behalf of the Province of Quebec on risks and warnings for video lottery terminals.

12. In addition to my teaching and other professional engagements, I am heavily involved in writing and publishing scholarly research articles. My own writing includes authoring or co-authoring more than 20 books and 300 articles, most of which focus on risks to health and safety, including risk perception and hazard warnings. I am one of the top 25 economists in the world in terms of overall citations to my work in the leading peer-reviewed economics literature. I am a founding editor of two journals: the *Journal of Risk and Uncertainty*, which publishes peer reviewed articles on issues relating to risk perception and analysis; and *Foundations and Trends: Microeconomics*. And I am currently on the board of several other academic journals, including *Regulation*; *Journal of Law, Economics and Policy*; *Journal of Tort Law*; *Contemporary Economic Policy*; *Regulation and Governance*; *Managerial and Decision Economics*; *Journal of Risk and Insurance*; *Journal of Benefit-Cost Analysis*; *Review of Environmental Economics and Policy*; *American Journal of Health Economics*; and *The Geneva Risk and Insurance Review*. I have also held editorial positions with such journals as *American Economic Review*, which is the official journal of the American Economic Association; *Review of Economics and Statistics*, a journal specializing in quantitative applied economics and based at Harvard University; *Journal of Environmental Economics & Management*; *Public Policy*; *International Review of Law and Economics*; and *Journal of Regulatory Economics*. I have served as a peer reviewer for dozens of other publications and for government agencies in countries throughout the world.
13. I have won several awards for my books and articles. These include the “Article of the Year” award from the Western Economic Association for an article on the valuation of life; the “Article of the Year” award from the Royal Economic Society, an international economic society based in England, for an analysis of how ambiguous risk information influences decision-making; and the “Article of the Year” award from the American Risk and Insurance Association for an article on automobile insurance regulation. I am also a four-time winner of the Kulp Award for “Book of the Year,” also given out by the American Risk and Insurance Association. Other recent professional awards include being named an Honorary

Member of the Academy of Economics and Finance; and winning the University of Chicago Law School's Ronald H. Coase Prize for an article on risk perception.

14. Much of my scholarly research and writing has focused on issues of risk and health relating to smoking. My work on risk analysis, risk perception, consumer behavior, and regulation as it relates to smoking has included extensive research into the history of the tobacco industry and the related public health discussions, as well as current events as they pertain to these issues. These articles have been widely disseminated and subject to peer review. I have also testified on tobacco-related issues and have submitted expert reports in proceedings in the U.S. and other countries on behalf of cigarette companies. However, none of my research has been funded by the tobacco industry or law firms representing the tobacco industry.
15. I have also written two books exclusively related to smoking. The first, *Smoking: Making the Risky Decision* (Oxford University Press, 1992) is about smoking and smoking risks, and analyzes how the available information about smoking has changed over time, how people have assessed the risks of smoking, and how those risk perceptions affect smoking behavior. The book also explains how changes in the price of cigarettes affect cigarette consumption. The second book, *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (University of Chicago Press, 2002), includes chapters on risk perceptions and addiction, youth smoking, environmental tobacco smoke, the promotion of potentially safer cigarettes, the settlement of the U.S. state litigation against the tobacco industry, the U.S. Master Settlement Agreement, and the financial costs of smoking. Both books were subject to peer review.

III. ASSESSING THE LIKELY EFFECT OF PLAIN PACKS ON WARNINGS EFFICACY

A. The "Effectiveness" of Health Warnings in the Light of the Health Objectives of Plain Packaging

16. For the plain packs requirement to meet any reasonable standard of efficacy, *i.e.*, of being able to provide a genuine contribution to the public health objective, it must further an actual behavioral objective (*i.e.*, reducing smoking initiation, increasing cessation and reducing relapse). Such a test is standard in assessing the economic

value of informational policies such as plain packs or warnings, because these regulatory efforts have no economic value if all consumer decisions remain unchanged.² Analogously, from the standpoint of policy, failure to promote any behavioral change would be an indicator that the policy did not pass an efficacy or genuine contribution test.

17. As I will explain further below, the studies relied on to promote plain pack policy do not demonstrate any effect of plain packs on risk beliefs, smoking behavior, or public health. Moreover, even if there were such a linkage, the results of the studies would be called into question by the failure of the hypothetical experiments used in the studies that are intended to evaluate plain packs to replicate the experience in which the smoker views warnings multiple times on a pack rather than a single time on a computer screen or some other artificial experimental context.
18. Before addressing the relevance of the study results relating to the mechanisms described above, it is important to first elaborate on the meaning of the term “effectiveness” of health warnings. Many studies of plain packs have framed the efficacy test in terms of measures not directly related to actual impacts. For example, the 2012 review of the plain packaging literature by the Public Health Research Consortium (2012 PHRC Review) cites the following categories of possible “benefits” of plain packaging: “The Framework Convention on Tobacco Control (FCTC) proposes that plain packaging would have three benefits: it would reduce the attractiveness and appeal of tobacco products, it would increase the noticeability and effectiveness of health warnings and messages, and it would reduce the use of design techniques that may mislead consumers about the harmfulness of tobacco products.”³ These criteria are not tantamount to measures of efficacy with respect to smoking behaviors. Increasing the effectiveness of warnings as measured by “recall, attention, seriousness and believability”⁴ is only of behavioral consequence if consumers currently have an informational deficit and do not find existing warnings credible, neither of which is established in any of the

² Howard Raiffa, *Decision Analysis: Introductory Lectures on Choices Under Uncertainty* (Random House, 1968).

³ Crawford Moodie, et al., *Plain Tobacco Packaging: A Systematic Review*, (University of Stirling, 2012).

⁴ *Id.*, at ii.

studies. To the extent that the studies in the literature deal with measures more directly related to risk beliefs or smoking behavior, the findings in the literature are largely consistent with my conclusion below that there is no substantive basis for concluding that plain packaging will decrease smoking prevalence rates or exposure to tobacco smoke.

19. In sum, whether plain packs will enhance the effectiveness of warnings on risk beliefs depends on how much people know about the risks of smoking and how much having warnings on plain packs rather than regular packs will alter these risk beliefs. In the next section, I review the state of public knowledge and the degree to which there is widespread awareness of the risks of smoking. Since plain packaging policies do not provide any new information, but only affect the appearance of the packaging, one would not expect any extra benefit from plain packaging if consumers are already cognizant of the messages currently being communicated.

B. The Current Extent of Risk Beliefs

20. Adopting a plain packs policy does not alter the informational content of the warnings being provided. Thus, before embarking on any new informational regulations, it is essential to inquire whether people are cognizant of the risks associated with smoking behavior.
21. It is generally recognized that one of the most remarkable public health achievements of the past 60 years has been the communication of the risks of smoking to the public and the resulting reduction in smoking rates. Much of the effect of cigarette warnings stemmed not from the wording of the warnings but from the fact that cigarettes were the first mass marketed consumer product to have safety warnings pertaining to inherent risks associated with the product. Over time the progress that can be made through additional warnings efforts will taper off as people become better informed of the risks of smoking. There is diminishing incremental efficacy of warnings efforts. Once people become generally aware of the major risks posed by cigarettes, such as the mortality risk and lung cancer risk, there will be fewer gains in risk awareness that can be achieved, if any.

22. Examination of the current state of consumer knowledge provides substantial insight into what informational efforts have already accomplished and whether the public has, in effect, reached a level of awareness in which there will be few if any additional gains to be derived from new informational efforts, let alone from efforts such as plain packaging that do not provide any new information. If consumers are adequately informed, there is no beneficial role for additional warnings efforts of a general nature. Policies designed to strengthen the existing warnings in some way will not produce the anticipated improvements to public health once there is substantial risk awareness.
23. The test for whether risk awareness is adequate takes on particular significance given the multiplicity of risks associated with cigarettes. In some product contexts, there may be a single risk, such as whether a braking system may fail. However, for cigarettes, medical researchers have documented multiple hazards, ranging in severity and their likelihood of occurrence. Examining the entire spectrum of risks consequently is important, but this must be done in a way that is linked back to how perceptions of this spectrum influence smoking behavior.
24. As a consequence, the full information reference point for judging a decision does not require that people be cognizant of all the risks of cigarettes. A person might overestimate the probability of some health hazards such as lung cancer and underestimate other risks, such as that of gum and mouth disease. Indeed, in the extreme case, there could be some health risks associated with smoking that a person is not aware of at all. The test for consumer decisions is whether taking into account the consumer's assessment of the risks of smoking and the harms to health associated with the risks the consumer is deterred from smoking to the same extent as would be the case if the consumer was further informed regarding the risks. This criterion is a different and more comprehensive test that focuses on the influence of the sum total of the role of risk beliefs rather than whether any particular health risk is known. As the data indicate, people are acutely aware that smoking poses the risk of lung cancer, death, life expectancy loss, and other hazards. Given these risk beliefs, it is unlikely that knowledge of other specific risks would change their smoking behavior. What additional information in terms of the risks associated with smoking needs to be conveyed to consumers in order to influence their

smoking behavior is important; it is however not a pertinent question, unfortunately, in the context of plain packaging given that a plain packaging measure does not provide any new information on the specific risks associated with smoking.

1. Risk Beliefs in Norway.

25. The public, including youth are well informed about the risks of smoking. Statistics reflect the widespread exposure of the public to anti-smoking messages, and indicate universal awareness of the potential health consequences of smoking. Youth are often taught about the dangers of smoking in schools, and are targeted in media campaigns that warn of possible health risks. Warnings on cigarette packets in Norway, which now cover 30% of the front and 40% of the back of cigarette packs, have reinforced the media coverage of smoking risks.
26. Public awareness in Norway about the risks of smoking cigarettes is effectively universal. Numerous media and awareness campaigns that downgrade and stigmatize smoking⁵ have been carried out over time by the government, non-government organizations, and interest groups targeting the general public, including youth.⁶ A study carried out in Norway in 1995 indicated that virtually all respondents were aware of the link between smoking and fatal diseases like lung cancer.⁷ This high level of awareness extends to the adolescents, as indicated by a further study involving the rating of harmful substances by a respondent pool comprised of university students across both rural and urban Norway.⁸ This study observed that students rated tobacco as having the highest physical harm score, amongst a number of other harmful substances.
27. I note that as a statistical matter, it is virtually impossible for any poll or public opinion survey to reach 100%; to quote a report on smoking from the U.S. Surgeon

⁵ See for example, The World Health Organisation, *Joint National Capacity Assessment on the implementation of effective Tobacco Control Policies in Norway*, page 28; Lund et al., "Contrasting smokers' and snus users' perceptions of their personal tobacco behaviour in Norway" at page 1.

⁶ The World Health Organisation, *Joint National Capacity Assessment on the implementation of effective Tobacco Control Policies in Norway*, page 30

⁷ A. Steptoe et al., "Tobacco smoking in young adults from 21 European countries: association with attitudes and risk awareness" 90, 571-582 *Addiction* (1995) at 576

⁸ W. Pederson et al., "Which substance is most dangerous? Perceived harm ratings among students in urban and rural Norway." *Scand J Public Health* June 2015 43: 385-392, first published on March 27, 2015.

General, it may be “unrealistic to set a goal above 90 percent of smokers for public knowledge.”⁹

2. Implications for Consumer Choice

28. A person’s decision to smoke is not a sign of ignorance of the risks or irrational behavior. Consumers do not become irrational just because they smoke or contemplate smoking. It is obvious that smokers can derive positive utility from smoking just as there might be a rational basis for undertaking any other risky activity in our daily lives. This is neither idiosyncratic nor reflexive, and it is not insubstantial. Smoking was once the norm among adults in many countries, and even today, empirical evidence on consumer smoking behaviors indicates that smokers continue to perceive substantial benefits from smoking.
29. The data also indicate that consumers’ decisions about smoking are rational and consistent with decision-making of the usual economic fashion, in which costs and benefits are weighed against each other. For example, cigarette demand declines as the price rises. In the rational economic framework, if the benefits of a product are high and the perceived risks are low, the net benefit of the product to the consumer will be high. If the risk is high and the benefit is low, the product will be unattractive for purchase by a rational consumer. People who perceive greater risks are less likely to smoke. The public is overwhelmingly aware of the dangers of smoking. In this environment, there is no beneficial role of plain packs for increasing the effectiveness of warnings or discouraging smoking initiation.

C. Assessment of the Studies Allegedly Supporting the Conclusion that Plain Packaging Increases the Effectiveness of Health Warnings.

30. In Appendix A of this report, I provide guidance on what properties sound experimental studies should have in order to properly test the efficacy of a policy such as plain packaging. I then undertake a critical review and assessment of the studies allegedly supporting the conclusion that plain packaging increases the effectiveness of health warnings. I find no evidence from these studies that plain packaging will increase the effectiveness of warnings. The main results of these

⁹ U.S. Public Health Service, “Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General,” at 221 (1989).

studies take the form of plain packs being less attractive than regular packs, which is exactly what one would expect given that plain packs resemble cheaper generic brands. Only a small number of plain pack studies have specifically focused on the effect of plain packs on risk beliefs, and these studies indicate that people think that smoking is dangerous whether presented in plain packs or regular packs. The findings from the studies reviewed provide no basis for concluding that plain packs will make warnings more effective.

31. The limitations of experimental studies in assessing the likely effects of plain packaging were noted by the Expert Panel Report for Health Canada (1995).¹⁰ That report considered plain pack studies in the literature at the time and concluded that there was little evidence that plain packs would affect youth smoking initiation. On page 2 the Expert Panel Report for Health Canada states:

“The study of consumer behavior is limited by methodological concerns about validity and reliability. Virtually all consumer behavior research is conducted in a contrived environment with simulated purchases, or through vignettes describing product decisions. The results may approximate real consumer behaviour but probably would not replicate it.”¹¹

32. The 2012 PHRC Review of the literature also acknowledges the limitations of the studies in assessing actual behaviors, stating that:

“Some caution is required in interpreting these findings, as expressed smoking-related intentions are not always predictive of future smoking behaviour (Ajzen & Madden 1986, Sheeran 2002) and perceptions of the impact of a future policy measure on the behaviour of others are of course subjective.”¹²

33. The 2012 PHRC Review¹³ and the 2013 update of that review¹⁴ (the 2013 PHRC Review; and together the PHRC Reviews) provide a general overview of plain packaging and related warnings issues. Neither of these reports presents new

¹⁰ Expert Panel Report for Health Canada. *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging on Tobacco Products* (March 1995).

¹¹ Expert Panel Report for Health Canada, *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging on Tobacco Products*, p2 (1995).

¹² Crawford Moodie, et al., *Plain Tobacco Packaging: A Systematic Review*, (University of Stirling, 2012) at 87.

¹³ Crawford Moodie, et al., *Plain Tobacco Packaging: A Systematic Review*, (University of Stirling, 2012).

¹⁴ Crawford Moodie, et al., *Plain Tobacco Packaging Research: An Update* (University of Stirling, 2013).

research or provides a thorough assessment of the scientific merits of the studies or any evidence regarding actual impacts of plain packs on smoking risk beliefs or smoking prevalence. Rather, the emphasis is on identifying and classifying the articles in the literature, which deal with various experimental contexts. Counting studies and the direction of the results does not certify the soundness of the experimental procedures, the relevance of the experimental effects to likely policy impacts, the statistical significance of the results, or the magnitude of the results.

34. The nature of the 2012 PHRC Review’s findings is reflected in the conclusion of the 2012 PHRC Review that 19 studies rated plain packs as less attractive, and 12 studies found that plain packs were perceived to be of poorer quality. Such counts are not informative of the quality or policy applicability of the studies. Moreover, for many of the key issues examined, the results were not clear-cut. The 2012 PHRC Review found that with respect to warning salience, 4 studies indicated a positive effect of plain packs, 1 found no difference, and 2 found mixed effects. The effects on perceptions of product harm and strength, as well as the effects on smoking behavior likewise were “mixed”. As my detailed critique of the studies in Appendix A shows, these results are based on hypothetical responses in experimental contexts and are far removed from actual behaviors.
35. Interestingly, the 2013 PHRC Review reported on one intervention in Scotland that was closer to a realistic experiment than the other studies reviewed in which a sample used their own cigarette brand for one week and a plain pack brand for one week. While respondents reported saying that they would look more closely at the plain pack and its warning, which one would expect given the unfamiliar appearance of the experimental packs, there was no impact of plain packs on risk beliefs: “No significant overall differences in salience, seriousness or believability of health warnings were found between the pack types.”¹⁵
36. The report of the independent review undertaken by Sir Cyril Chantler on standardized packaging of tobacco (the Chantler Report) relies on the two PHRC Reviews and an assessment of those reviews.¹⁶ The assessment does not involve a

¹⁵ Crawford Moodie, et al., Plain Tobacco Packaging Research: An Update (University of Stirling, 2012), at 6.

¹⁶ Standardised Packaging of Tobacco, Report of the Independent Review Undertaken by Sir Cyril Chantler, April 2014.

critical scientific appraisal of the studies or presentation of any new empirical evidence in support of plain packs. Much of the report consists of an endorsement of the PHRC Reviews (referred to in the Chantler Report as the Stirling Systematic Review) such as the following: “The Stirling evidence has been criticized for relying on stated intentions in hypothetical situations. I recognize that stated intentions are generally weak predictors of behaviour (regardless of whether the situation is hypothetical or not). I see the importance of Stirling as being the consistency of its results on appeal, salience and perceptions of harm, most notably that standardized packaging is less appealing than branded packaging.”¹⁷ This and related defenses of the PHRC Reviews are based solely on a subjective judgment by Sir Cyril Chantler and do not add in any way to the weight or policy implications of the empirical evidence in the PHRC Reviews.

IV. ASSESSING THE IMPACT OF PLAIN PACKAGING IN LIGHT OF THE ROLE OF WARNING PROMINENCE AND COLORS ON RISK BELIEFS

37. Cigarette packaging can differ on dimensions such as size and type of the warning and pack colors. The question addressed in the next section is whether such aspects of the pack may undercut the effectiveness of health warnings.

A. Warning Prominence

38. The experimental evidence on the role of warning prominence for cigarette packs is generally consistent with basic warnings principles. Eventually, there is diminishing marginal effectiveness of making any warning more prominent. And once a warning has achieved noticeability, increasing the warning size or prominence does not have an influence on smoking behaviors.

39. The review of the literature on warning size by Kleijnen Systematic Reviews (2011) concluded that there was a “lack of good quality evidence” indicating that an increase in warning size from 30 percent to 50 percent of the front of the pack would affect smoking initiation, prevalence, or cessation.¹⁸

¹⁷ *Id.*, at 5.

¹⁸ Kleijnen Systematic Reviews Ltd., *Systematic Review of the Effectiveness of an Increase in the Size of Tobacco Health Warning Labels on Cigarette Packs in Reducing Smoking: Final Report* (June 2011).

40. An interesting tobacco-related study that documents the role of informational saturation with respect to the size of cigarette warnings is the study by Bansal-Travers et al. (2011a).¹⁹ Respondents addressed the question of which cigarette they would buy if they were trying to reduce the risk to their health. The percentage choosing cigarette packages with different warning labels was 34 percent for warnings comprising 30 percent of the label, 11 percent for warnings comprising 50 percent of the label, and 53 percent for warnings comprising 100 percent of the label. This U-shaped pattern of concern for averting risk and its relation to the percentage of warnings on the pack implies that there is no consistent relationship at all between the amount of warning information and choices based on health risk. And once again, the study's focus avoids the more fundamental issue of whether increasing the warning label's percentage significantly affects whether the warning is read, understood, and leads people to have more accurate risk beliefs. And if there are such effects, will they be observed for regular smokers rather than in a one-time experiment?
41. The most meaningful test of whether graphic warnings will have an effect on smoking behavior is to analyze the effect of those warnings on smoking prevalence in countries that have implemented these warnings. The only government agency that has done this to date in relation to a proposal to introduce graphic warnings is the U.S. Food and Drug Administration (FDA).
42. In 2011 the FDA undertook a study to analyze the effect of graphic health warnings on Canadian smoking prevalence rates. In an analysis that accounted for the effect of cigarette tax changes but ignored the role of smoking trends, the FDA estimated an effect of graphic warnings on smoking prevalence rates of 0.574 percentage points in a comparison of 2001-2009 to 1994-2000.²⁰ However, in an analysis that also recognized trends in the U.S. experience as a control for existing smoking trends in Canada, which the FDA indicates is its "preferred estimation method," then the estimated effect of graphic warnings is only 0.088 percentage points. The FDA is correct in preferring a statistical approach that accounts for cigarette tax

¹⁹ M. Bansal-Travers, et al., *The Impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.* American Journal of Preventive Medicine 40(6), 674-682 (2011a).

²⁰ U.S. Dept. of Health and Human Services, Food and Drug Administration, Required Warnings for Cigarette Packages and Advertisements, *Federal Register*, Vol. 76, No. 120, June 22, 2011, p. 36756.

changes and accounts for U.S. smoking trends so as to control for what Canadian trends would have been without the graphic warnings. After making these adjustments, the FDA estimates that the effect of graphic warnings on smoking prevalence rates is less than one-tenth of a percentage point. Not surprisingly, the FDA concluded that their “effectiveness estimates are in general not distinguishable from zero; we therefore cannot reject, in a statistical sense, the possibility that the rule [requiring graphic warnings] will not change the U.S. smoking rate.”²¹

43. As a second level of analysis the FDA commissioned a survey to measure consumer attitudes, beliefs, perceptions, and intended behaviors related to cigarette smoking in response to graphic warning labels.²² This study included approximately 18,000 participants and is the largest survey of stated consumer responses to cigarette graphic health warnings ever conducted.²³ This study tested the relative efficacy of 50% graphic warnings relative to a control of a text only warning statement. The control group viewed a pack of cigarettes with just a text warning statement presented on the side of the packet in accordance with the current standard warning on cigarette packets in the U.S. The treatment groups (exposed to warning images) viewed a hypothetical pack of cigarettes that included the graphic warning label. The study failed to find a consistent pattern of significant effects on risk beliefs for a wide variety of possible graphic health warnings.²⁴ Notably, the authors concede that “[t]he graphic cigarette warning labels did not elicit strong responses in terms of intentions related to cessation or initiation.”²⁵
44. The study design is less informative than the examination of smoking prevalence trends for a number of reasons. The study presented respondents with computer images of different graphic warnings and compared their smoking attitudes and

²¹ *Id.* at 36776.

²² Nonnemaker, J., et al., Experimental Study of Graphic Cigarette Warning Labels: Final Results Report Prepared for Center for Tobacco Products, Food and Drug Administration, Contract No. HHSF-223-2009-10135G, Dec. 2010 at 1-2.

²³ US FDA, Frequently Asked Questions: Final Rule “Required Warnings for Cigarette Packages and Advertisements” (“FDA FAQ”), available at <http://www.fda.gov/TobaccoProducts/Labeling/CigaretteWarningLabels/ucm259953.htm>.

²⁴ For example, the study concluded with respect to the warning for fatal lung disease: “None of the warning images were significantly associated with the likelihood of quitting in the next 30 days (among adults and young adults) or the likelihood of smoking 1 year for now (among youth) compared with the control group.”

²⁵ Nonnemaker, J., et al., Experimental Study of Graphic Cigarette Warning Labels: Final Results Report Prepared for Center for Tobacco Products, Food and Drug Administration, Contract No. HHSF-223-2009-10135G, Dec. 2010 at 4-4.

stated smoking intention responses to those elicited without the use of graphic warnings. This design does not in fact measure actual behavior (*e.g.*, quitting smoking) following exposure to these messages. Rather, it employs a proxy measure—stated intention to quit—that is known to be unreliable and inaccurate and that undoubtedly overestimates actual behavior.²⁶ Many smokers who indicate an intention to quit make no effort to do so. This may be attributable to social-desirability bias associated with questions pertaining to this and similar subjects.²⁷ Consequently, quit intentions such as this tend to significantly overestimate the number of smokers who actually intend to quit as a result of the proposed warnings. There was no effort to account for this bias other than to acknowledge it.

45. Finally, this study also sought to assess the impact of the proposed graphic warning labels on discouraging smoking initiation among youth respondents.²⁸ Even accepting the research design at face value, the report to the FDA concluded that the data do not support the conclusion that exposure to the graphic warning labels will discourage smoking initiation²⁹ (“For youth, we used a measure of how likely [they] felt they were to be smoking 1 year from now as a measure of the impact of viewing the warning images on potential initiation. We did not find much evidence for an impact of the warning labels on this outcome.”). This study failed to find any demonstrable impact of graphic warnings over and above text warnings, on intentions related to smoking initiation or cessation.
46. Warnings on cigarette packages have contributed to widespread awareness levels of the dangers of cigarettes. Increasing the size of warnings or applying different warning formats (*e.g.*, use of warning colors, safety symbols, signal words, *etc.*) to information does not increase behavioural compliance. Bolder warnings do not convey unknown information and telling people something that they already know in **bold** letters or **LARGE TYPE FACE** or with graphics does not change that.

²⁶ See, *e.g.*, L. Kozlowski, “What Researchers Make of What Cigarette Smokers Say: Filtering Smokers’ Hot Air,” *Lancet*, at 699.

²⁷ See Sutton, S., et al. “Explaining Smokers’ Decisions to Stop: Test of an Expectancy – Value Approach” *Social Behaviour* 2: 35-49 (1987) at 47: “*Furthermore, responses to the intention items may have been influenced by desirability or demand effect, with some smokers perhaps feeling that they should say that they intend to try*”.

²⁸ Nonnemaker, J., et al., *Experimental Study of Graphic Cigarette Warning Labels: Final Results Report Prepared for Center for Tobacco Products, Food and Drug Administration, Contract No. HHSF-223-2009-10135G, Dec. 2010 at 1-1*. Note that this issue was only evaluated among youth respondents.

²⁹ *Id* at 4-4.

Once a warning has achieved noticeability, increasing the warning size or prominence does not have an influence on risk beliefs or smoking behaviours. There is no empirical evidence that “shouting” works in increasing behavioural compliance in this context.³⁰ The underlying assumption for these changes is presumably that people are not aware of the risks or do not sufficiently appreciate the seriousness of those risks. As shown above, that assumption is inaccurate.

47. Warnings can change behavior, but unlike regulations, warnings do not demand compliance, warnings do not demand obedience under threat of sanctions but communicate information. It follows that warnings can only change behavior through the effect on risk beliefs by providing relevant information of which an individual was previously unaware. Once such warnings have achieved their objective, their effectiveness is not further increased by ever increasing the size of the warnings or by putting the large warnings in a plain pack environment.

B. Colors

48. Viewed from the standpoint of public health, if there are particular colors that undermine the warning messages, any government can assess whether to ban these specific colors under existing legal provisions. Presumably, all colors are not equally misleading if indeed any colors are. But as the review of the research in Appendix B shows, there is no evidence demonstrating the link of any color to undermining the efficacy of warnings or misleading consumers as to the risks of smoking.

V. ASSESSING THE LIKELY EFFECT OF PLAIN PACKS ON SMOKING INITIATION

A. Drivers of Smoking Initiation

49. If a person starts smoking, it does not mean that the person did not understand the risks or that cigarette packaging is responsible for the smoking behavior. A substantial literature has documented the principal drivers of smoking initiation, and these key factors do not include cigarette packaging, branding, and related factors.

³⁰ Experimental evidence on the diminishing benefits of increased print size is provided in Wesley Magat and W. Kip Viscusi, *Informational Approaches to Regulation*, (MIT Press, 1992).

50. The main determinants of smoking initiation, which typically takes place when one is young, involve factors other than influences that can be controlled through changes in cigarette packaging. The causes of youth smoking have been the subject of two reports by the U.S. Surgeon General as well as dozens of studies throughout the world. As the review below indicates, the key contributing factors to smoking initiation by youths are influences involving one's parents, siblings, friends, peers, access to cigarettes, personal characteristics, and cost.
51. The overviews of the literature echo a consistent theme. The U.S. Surgeon General (1994) report listed factors driving smoking initiation such as low socioeconomic status, peer and sibling use and approval of tobacco, lack of parental support, low levels of academic achievement, and low self-image.³¹ The more recent U.S. Surgeon General (2012) report reiterated these themes and added emphasis on the high accessibility and availability of tobacco products, such as obtaining tobacco products from parents, siblings, or peers.³² More generally, parental support, use by friends, and religion are among the other causal factors cited.
52. Cigarette smoking is but one of many risky behaviors for youths, which include the use of illegal substances like alcohol consumption and drug use, and is subject to similar kinds of societal influences. The determinants of these risky behaviors are very similar as they involve peer influences, family background including parental and sibling influences, the school environment, and socioeconomic status.
53. Individual country studies generally explore the nature of the influences on youth initiation in greater detail but nevertheless focus on the same pivotal paths of influence. Most of the studies highlight one or more of the principal influences among those cited in the more comprehensive reviews above. The Canada Smoking Profile 2008/2009 found that peer and family member situations are associated with increases in youth smoking, as 76 percent of youth smokers have family members who smoke as opposed to 45 percent of non-smokers.³³ Similarly, 95 percent of smokers have close friends who smoke, as compared to 45 percent for

³¹ U.S. Dept. of Health and Human Services, *Youth and Tobacco: Preventing Tobacco Use Among Young People*, A Report of the Surgeon General (1994).

³² See U.S. Dept. of Health and Human Services, *Preventing Tobacco Use Among Youth and Youth Adults*, A Report of the Surgeon General (2012).

³³ *Smoking Profile for Canada*, The 2008/2009 Youth Smoking Survey, Health Canada (2010).

non-smokers, and most youths in Canada obtain their cigarettes from family and friends. Ali and Dwyer (2009) undertook a longitudinal analysis of the effect of classmates, as having a close friend who smokes has a long-term effect that continues until adulthood.³⁴ Similarly, a study tracking smoking behavior by 3rd to 5th graders through 12th grade by Bricker et al. (2006) found that the smoking behavior of parents, older siblings, and close friends all boosted smoking rates.³⁵ In the U.S., the study by DiFranza et al. (1994) found that friends were the source of the first cigarette for 69 percent of their sample of 721 youths aged 10-17 years.³⁶ Irrespective of the country, the role of factors such as these is a prominent determinant of smoking initiation. Cigarette packaging simply is not a factor leading to smoking initiation.

B. The Studies Supporting Plain Packaging Do Not Examine the Drivers of Initiation

54. The plain pack smoking initiation studies did not examine the influence of plain packaging on any of these drivers of smoking initiation and did not even ascertain how plain packs would affect the respondent's likelihood of starting smoking. Rather, the studies usually asked people whether they thought that plain packs would lead others to start smoking. Such questions not only did not deal with actual smoking behavior, or whether plain packs would affect the respondent's behavior, but inquired about third party opinions of how they thought plain packs would affect others. Such opinions are subject to very severe demand effects whereby respondents give the interviewer the answer that they think the interviewer wants to hear.
55. Moreover, at a more fundamental level, such studies of plain packs and smoking initiation are simply not legitimate scientific inquiries. Suppose that the matter of interest is whether exposure to some stimulus causes a behavioral effect. The appropriate scientific test is to vary the stimulus across experimental groups and examine whether their behavior differs. The approach in the plain pack studies is

³⁴ M. Ali and D.S. Dwyer, *Estimating Peer Effects in Adolescent Smoking Behavior: A Longitudinal Analysis*, Journal of Adolescent Health 45(4), 402-408 (2009).

³⁵ J.B. Bricker, et al., *Close Friends', Parents', and Older Siblings' Smoking: Reevaluating Their Influence on Children's Smoking*, Nicotine & Tobacco Research 8(2), 217-226 (2006).

³⁶ DiFranza, J. R., et al., *Tobacco Acquisition and Cigarette Brand Selection among Youth*. Tobacco Control 3(4), 334-338 (1994).

quite different as the researchers asked people whether they thought that the stimulus (in this case plain packs) would have behavioral effects on others. Subjective opinions on this relationship are irrelevant and provide no scientific basis for drawing any conclusions.

56. A detailed discussion of the plain packaging studies and their failure to examine drivers of initiation can be found in Appendix C.

VI. CONCLUSION

57. It is instructive to put the plain packs measures in perspective based on what is known about informational regulations generally. Warnings policies have diminishing incremental effectiveness as the amount of warnings increases. Once warnings have achieved an adequate degree of noticeability, as cigarette warnings in Norway have, increasing the size or prominence of the warnings will not foster the public health objectives.
58. One can best understand the overall merits of a plain packs policy proposal within the context of the entire set of smoking risk information efforts. For many years, Norway has had a vigorous cigarette warnings program and broad-based smoking information efforts. As a result, there is widespread knowledge of the hazards of smoking and awareness of the current warnings. Given this degree of risk awareness, there is no demonstrable need for seeking to enhance the current warnings and no reason to believe that changes in cigarette packaging would have a beneficial effect on public health.
59. The experimental literature on plain packs provides no evidence to support the claim that a plain packs policy will make warnings more effective, increase risk awareness, or alter smoking behaviors. Many studies of plain packs do not even set out to address any of these fundamental concerns but instead focus on third person opinions of how plain packs will affect the attractiveness of cigarettes to others.
60. Consideration of the likely efficacy of plain packs policies or other interventions should exploit our existing knowledge of what is known about the determinants of risk awareness and smoking behavior. A great deal is known about the determinants of smoking initiation, and the documented drivers of smoking

initiation do not pertain to cigarette packaging. Rather, the important influences are factors such as peer groups, the family environment, access to cigarettes in the home or from friends, performance in school, and socioeconomic status. The plain pack smoking initiation studies did not examine the influence of plain packaging on any of these drivers of smoking initiation and did not even ascertain how plain packs would affect the respondents' likelihood of starting smoking.

61. Moreover, the proposed shift to plain packs involves a change in the format and structure of the packaging rather than its content. There is no evidence that such changes will promote public health. If specific information gaps with respect to the knowledge of the risks of smoking are identified or specific colors are problematic, it would be preferable and more effective to employ targeted policies to address these issues rather than a less focused plain packs policy.
62. Based on my analysis of the evidence and my many years of research on the use of hazard warnings and consumer behaviors, I am of the view that there is no sound basis to conclude that plain packaging would be effective in increasing risk awareness or reducing smoking behavior.

W. Kip Viscusi

June 5, 2015

W. Kip Viscusi

Date

University Distinguished Professor of Law, Economics,
and Management

Vanderbilt University Law School, Department of
Economics, and Owen Graduate School of Management

APPENDIX A

Analysis of the Studies Allegedly Supporting the Conclusion that Plain Packaging Increases the Effectiveness of Health Warnings

1. General Comments on Methodology

1. As a preliminary matter, I note that the studies often raise similar methodological issues. Almost invariably, these studies are experimental studies using a survey methodology and do not address impacts on smoking prevalence rates. It is useful to outline some of the properties sound experimental studies should have in order to frame the subsequent discussion. In a previous submission to the U.S. Food and Drug Administration, I took a pro-active role in suggesting how a study might be designed to test the efficacy of a graphic warnings policy.³⁷ Many of my recommendations were based on the principles embodied in a series of experimental studies that I undertook on chemical and pesticide warnings for the U.S. Environmental Protection Agency.³⁸ Below I provide some similar guidelines that could be used to assess plain packaging.

a) Adopt sound survey methodologies

2. Surveys are problematic for a number of reasons and cannot replace naturalistic or experimental studies that track actual behavior. However, if surveys are to be used, a number of typical problems with survey evidence need to be avoided. The first matter of concern in relation to surveys, which is the predominant study methodology in this area, is the sample used for any survey. Many of the plain packaging studies have used Internet samples. An Internet panel can often be useful in studies of adults aged 18 and over, but less is known about the properties of such panels for the target youth smoking groups, who are usually the principal focus of studies pertaining to smoking initiation. Obtaining meaningful responses from this under-age group is complicated by the fact that their purchase of

³⁷ Statement of W. Kip Viscusi, U.S. Food and Drug Administration, Docket No. FDA-2010-N-0079 (April 21, 2010).

³⁸ W. Kip Viscusi and Wesley A. Magat, *Learning about Risk: Consumer and Worker Responses to Hazard Information* (Harvard University Press, 1987); Wesley A. Magat and W. Kip Viscusi, *Informational Approaches to Regulation* (MIT Press, 1992).

cigarettes is usually illegal, and their responses may be affected by a concern on their part that their parents will or may be aware of their participation in the survey, and aware of the substance of their responses if done on a home computer. It is important to verify that honest, accurate, and representative responses can be obtained from this under-age group. Thus, while it is not infeasible to use an Internet sample to study youth smoking, great care must be exercised to ensure that the responses are meaningful.

3. Experimental explorations of the likely effects of major policies also should be based on results for a sample that is nationally representative and reflects the population being targeted by the policy. The plain pack studies generally make no pretense that the sample meets this standard. Most are based on convenience samples prone to serious sample selection effects, such as student groups or subjects recruited at shopping malls. Convenience samples are often useful for pretests prior to a major study and can be used for some limited research purposes, but they should not be used for a study which is of major policy relevance because the results cannot be projected to any broader population of interest.³⁹
4. Moreover, the survey research design should test across subjects, as opposed to within subjects, to assess any experimental effects. For example, if the study is testing two different types of packaging, different respondents should view the different packaging in order to avoid demand effects stemming from the survey. Failure to use such an across-subject design will lead to an overestimate of the effect of, for example, bolder warnings or plain packaging. If the study is done within subjects, as most plain packs studies are, the experimental plain packaging will tend to prompt a higher reported risk assessment.
5. Even a well-conceived survey design such as an Internet study of different types of packaging, however, is not capable of providing information from which conclusions regarding the relationship between exposure to plain packaging, on the

³⁹ A convenience sample is a survey sample of respondents who typically can be recruited quickly and without great expense. Convenience samples are not based on a random probability-weighted sample of the population and do not purport to be representative of the entire population. Convenience samples, such as interviewing people at mall intercepts or using people who volunteer to take an Internet survey on a particular topic, provide measures of how that particular sample responds, but the results are not generalizable to the broader population. Convenience samples are often used at the pretesting stage for a survey that will subsequently be fielded to a representative population.

one hand, and quitting smoking (or not starting, or re-starting), on the other hand, can be based. Surveys of this type that have been undertaken for plain packs are cross-sectional. In other words, they are capable of providing information about a single point in time (*i.e.*, when they are undertaken), about a particular group of individuals (*i.e.*, the respondents, and possibly, if the respondents are statistically representative of a larger population, the larger population of which the respondents are representative). Such cross-sectional surveys are not useful in terms of providing information on the genuine contribution that a regulatory measure may have on the policy outcome.

6. Many studies of plain packs contrast plain packs with branded packs in the same survey. Thus, they are within-subject comparisons rather than across-subject comparisons that will be less subject to demand effects and related biases. In the current cigarette market, the plain packs tend to be generic cigarette brands that are priced lower and are generally believed to be of lower quality than the branded cigarettes. Even if the person is a non-smoker and has had no experience with generic brands, inferences based on experience with generic brands in other contexts will usually lead people to believe that they are of lower quality. If that were not the case, given the lower price for generics they would drive all regular branded products out of the market.
7. Finally, the most exploratory type of study that has been undertaken with respect to plain packs is a focus group discussion. Focus groups generally consist of 6 to 10 people and a moderator, who leads them through a discussion of a particular topic, in this case, the consumer reactions to plain packaging. While focus groups are often useful as an exploratory first step in developing a more formal study, the outcome of focus group discussions can be very sensitive to the leadership of the moderator. In addition, focus groups have well-known shortcomings in that participants may say things to maintain their self-image during the focus group discussions or may be unduly influenced by an outspoken member of the group. “There is always the ‘loudmouth’ problem—when one highly opinionated person drowns out the rest of the group.”⁴⁰ Even if a study includes a large number of

⁴⁰ Phil Kotler and Kevin Keller, *Marketing Management*, 106 (12th ed., 2006).

focus groups, the results do not have statistical validity since the statements by the individuals are not independent of one another and also are not independent of the influence and potential bias of the focus group moderator. More generally, focus groups are not a substitute for more formal experimental or survey research.⁴¹

8. The studies of plain packs and warnings generally suffer from a series of these fundamental deficiencies—reliance on unrepresentative convenience samples, use of focus groups that have no statistical validity, and various shortcomings of the study design that make it infeasible to draw any conclusions about the effect of plain packs on the efficacy of warnings in altering either risk beliefs or smoking behaviors.

b) Obtain a baseline of risk beliefs

9. In order to determine the extent to which plain packaging affects risk beliefs, any study will need to carefully assess the baseline knowledge among respondents on those topics. There is a need for such a baseline in order to gauge whether the tested packaging in fact increases awareness, including along various demographic strata (age, smoking status, gender, *etc.*). The dimensions on which the baseline risk perception measures are defined should make possible meaningful comparisons with risk beliefs elicited after providing the warnings in a plain pack environment. The baseline risk perception measures should be defined so as to relate to the objective of fostering sound, informed smoking decisions.
10. The baseline risk perception questions could be at different levels of refinement. At the most fundamental level is a risk awareness question inquiring whether smoking increases the risk of certain diseases such as heart disease. But it would also be instructive to ascertain whether plain packs would lead people to increase their assessment of the level of the risk even if they were already aware of the hazard. Quantitative measures that I have used in my previous work include assessments of the life expectancy loss due to smoking and the increased probability of death, lung

⁴¹ “Although many useful insights can emerge from thoughtfully run focus groups, there can be questions as to their validity, especially in today’s marketing environment....Even when multiple focus groups are involved, it may be difficult to generalize the results to a broader population.” *Id.*

cancer, or heart disease due to smoking.⁴² Other measures of the strength of risk belief also may be instructive to the extent that they make it possible to ascertain whether plain packs would increase respondents' assessment of the level of the risk.

11. None of the existing plain packaging studies starts from a determination of the existing risk beliefs to compare with the risk beliefs resulting from plain packaging.

c) Reflect what will be experienced in practice

12. Many types of surveys, including those done via the Internet, are not well suited to analyzing product packaging and warnings that appear on a product. In my various studies of alternative product warnings for the U.S. government, my colleagues and I have prepared actual mock-up products with labels as they will appear in commercial use.⁴³ Cigarette packages have a front, back, and sides that will include product information or warnings. The test warnings in plain packs studies should incorporate these aspects of product design. Examining the actual packaging is a much more meaningful approach to assessing plain packaging than seeing the front of such packaging on a computer screen. The salience of a warning is quite different when the warning is placed on a product that the consumer can examine, as in a realistic cigarette-usage situation.
13. More generally, when the packaging policy is implemented, people will not be viewing a series of alternative types of cigarette packaging, but will only be responding to the particular packaging and accompanying warning that is selected. For the survey to parallel the ultimate policy reality, it is essential to ascertain how respondents will react to that particular packaging rather than a set of possible alternative packaging.
14. Unfortunately, however, most of the experimental studies discussed below do not provide cigarettes in plain packaging that resembles actual packaging, but rather provide pictures of the packaging, often on computer screens and restricted to the front of the pack. As noted above, the salience of a warning is quite different when the warning is isolated on the screen rather than placed on the product so that the

⁴² See W. Kip Viscusi, *Smoking: Making the Risky Decision* (1992); and *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (2002).

⁴³ *Id.*

consumer can examine the warning as in a realistic cigarette-usage situation.⁴⁴ Because cigarette packages have a front, back, and sides that include product information or warnings, proper test warnings should incorporate those aspects of product design. Plain pack studies generally have failed on this dimension.

d) Assess risk beliefs and informational inadequacies

15. To assess the informational value of plain packs, researchers should establish individuals' baseline risk beliefs before considering the warnings on plain packs and then ascertain whether these risk beliefs have increased after seeing the warnings on plain packs. If there is no increase in risk beliefs, then one cannot conclude that plain packs foster a greater understanding of smoking risks.
16. Even if risk knowledge rises after viewing a warning on cigarettes packs with plain packaging, there are two caveats before one can conclude that plain packs are effective. First, are the risks for which beliefs have increased among the major health risks or are they minor hazards compared to the more fundamental risks such as those pertaining to cancer, heart disease, and total smoking mortality? Second, what is the magnitude of the increase and is this increase of sufficient consequence to alter smoking behavior in a meaningful way? In any case, plain packaging does not provide any new warning information and there is no evidence that new warnings were not noticed before plain packaging. The plain pack studies fail to assess the alleged information deficit that plain packaging would fill and do not examine whether people's risk beliefs change as a result of plain packaging. General statements reflected in some of the studies that plain packs look less attractive, are considered as "stronger" in taste or are believed to be less misleading about the harmful nature of the product, do not address the key question of whether consumers are more aware of the risk of smoking once all cigarettes are sold in plain packs and that consumers beliefs are affected in such a way that they will change their behavior.

⁴⁴ In my various studies of alternative product warnings—such as those included in my two hazard warnings books with Wesley Magat that are cited above—my colleagues and I prepared actual mock-up products with labels as they would appear in commercial use.

e) **Explore effects on actual smoking behavior**

17. A meaningful survey to assess the effectiveness of plain packaging with respect to encouraging cessation of smoking among current smokers would need to be longitudinal and to monitor actual smoking behavior over time rather than stated intentions. In other words, the survey should track a constant population over time to determine whether the exposure to a particular stimuli (here, plain packaging) has led to cessation.
18. Stated quit intentions have little relevance. Respondents may simply give the socially acceptable answer.⁴⁵ Questions that ask respondents whether they will engage in activity that is either illegal (among the minor respondents) or socially undesirable (smoking), may be biased by the likely desire of respondents to offer the legal and/or socially desirable response. This effect, which is often referred to as a social approval bias or a social desirability bias, is a well-established effect that has been observed with respect to other reported personal behaviors, such as dietary intake.⁴⁶ Recognition of such an influence is not new in smoking research. As Dr. Kozlowski noted in his *Lancet* paper more than 25 years ago, “Given the widespread harassment of cigarette smokers and the evidence that smoking is actually dangerous to health, it is not surprising that smokers sometimes lie about their smoking.” “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? And, if the questioner asks if the attempts to stop have been serious, who would want to confess a half-hearted effort? Yet, answers to questions on ‘wanting to stop’ and ‘trying to stop’ have regularly been used uncritically - as if smokers now must be telling the truth.”⁴⁷
19. The great majority of smokers indicate in surveys that they intend to quit, but they may make these statements independent of any actual quit intentions. As a result,

⁴⁵ S. Sutton, et al., *Explaining Smokers' Decisions to Stop: Test of an Expectancy-value Approach*, *Social Behavior* 2(1), 35-49, at 47 (1987) (“Furthermore, responses to the intention items may have been influenced by a desirability or demand effect, with some smokers perhaps feeling that they should say that they intend to try.”).

⁴⁶ J. R. Hebert, et al., *Social Desirability Bias in Dietary Self-Report May Compromise the Validity of Dietary Intake Measures*, *International Journal of Epidemiology*, 24(2), 389-398 (1995).

⁴⁷ L. Kozlowski, et al., *What Researchers Make of What Cigarette Smokers Say: Filtering Smokers' Hot Air*, *Lancet* 315 (8170), 699-700, at 699 (1980). *See also* Giovino et al., *Trends in cigarette smoking cessation in the United States*, *Tobacco Control* 2(S), S3-S10, at S9 (1993) (“In 1991, 76 percent of current smokers stated that they wanted to quit, and the number hasn't changed much over time. Answering ‘no’ to this question is probably a socially unacceptable answer. We will need to consider that in our deliberations.”).

stated intentions in this context may be meaningless. The object of any study should be to determine which informational interventions will lead to actual quit behavior, not stated quit intentions. To achieve that objective, one needs to use a survey with a longitudinal capability that focuses on actual behavior.

20. Designing a survey that attempts to predict whether exposure to plain packaging discourages initiation of smoking among youth and former smokers involves still further methodological considerations. Again, the design would need to follow a group of non-smoking youth and former smokers over time and, controlling for variables associated with smoking among each of those two groups, determine whether exposure to the stimuli health messages, all else being equal, predicted initiation among each of these populations, respectively. It is appropriate to have a control group that is not exposed to the stimuli, so as to distinguish the effect of the different warnings from the influence that arises from having smoking risks highlighted by the survey, itself.
21. Another significant limitation applies to an attempt to obtain through a survey information about future behaviors related to tobacco use. Quitting smoking may involve a series of actions that should be monitored to ensure that respondents follow through on their quit intentions. In his *Lancet* article cited above, Dr. Kozlowski also reports the results of a Philadelphia smoking cessation effort in which only 5 percent of those who expressed an interest in attending a smoking-cessation clinic actually did so (at 699).⁴⁸ The ideal way to control for the discrepancy between stated quit intentions and actual quit behavior is to measure what smokers actually do, not what they say, in response to questions about future tobacco use.
22. The plain packaging studies fail to examine actual behavior.

⁴⁸ Similar estimates are cited by Drs. Prochaska and Goldstein for a different smoking-cessation effort. J. Prochaska & M. Goldstein, *Process of Smoking Cessation: Implications for Clinicians*, *Clinics in Chest Medicine* 12(4), 727-735, at 729 (1991) (“In one of the largest HMOs in the Northwest, smokers were surveyed, and 70 percent to 80 percent said they would take advantage of free self-help programs. After an intensive publicity campaign, 4 percent requested the action-oriented materials.”). More recent studies have made similar observations about the disconnect between stated smoking intentions and concrete quit efforts. M. Goldstein, *Bupropion Sustained Release and Smoking Cessation*, *Journal of Clinical Psychiatry* 59(S.4), 66-72, at 66 (1998) (“Although approximately 70 percent of current smokers say they want to quit smoking, only about 20 percent are actively attempting to do so.”).

Conclusion

23. In conclusion, research designed to assess the possible effects of plain pack policies should: i) adopt sound survey methodologies, ii) obtain a baseline measure of risk beliefs, iii) provide cigarettes in packaging and frequency of use that closely follows what will be experienced in practice, iv) assess risk beliefs after receiving the warnings in a plain pack environment and ascertain whether the plain presentation of the pack and the warnings address informational inadequacies, and v) explore the likely effects on smoking behavior and public health based on an actual field experiment in which the effects of plain packs on smoking behavior are monitored. Unfortunately, the available research has not met these standards, as it has fallen short on almost all of these dimensions.
24. As discussed, although studies may have inherent limitations given the artificial attempt to simulate actual consumer decisions, the specific studies that I assess below have even more fundamental shortcomings than these inherent limitations.

2. Discussion of Specific Studies of Plain Packs and Warnings Efficacy, Including Its Impact on Health Risk Information

25. Here I will consider some of the more prominent studies of plain packs that are claimed to establish that warnings are more effective on plain packs.

a) Beede and Lawson (1992)

26. One of the first studies often cited in support of plain packs is the study of adolescent children in New Zealand by Beede and Lawson (1992).⁴⁹
27. In this study, the sample was a convenience sample of 568 adolescents that was not representative. As with many other plain packs studies, the experimental design was a test of branded packs including additional information versus plain packs, which the researchers modeled on generic products. The study utilized focus group discussions followed by individual interviews with the focus group participants. Consequently, all data are contaminated by the group discussions led by the focus group moderator. There are no independent observations that can be used for

⁴⁹ P. Beede, and R. Lawson, *The Effect of Plain Packages on the Perception of Cigarette Health Warnings*. Public Health 106(4), 315-322 (1992).

purposes of scientific tests. As discussed above, such focus group studies yield no meaningful data because all of the responses are influenced by the group discussions and the comments by the focus group moderator.

28. The authors found a greater unaided and aided recall of ten health warnings for the plain packs, with modest discrepancies such as 74 percent recall for plain packs versus 64 percent recall for regular packs. These differences were concentrated among U.S. brands that were not familiar to the respondents. Consequently, the effects that would be observed for domestic brands would be less because people can process and recall the warning information on familiar domestic packaging more readily. Differences in recall rates also do not imply that there are any differences in risk beliefs for different kinds of packs. Even taken at face value, this study provided no evidence that plain packs were more successful in altering risk beliefs or smoking behavior.
29. Moreover, any possible effect of plain packs on recall rates has not generalized to other experimental situations. Germain et al. (2010) tested the recall of warnings for current cigarette packs modeled on the three most popular Australian brands and four plain pack variants that differed in terms of their format of brand names and fonts. All treatments included the same graphic health warning on the top, and one plain pack also included a large graphic health warning. Somewhat remarkably, despite the various packaging differences there were no statistically significant differences among the packs in the recall of the graphic health warning information: “Overall, 58% of the sample correctly recalled the graphic health warning and this did not vary by pack condition ($p > .10$).”⁵⁰

b) Rootman and Flay (1995)

30. The ease of seeing the warnings rather than the more fundamental effect of plain packs on risk beliefs was also the focus of the study by Rootman and Flay (1995).⁵¹

⁵⁰ D. Germain, et al., *Adolescents' Perceptions of Cigarette Brand Image: Does Plain Packaging Make a Difference?* *Journal of Adolescent Health* 46(4), 385-392, at 389 (2010).

⁵¹ I. Rootman and B. Flay, *A Study on Youth Smoking: Plain Packaging, Health Warnings, Event Marketing and Price Reductions*. University of Toronto, University of Illinois at Chicago, York University, Ontario Tobacco Research Unit, Addiction Research Foundation (1995).

31. Their study consisted of focus groups plus classroom surveys for students in grades 7 and 9 in Ontario and Chicago. The authors noted that warnings are prominent and remembered by four out of five Ontario students in grades 7 and 9, regardless of whether they are on plain or regular packaging, demonstrating that warnings are seen and assimilated. Furthermore, while the percentage remembering the warnings in Rootman and Flay's (1995) Canadian classroom study was greater in the Canadian study of plain packs versus regular packs (82 percent versus 62 percent), the authors found no difference between plain packs and regular packs when the study was replicated using a Chicago sample.⁵² The students did indicate a preference for regular packs over plain packs, but this result implies nothing whatsoever about whether plain packs will make the warnings more effective and promote public health.

c) Goldberg (1999)

32. Goldberg's (1999) study of plain packs focused on the recall of warnings but still does not address risk beliefs.⁵³
33. This study represents a more refined experimental test than in an earlier study by Goldberg et al. (1995), which included two noteworthy research components in addition to a literature review.⁵⁴ First, in the 1995 study, the authors undertook a national survey of 1,200 teenagers at mall intercepts and asked them to assess what effect plain and generic packaging would have on smoking rates. The results suggested that the effects would be small since only 30-40 percent of the sample thought that plain and generic packaging would make a difference, and the size of the likely effects for those indicating a difference were believed to be small in magnitude.⁵⁵ Second, the authors undertook a recall and cognition experiment in which teens who viewed plain packs and regular packs on a computer screen were more likely to recall the warning, "Smoking can kill you", on the plain pack.⁵⁶

⁵² See *id.*

⁵³ M. Goldberg, *The Effect of Plain Packaging on Response to Health Warnings*, *American Journal of Public Health* 89(9), 1434-1435 (1999).

⁵⁴ M.E. Goldberg, et al., *When Packages Can't Speak: Possible impacts of plain and generic packaging on tobacco products*. Expert Report Prepared for Health Canada. Ottawa: Health Canada (1995).

⁵⁵ *Id.*, at 7.

⁵⁶ *Id.*, at 10.

This study can be viewed as a limited pilot exploration for the Goldberg (1999) study described below.

34. In the 1999 study, using a mall intercept in Canada to recruit a sample of teens aged 14-17, Goldberg examined the recall of warnings for regular packs versus plain white packs. Subjects viewed the “packs” on computer screens. While plain packs were associated with increased recall of two warnings ("smoking can kill you", "cigarettes are addictive"), there was a 14 percent drop in recall rates for the warning pertaining to fatal lung disease for non-smokers. For this risk of smoking, plain packs decreased the recall of the health hazard.
35. In addition to providing very mixed results, the findings do not bear on the more fundamental issue of how effective plain packs would be compared to regular packs when people have repeated exposure to the packs and examine all sides of an actual pack rather than a computer image. In addition, in the event of any differences in the rates of recall, the study does not demonstrate whether such differences will translate into differences in risk beliefs and smoking prevalence, for the reasons explained above about the limited informational value of recall rates in the absence of an information deficit.

d) Hammond et al. (2009)

36. The study of U.K. adults and youths by Hammond et al. (2009) focused on risk beliefs and likewise did not produce evidence in support of plain packs.
37. The study utilized an Internet sample of 516 adult smokers and 806 youths aged 11 to 17 with a mean age of 14.6.⁵⁷ The sample participants viewed pairs of cigarette packs on the computer screen and rated them on various dimensions. A principal question of interest from the standpoint of plain pack warnings pertains to health risk beliefs: “If you were to choose between them, which one would you buy if you were trying to *reduce the risk* to your health?” The study included several pairwise comparisons, four of which involved plain packs versus regular packs without

⁵⁷ D. Hammond et al., *Cigarette pack design and perceptions of risk among UK adults and youth*, European Journal of Public Health, 19(6), 631-637 (2009). The youths’ parents approved their participation, and the authors do not disclose what information was provided to the parents about the study. Whether the responses by youths are meaningful was not discussed in the article, and the authors present no evidence to suggest that the survey responses by youths should be taken at face value.

additional confounding complications such as including descriptors such as “smooth” on some packs but not others. Note that even the very weak results discussed below will overstate any relative impact of plain packs due to the influence of demand effects that arise in a within-subject experimental design.

38. Examination of the study results indicates that most respondents did not see any difference in the health risk of plain packs. The percentages for adults (youths) were as follows:
- For the Mayfair king size white background plain packs, 75 percent (71 percent) saw no difference in the health risk, 20 percent (17 percent) preferred the plain packs, and 5 percent (12 percent) preferred the regular packs.
 - For the Mayfair king size brown background plain packs, 78 percent (71 percent) saw no difference in the health risk, 11 percent (13 percent) preferred plain packs, and 11 percent (16 percent) preferred regular packs.
 - The results for the Lambert and King white background versus regular packaging had 77 percent (69 percent) finding no difference in the health risk, 17 percent (16 percent) preferring plain packs, and 6 percent (15 percent) preferring regular packs.
 - For the brown background Lambert and Butler packs, 75 percent (67 percent) saw no difference in the health risk, 9 percent (13 percent) preferred plain packs, and 15 percent (20 percent) preferred regular packs.
39. For all four sets of comparisons, about three-fourths of all respondents expressed no preference, and the remainder of the respondents is divided across the two types of packs to degrees that usually are not statistically significant.
40. The study also explored other comparisons of plain packs and regular packs with respect to lower tar, smoother taste, more attractive, easier to quit (for adult sample), and choice if going to try smoking (youths). Similar to the health risk ratings, over half of the respondents saw no difference on any of these dimensions in all but one instance. The only exception pertained to the attractiveness rating for which just under half – 40 percent to 49 percent – expressed no difference between the packs. For those who thought that plain packs were less attractive, the study

provides no insight into whether a person would be more likely to quit or less likely to try smoking if the only choices in the market were plain packs. Indeed, in the case of youths, the question regarding pack preference was conditional on wanting to smoke so that the findings provide no evidence that plain packs will discourage youth smoking.

e) Hoek et al. (2011)

41. In a New Zealand study of plain packs using a convenience sample of young adult smokers, Hoek et al. (2011) elicited from respondents an ordinal ranking of the attractiveness of different packs as well as a cessation index.⁵⁸
42. Removing branding and increasing the size of the warnings would decrease the attractiveness of cigarettes and increase their assessed likelihood of cessation-related behaviors.⁵⁹ However, the finding with respect to warning size is inconsistent with the study below by Wakefield et al. (2012), which found no effect of increasing the warning percentage on the front of the pack from 30 percent to 70 percent, and then to 100 percent.⁶⁰ This may be explained by the effect that this study asked participants to compare a branded pack with a 30% graphic health warning with a plain pack with a larger 75% graphic health warning thus not allowing differentiation between the effects of larger warnings and plain packaging.
43. The Hoek et al. (2011) study did not address risk beliefs but did develop a cessation index for which plain packs scored higher.⁶¹ However, cessation intentions may change once all packs sold are plain packs. The authors themselves cautioned that the cessation results may be problematic and not reflective of likely behavior since the subjects in the control pack treatment gave higher stated cessation rates than are reflected in current cessation behavior.⁶² As with other such hypothetical experiments and overstatements of quit intentions, there is a potential influence of demand effects in which respondents give the answers that they believe the

⁵⁸ J. Hoek, et al., *Effects of dissuasive packaging on young adult smokers*. Tobacco Control 20(3), 183-188 (2011).
⁵⁹ *Id.*, at 183.

⁶⁰ M. Wakefield et al., *Do Larger Pictorial Health Warnings Diminish the Need for Plain Packaging of Cigarettes?*, *Addiction*, 107(6), 1159-1167 (2012).

⁶¹ J. Hoek et al., *Effects of dissuasive packaging on young adult smokers*. Tobacco Control 20(3) 183-188 (2011).

⁶² *Id.*, at 187. The authors observe that "...respondents' use of the Juster Scale to estimate likely cessation behaviours was higher for the control pack than suggested by current behavior..." and that "...additional research is required to estimate the predictive validity of the Juster Scale when used to estimate population health behaviours..."

researchers want to hear. Such behavior will generate apparent results that will not actually be realized if a plain packs policy is adopted.

f) Munafo et al. (2011)

44. Another way to assess what people are reading on a pack is to use an eye-tracking study such as that of Munafo et al. (2011).⁶³
45. Such studies monitor what individuals are looking at on a pack. An eye-tracking study will produce apparent effects of the plain pack approach almost tautologically as plain packs have less to read so that there will be increased visual attention to the warning (*i.e.*, the test measure of attention to different information is based on the number of saccades in the eye tracking test). Thus, even if there were an apparent effect of plain packs on the number of saccades in the eye tracking test, such a difference does not imply that people do not receive and process the warning information and give that information sufficient attention. Thus, a lower score for regular packs consequently would not imply that there is information overload or that the risk information is not being conveyed adequately on branded packs.
46. However, the results of the study failed to indicate any advantage of plain packs for regular smokers even though the nature of the eye tracking test would make the study predisposed to finding such an effect for plain packs. This U.K. study used a small convenience sample of 15 non-smokers, 14 weekly smokers, and 14 daily smokers. Experimental participants viewed images on an LCD screen rather than packs. The experiment analyzed the differences in eye movements and the degree of attention paid to the health warnings. A major finding of the study is that for daily smokers there was no effect whatsoever of viewing plain packs rather than regular packs. This result suggests that familiarity with cigarette packs eliminates any apparent effect of plain packs in the attention devoted to the warning information.
47. This study by Munafo et al. (2011) is perhaps most noteworthy for their comment on the research by others.⁶⁴ They concluded: “Our results are the first to show an

⁶³ M. Munafo, et al., *Plain Packaging Increases Visual Attention to Health Warnings on Cigarette Packs in Non-Smokers and Weekly Smokers but Not Daily Smokers*. *Addiction* 106(8), 1505-1510 (2011).

effect of plain cigarette packaging on objective measures of behaviour.” It should be emphasized that this concept of “behaviour” is quite limited because it does not pertain to beliefs or actions. Accordingly, such eye tracking studies have quite limited value and provide little insight into whether plain packs will achieve any of the avowed objectives of plain packs. However, the study is noteworthy in emphasizing how little evidence there was in support of plain packs. Put somewhat differently, according to the authors of the study, as of 2011, no studies had ever demonstrated a behavioral effect of plain packs. Moreover, the authors concluded with the type of cautionary observation that pertains not only to their study but to all other studies of plain packs: “[i]t is unclear whether increased visual attention to health warnings will translate to differences in actual smoking behaviour.”

g) Wakefield et al. (2012)

48. The apparent differences between regular packs and plain packs in terms of attractiveness and risk beliefs were the focus of a study by Wakefield et al. (2012).⁶⁵
49. The study used a convenience sample of Australian adult smokers. Altering the percentage of the front of a plain pack that was devoted to the warning (30 percent, 70 percent, and 100 percent) did not have any significant effect on whether the cigarettes got a positive rating by respondents. Plain packs in general did have a lower positive rating than regular packs, as one would expect given the similarity of plain packs to generic brands. A key matter of concern is whether people think that plain packs are more risky than regular packs because the warning is more prominent. Using a 10 point scale with higher scores indicating higher risk to characterize the negative harm characteristics of the cigarettes, the authors found a rating of 7.7 for branded packs for all warning sizes (30 percent, 70 percent, and 100 percent) versus 7.6 for plain packs with 30 percent of the front devoted to the warning, 7.4 for plain packs with 70 percent of the front devoted to the warning, and 7.8 with 100 percent of the front devoted to the warning. Branded and plain

⁶⁴ See *id.*

⁶⁵ M. Wakefield, et al., *Do Larger Pictorial Health Warnings Diminish the Need for Plain Packaging of Cigarettes?*, *Addiction* 107(6), 1159-1167 (2012).

packs do not materially differ on the negative harm dimension, and indeed, based on the point estimates, regular packs are viewed as more risky rather than less risky in two of the three instances.

50. Moreover, the percentage of the pack devoted to the warning had no material effect on the negative harm characteristics rating. The results of this study consequently call into question the relevance of studies that focus simply on the attractiveness of the packaging and do not delve further to examine how plain packs and warning size affect risk beliefs.

h) Maynard et al. (2013)⁶⁶

51. This article reports on the results of an eye tracking study that utilized a convenience sample of 85 adolescents aged 14-19 years. The study monitored the number of eye movements to health warnings and the number of eye movements to the branding for both plain packs and branded packs. What the study did not seek to measure is what the effect of packaging was on either the knowledge of the risks of cigarettes or risk beliefs. The study was not concerned with any effect of plain packs on smoking prevalence rates.
52. The authors present the findings of their study in relative terms that provide a distorted assessment of the results. The authors found “more eye movements to health warnings than branding on plain packs, but an equal number of eye movements to both regions on branded packs.” One might expect subjects to have more movements to the branding on a branded pack. But looking at a branded pack does not imply that the subjects did not look at the warning information on a branded pack. Even if eye movements are an appropriate measure of reading and understanding of a warning, what is more consequential is the total amount of movements devoted to warnings not the number of movements relative to looking at the brand.
53. There was actually no statistically significant difference between the number of eye movements per pack for the health warnings on the branded packs (14.7 with a

⁶⁶ Maynard, O.M., Munafo, M.R., and Leonards, U. (2013). “Visual Attention to Health Warnings on Plain Tobacco Packaging in Adolescent Smokers and Non-Smokers,” *Addiction*, 108(2): 413-419, doi: 10.1111/j.1360-0443.2012.04028.x.

confidence interval from 13.8 to 15.4) and the plain packs (14.9 with a confidence interval from 14.0 to 15.4). Indeed, for never-smokers, there were 16.5 eye movements for health warnings on branded packs as compared to only 15.4 movements for plain packs.

54. In short, this eye tracking study provides no evidence that warnings on plain packs are more effective in inducing people to read the warning information on cigarette packaging.

i) Rousu and Thrasher (2013)⁶⁷

55. This study involved an experimental auction in which subjects bid for different cigarette packs. The authors “find that pictorial labels and pictorial labels accompanied by plain packaging are more effective at reducing demand for cigarettes than only a front text warning label.”
56. Even taken at face value, this result does not provide support for the efficacy of plain packaging or any effect on smoking prevalence rates. The study never isolated the incremental effect of plain packaging on the bids in the auction. Rather, plain packaging was always combined with pictorial labels, which the experimental subjects compared to cigarette packs with a front text label. Thus, two characteristics of the packs changed simultaneously in this comparison—plain packaging and the use of a pictorial label—so that it is not feasible to isolate the influence of plain packaging as compared to the packs with a front text label and standard packaging.
57. In an auction setting in a cigarette sales regime in which plain packs are viewed as generic cigarettes, one would expect the bidding for cigarettes in plain packs to be reduced.

j) Moodie and Mackintosh (2013)⁶⁸

58. This article elicited cognitive and emotional responses to plain packs using a sample of young adult women who used their own cigarette packs for one week and

⁶⁷ Rousu, M., and Thrasher, J. (2013). “Demand Reduction from Plain and Pictorial Cigarette Warning Labels: Evidence from Experimental Auctions,” *Applied Economic Perspectives and Policy* (2013, Vol. 35, No. 1, pp. 171-184. Doi:10.1093/aep/pps049.

⁶⁸ Moodie, C.S. and Mackintosh, A.M. (2012). “Young Adult Women Smoker’s Response to Using Plain Cigarette Packaging: A Naturalistic Approach,” *BMJ Open* 2013; 3:e002402. Doi:10.1136/bmjopen-2012-002402.

plain cigarette packs for one week. The authors explored attitudes towards the cigarettes such as pack perceptions and feelings. Whether plain packs would affect smoking prevalence rates was not addressed in the study, as the focus was limited to various subjective attitudes.

59. The subjects were less comfortable displaying the experimental plain packs, as one might expect given that they are differentiated from all currently marketed cigarettes and are not the respondents' chosen brand.
60. Although respondents claimed that they devoted somewhat more attention to the health warnings on the experimental plain packs, the most pertinent aspect of the study is the set of results pertaining to the salience and credibility of the health warnings. Were the warnings noticed, viewed as being serious, and believable? The composite score on these dimensions for what the authors term the "overall warning response" indicated no statistically significant differences between the experimental plain packs and the respondents' regular packs.

k) Guillaumier, Bonevski, and Paul (2014)⁶⁹

61. This study reports on the results of six focus groups in Australia in which participants discussed the efficacy of television campaigns and plain cigarette packs after the plain packaging requirements had gone into effect. Thus the study did not have an experimental design and did not formally test any hypothesis, but only provided a sense of the groups' reaction to plain packs. The study did not demonstrate any effect of plain packs on smoking prevalence rates.
62. In focus groups conducted after the implementation of plain packaging, participants judged that the change had little effect on their smoking behavior, other than at time of purchase having to "double check whether they're giving you the right cigarettes"(Group 4)." Most participants said they generally 'do not even look at the warning' (Group 2), others indicated 'they don't affect me at all. I get desensitised really quickly' (Group 5). While most participants admitted they noticed the new health warning labels that accompanied plain packaging at first, the

⁶⁹ Guillaumier, A., Bonevski, B., and Paul, C. 2014. "Tobacco Health Warning Messages on Plain Cigarette Packs and in Television Campaigns: A Qualitative Study with Australian Socioeconomically Disadvantaged Smokers. Health Education Research Advance Access, June 25, 2014, doi:10.1093/her/cyu037.

idea of being desensitized to the graphic images in health warning labels was repeatedly mentioned. Even on a retrospective basis the participants did not claim that plain packs altered their smoking behavior.

Conclusions on Implications for Plain Packs and Warnings Efficacy

63. The findings from the studies reviewed above provide no basis for concluding that plain packs will make warnings more effective. The main results of these studies take the form of plain packs being less attractive than regular packs, which is exactly what one would expect given that plain packs resemble cheaper generic brands. Only a small number of plain pack studies have specifically focused on the effect of plain packs on risk beliefs, and these studies indicate that people think that smoking is dangerous whether presented in plain packs or regular packs.

APPENDIX B

Analysis of the Studies Allegedly Supporting the Conclusion that Plain Packaging Reduces the Potential for Pack Colors to Undermine the Effectiveness of Health Warnings

a) Hammond and Parkinson (2009)

1. Hammond and Parkinson (2009) asked subjects in an Ontario mall intercept to rate different experimental brands based on tar, taste, and health on an ordinal scale from 0 to 9.⁷⁰ Packs with a lighter color, white symbol, and charcoal filter had lower scores on these dimensions. The magnitudes of the differences are not known since the ordinal scale does not permit such judgments. The questions with respect to risk beliefs that could have been addressed were not. This study did not address individuals' understanding of the warning information for packs with different colors, or the absolute risk beliefs and the effect on smoking behavior of package color. In the absence of such effects, these experimental results are largely irrelevant. At present, cigarettes are sold in packs with a wide range of colors. Neither this study nor any other study has demonstrated a significant relationship between pack color and risk beliefs or smoking behavior.

b) Moodie and Ford (2011)

2. Many pack colors had appeal in a U.K. study of young adults and cigarette packaging by Moodie and Ford (2011).⁷¹ The authors used a series of focus groups with 54 young adult smokers aged 18-35 years, which is an approach that has all the attendant limitations of focus group studies as discussed above in Appendix A. The study did not elicit responses to specific questions or examine risk beliefs but instead focused on qualitative responses regarding feelings about smoking and perceptions of packs. Respondents associated colored packs with different types of cigarettes, such as green indicating menthol. However, when considering plain packs in dark brown color, younger males in general did not think that plain packs would alter their smoking behavior, and similar results were found for older males: "All older males were adamant that the introduction of plain packaging would not

⁷⁰ D. Hammond and C. Parkinson, *The impact of cigarette package design on perceptions of risk*. *Journal of Public Health* 31(3), 345-353 (2009).

⁷¹ C. Moodie and A. Ford, *Young Adult Smokers' Perceptions of Cigarette Pack Innovation, Pack Colour and Plain Packaging*, *Australasian Marketing Journal* 19(3), 174-180, 2011.

alter their smoking behaviour...” Most females likewise did not think that plain packs would alter smoking behavior.

c) Doxey and Hammond (2011)

3. The studies of pack colors did not single out any role of particular pack color in undermining the effect of warnings, but there is a study of whether pink appeals to women. Doxey and Hammond (2011) used a Canadian convenience sample of 512 women between the ages of 18 and 25 to analyze the effect of pack colors on brand preferences.⁷² They found that pink branded packs were more attractive to the female sample than white packs, *i.e.*, no colors, as in the colors for generic packs. Influencing attractiveness did not lead to any confusion about the riskiness of the cigarettes. Ratings of attractiveness did not imply differences in risk beliefs. The percentage of respondents in any variant of their study who thought that cigarettes posed “a little” or “a lot” less health risk than other brands is close to zero. And none of the differences in risk assessments across brands involving standard packs as compared to plain packs were statistically significant.

d) Bansal-Travers et al. (2011a,b)

4. Unlike the study by Doxey and Hammond (2011), which asked people to assess the riskiness of the packs,⁷³ Bansal-Travers et al. (2011a,b) asked people to choose packs if they were concerned with health.⁷⁴ The Bansal-Travers et al. (2011a) study utilized a convenience sample at a U.S. mall intercept consisting of 197 adult smokers and 200 non-smokers.⁷⁵ The study participants chose among 12 sets of packs. Not surprisingly, there was a preference for branded packs over plain white packs. This result is consistent with plain packs resembling generic packs in the current U.S. market.

⁷² J. Doxey and D. Hammond, *Deadly in Pink: The Impact of Cigarette Packaging among Young Women*, *Tobacco Control* 20(5), 353-60 (2011).

⁷³ See *id.*

⁷⁴ M. Bansal-Travers, et al., *The Impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.*, *American Journal of Preventive Medicine* 40(6): 674-682 (2011a); M. Bansal-Travers, et al., *What Do Cigarette Pack Colors Communicate to Smokers in the U.S.?*, *American Journal of Preventive Medicine* 40(6), 683-689 (2011b).

⁷⁵ M. Bansal-Travers, et al., *The Impact of Cigarette Pack Design, Descriptors, and Warning Labels on Risk Perception in the U.S.*, *American Journal of Preventive Medicine* 40(6): 674-682 (2011a).

5. The real question of interest is how respondents perceive the riskiness of the packs. When asked which cigarettes they would buy if trying to reduce the risks to their health, the results were split between branded packs (46 percent) and plain packs (48 percent), with missing observations (6 percent) constituting the remainder. For the key matter of concern, plain packs offer no material difference. And the study's results found that the cigarettes with the most tar were branded packs (54 percent) rather than plain packs (37 percent), which suggests that regular packs better communicate a key risk-related measure of the hazards of smoking. Only on smoother taste and overall brand preference independent of price did the branded packs have the edge over plain packs.
6. The companion study by Bansal-Travers et al. (2011b) focused on differences in colors. The convenience sample of 193 subjects viewed cigarettes online.⁷⁶ Respondents were asked to match colors with descriptors such as menthol. This matching process is more a test of the knowledge of the cigarette market than a measure of risk awareness. White packs were most associated with perceptions of safety. In this study and the predecessor, the authors never address the fundamental issues. How would people respond to actual cigarette packs rather than pictures of the fronts of the pack on a computer screen? Did respondents read the warning on the packs? Did the pack color interfere in any way with their processing of the risk information? If the person were to smoke cigarettes regularly, what would the effect of pack color be? And finally, what are their risk beliefs regarding smoking both before and after viewing the different packs?

Conclusion

7. The findings from the studies reviewed above provide no basis for concluding that pack colors affect the understanding of warnings, risk beliefs, or smoking behaviors.

⁷⁶ M. Bansal-Travers, et al., *What Do Cigarette Pack Colors Communicate to Smokers in the U.S.?*, American Journal of Preventive Medicine 40(6): 683-689 (2011b).

APPENDIX C

Analysis of Plain Packaging Studies and Their Failure to Examine Drivers of Initiation

1. The study of third party opinions of plain packs by Beede and Lawson (1991) consisted of 80 focus group discussions in which New Zealand adolescent students participated in discussions of plain packs.⁷⁷ As discussed in my review of the studies in Appendix A, focus groups are at best exploratory efforts with no scientific validity because any results from such studies are subject to group influences in the focus group discussions as well as influences based on input from the focus group leader. Given the limits of the study design, the authors reported no statistical tests or any formal analysis of the strength of the influences being explored since such tests would not have meaning. The article instead reported on group discussions that included the opinion that plain packs would discourage smoking initiation among children since plain packs were viewed as dull and boring.
2. It is noteworthy that the discussions did not touch on whether they personally would be less likely to start smoking, which is more pertinent than whether others would start smoking. We also don't know how prevalent the view with respect to plain packs and smoking initiation was or what proportion of the participants had this view. Furthermore, such judgments were comparative statements made relative to the current cigarette market. While plain packs may be viewed as relatively dull compared to other cigarette packaging, they would not be relatively dull if all cigarettes are sold in plain packs. Thus, there may not be any effect on smoking initiation once all cigarettes have the same packaging so that current regular packs are not the frame of reference.
3. The study by Donovan (1993) used a convenience sample in Australia, in this case a mall intercept of 11-13 year olds accompanied by their parents.⁷⁸ The study involved showing participants various different kinds of packaging including

⁷⁷ P. Beede and R. Lawson, R, *Brand Image Attraction: The Promotional Impact of Cigarette Packaging*, *New Zealand Family Physician* 18, 175-177 (1991).

⁷⁸ R. Donovan, *Smokers' and Non-Smokers' Reactions to Standard Packaging of Cigarettes*. University of Western Australia (1993).

standard packaging, current packaging, and current packaging in which warnings cover the entire back of the pack. Subjects were asked what effect they thought the packaging would have on other people's decisions to smoke. Most respondents (51.5 percent) thought that standard packaging would make no difference, with 13 percent thinking that all/most would smoke less and 25 percent thinking some would smoke less. Among non-smokers, there was no significant difference in the ratings for current packs and packs with expanded warnings. Such studies are an inappropriate research approach for exploring the possible influence of plain packs or expanded warnings since there is no exploration of how these changes affect the factors that determine smoking behavior. Rather, the researchers are taking the unscientific shortcut of trying to ask children for the answer regarding how they think plain packs and increased warnings will affect other people's decisions.

4. Two Canadian studies examining plain packs led to results that suggest such packaging would not be influential in changing smoking behaviors. Both studies focused on the earlier warnings era of 1994-1995 so that the switch to plain packs would be a greater packaging change than introducing plain packs in the current warning environment where the warnings are bolder and more extensive. Northrup and Pollard (1995) interviewed students in grades 7 and 9 and ascertained their third party opinions of the likely effect of plain packs.⁷⁹ Only one-third of the students thought that people would be less likely to start smoking if cigarettes were sold in plain packs, and this response was based on students thinking that plain packs were boring, not because the warnings would be conveyed more effectively. Students shown a poster with plain packs and with regular packs were able to recall the health warning in each case so that there was no evidence of an effect on risk awareness.
5. Ontario students interviewed for the study by Rootman and Flay (1995) likewise gave only lukewarm support to plain packs.⁸⁰ With respect to whether plain packs would lead smokers to smoke less, 71 percent said that it would make no difference

⁷⁹ D. Northrup and J. Pollard, J, *Plain Cigarette Packing and Other Tobacco Issues: A Survey of Grade 7 and Grade 9 Ontario Students*. Institute for Social Research Newsletter, York University (1995).

⁸⁰ I. Rootman, and Flay, B. *A Study on Youth Smoking: Plain Packaging, Health Warnings, Event Marketing and Price Reductions*, University of Toronto, University of Illinois at Chicago, York University, Ontario Tobacco Research Unit, Addiction Research Foundation (1995).

while 24 percent thought that it would. Most respondents (62 percent) thought that plain packs would make no difference in whether non-smokers would start smoking, and only 35 percent indicated that they thought plain packs would make non-smokers less likely to start.

6. A slightly different third party perspective on plain packs is the study by RBJ Health Management Associates (1993), which is even further removed from ascertaining the preferences of those likely to be affected by plain packs.⁸¹ This study asked “experts” in marketing and tobacco research what factors affect youth smoking, and if they thought that packaging and plain packs may matter. Asking third parties, some of whom may have prior policy beliefs, how the members of the public in a different demographic group (*i.e.*, youths) will react to plain packs is an unreliable substitute for analyzing how people themselves will respond. Even as a survey of experts, the paper falls short because there is no reporting of the distribution of the responses of the experts or a linkage of these responses to their areas of expertise. The results are anecdotal. The article also included the caveat: “However, plain packaging may or may not affect readability or believability, depending on the content of the message itself.” The study reported no empirical results.
7. Given the absence of an effect of plain packs on the efficacy of warnings or risk awareness, it is not surprising that plain packs would not decrease rates of smoking initiation. Interestingly, the studies of plain packs and smoking initiation do not even attempt to delve into the influence on risk beliefs. Indeed, they do not even inquire how the respondents might be affected by plain packs. Rather, most of the studies ask for third party opinions of how plain packs might affect other people’s decisions to smoke. In addition to lacking any scientific validity, these studies do not support plain packs as an effective policy instrument for discouraging smoking initiation because they do not address the drivers of smoking initiation.

⁸¹ RBJ Health Management Associates. *Impact of Plain Packaging of Tobacco on Youth Perceptions and Behavior*. Report of Study 1, Toronto, Canada (1993).