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# AN ASSESSMENT OF THE EFFECT OF AUSTRALIAN PLAIN PACKAGING REGULATION: ANALYSIS OF ROY MORGAN RESEARCH DATA, CITTS DATA, AND NTPPTS DATA:

**2 JANUARY 2018**

## I. INTRODUCTION

1. I am the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University. I hold a Bachelor's degree in Economics, two master's degrees, and a Ph.D. in economics, all from Harvard University. I have published more than 350 articles and 20 books dealing primarily with health and safety risks, and I have been ranked among the top 25 economists in the world based on citations in economics journals. I worked extensively with the U.S. Environmental Protection Agency ("EPA") on a continuous basis from 1983 to 2012, where much of my work was focused on the development of guidelines for hazard warnings for dangerous pesticides and chemicals. I also have extensive professional experience evaluating regulatory impact analyses and the economic methodology used in benefit-cost analysis, including being the Deputy Director of the President's Council on Wage and Price Stability from 1979–1980, which was responsible for White House oversight of all new federal regulations during that period as well as executive branch review of all regulatory impact analyses. Further details of my educational background and professional experience are set out in Appendix D of this report.

2. I have been asked to provide a report that examines empirical data from Australia to see what effect, if any, plain packaging of tobacco products[1] ("Plain Packaging" or "PP") has had on smoking behaviors in Australia following its implementation.[2]

3. In particular I have been requested to:

[1] Plain packaging, also known as standardized packaging, generally refers to regulation that requires the removal of all branding (colors, imagery, corporate logos and trademarks) from product packaging, permitting manufacturers to print only the brand name in a mandated size, font, and place on the pack, in addition to the health warnings and any other legally mandated information. The appearance of all tobacco packs is also standardized, including the color of the pack.

[2] Plain Packaging was introduced in Australia under the Tobacco Plain Packaging Act 2011, No. 148, 2011 with all tobacco products sold in Australia required to comply with the requirements from December 1, 2012.

a. Review the following datasets:

i. Roy Morgan Single Source Survey ("RMSS") data: a nationally representative, repeated cross-sectional survey of Australians aged 14 and above covering the period from January 2001 to December 2016.

ii. The Australian National Tobacco Plain Packaging Tracking Survey ("NTPPTS") data: A continuous survey of Australian smokers and recent ex-smokers commissioned by the Australian Government's Department of Health and Ageing to evaluate the impact of changes in the packaging of tobacco products in Australia for the period from 9 April 2012 to 30 March 2014.[3]

iii. The Cancer Institute New South Wales (NSW) Tobacco Tracking Survey ("CITTS") data: a serial, weekly cross-sectional survey of adult smokers and recent quitters in New South Wales, Australia, for the period from February 2009 to June 2016.[4]

b. Review and comment on the following publications in relation to the above datasets:

i. Analysis of the Australian RMSS data presented in:

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[3] The data collected in the National Tobacco Plain Packaging Tracking Survey is available on request from the Australian Department of Health, see http://www.health.gov.au/internet/main/publishing.nsf/content/tobacco-plain-packaging-evaluation, accessed 29 June 2017. See also the Australian National Tobacco Plain Packaging Tracking Survey: Technical Report, available at http://tobaccocontrol.bmj.com/content/suppl/2015/02/16/tobaccocontrol-2014-052050.DC1/tobaccocontrol-2014-052050supp.pdf, accessed 29 June 2017.

[4] I have previously addressed the CITTS data and NTPPTS data in reports that I submitted for British American Tobacco in October 2015 in UK legal proceedings in which PP was being challenged, and in November 2015 in relation to the Australian Government Department of Health Post-Implementation Review of the Tobacco Plain Packaging Act 2011 (Aus). My current report provides a more extensive analysis of these data including detailed multivariate controls, an empirical assessment of additional CITTS data, and a longer time period for the CITTS data, and also examines aspects of the cohort component of the NTPPTS data that I did not consider previously. In addition, this report also includes an analysis of the RMSS data, which I have not considered previously.

- The report of Dr. Tasneem Chipty entitled "Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia" (January 24, 2016), which was commissioned by the Australian Department of Health and is the only econometric analysis of data that is relied on in the Australian Government's Post Implementation Review Report of the Australian Tobacco Plain Packaging Act 2011 ("TPP Act") published in February 2016.[5]
- Diethelm and Farley (2015) "Refuting tobacco-industry funded research: empirical data shows a decline in smoking prevalence following the introduction of plain packaging in Australia."[6]

ii. Analysis of the Australian NTPPTS data presented in several papers published in *Tobacco Control*, (April 2015), Volume 24, Suppl. 2, titled "Implementation and evaluation of the Australian tobacco Plain Packaging policy,"[7] which papers are also relied on in the Australian Post Implementation Review Report;[8] and

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5 The Australian Post Implementation Review Report and its appendices, including Dr. Chipty's report are available on the Australian Government Office of Best Practice Regulation website at http://ris.dpmc.gov.au/2016/02/26/tobacco-plain-packaging/, accessed 29 June 2017. Some program codes and data files relating to Dr. Chipty's report are also available on request from the Australian Department of Health at http://www.health.gov.au/internet/main/publishing.nsf/Content/foi-disc-log-2015-16, accessed 29 June 2107.

6 Pascal A Diethelm, Timothy M Farley, "Refuting tobacco-industry funded research: empirical data shows a decline in smoking prevalence following the introduction of plain packaging in Australia," Tob. Prev. Cessation 2015;1(November):6 http://dx.doi.org/10.18332/tpc/60650.

7 Available at http://tobaccocontrol.bmj.com/content/24/Suppl_2.toc. The papers in this publication that analyze the Australian NTPPTS data are:

- Melanie Wakefield, Kerri Coomber, Meghan Zacher, Sarah Durkin, Emily Brennan, and Michelle Scollo, "Australian Adult Smokers' Responses to Plain Packaging with Larger Graphic Health Warnings 1 Year after Implementation: Results from a National Cross-Sectional Tracking Survey," Tobacco Control 2015;24:ii17-ii25. doi:10.1136/tobaccocontrol- 2014-052050;

iii. Analysis of the New South Wales CITTS data presented in Dunlop et al (2014) "Impact of Australia's Introduction of Tobacco Plain Packs on Adult Smokers' Pack-Related Perceptions and Responses: Results from a Continuous Tracking Survey,"[9] which is also relied on in the Australian Post Implementation Review Report.

c. Review the Australian Government's Post Implementation Review Report of TPP Act published in February 2016 (the "PIR"),[10] and comment on the validity of the conclusions expressed in the report regarding the impact of Plain Packaging on smoking behaviors.

4. To the best of my knowledge, the analysis of Australian data that I provide in this report is the most up to date and comprehensive analysis of the data that has been provided to date. In particular:

a. My analysis of the RMSS data extends through December 2016, thus providing 15 more months of data in the post-PP period than analyzed in the report of Dr.

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- Sarah Durkin, Emily Brennan, Kerri Coomber, Meghan Zacher, Michelle Scollo, and Melanie Wakefield, "Short-Term Changes in Quitting-Related Cognitions and Behaviours after the Implementation of Plain Packaging with Larger Health Warnings: Findings from a National Cohort Study with Australian Adult Smokers," Tobacco Control 2015;24:ii26-ii32. doi:10.1136/tobaccocontrol-2014-052058;
- Emily Brennan, Sarah Durkin, Kerri Coomber, Meghan Zacher, Michelle Scollo, and Melanie Wakefield, "Are Quitting-Related Cognitions and Behaviours Predicted by Proximal Responses to Plain Packaging with Larger Health Warnings? Findings from a National Cohort Study with Australian Adult Smokers," Tobacco Control 2015;24:ii33-ii41. doi:10. 1136/tobaccocontrol-2014-052057; and
- Michelle Scollo, Meghan Zacher, Kerri Coomber, Megan Bayly, and Melanie Wakefield, "Changes in Use of Types of Tobacco Products by Pack Sizes and Price Segments, Prices Paid and Consumption Following the Introduction of Plain Packaging in Australia," Tobacco Control 2015;24:ii66-ii75.

[8] Supra at footnote 5.

[9] Sally M. Dunlop, Timothy Dobbins, Jane M. Young, Donna Perez, and David C. Currow, "Impact of Australia's Introduction of Tobacco Plain Packs on Adult Smokers' Pack-Related Perceptions and Responses: Results from a Continuous Tracking Survey," *BMJ Open* 2014; 4(12): e005836, Available at http://bmjopen.bmj.com/content/bmjopen/4/12/e005836.full.pdf.

[10] Supra at footnote 5.

Chipty and 3 additional years of data in the post-PP period than in Diethelm and Farley (2015);

b. My analysis of the Australian NTPPTS data and the New South Wales CITTS data includes an analysis of all of the survey outcomes, rather than a selection of the outcomes as presented in the published papers on these data. Also, unlike the the Australian Government's Australian Post Implementation Review Report which simply relies on the conclusions from the published papers on these data, I also undertake a review of the papers and analyze the underlying data; and

c. My analysis of the CITTS data includes a longer time period than in any published study as it extends through June 2016, which includes an additional 37 months of data from that considered by Dunlop et al. (2014) in their analysis of the CITTS data.

5. As noted in the report of Dr. Chipty, at the same time that Australia introduced tobacco Plain Packaging it also introduced updated and enlarged graphic health warnings on tobacco product packaging under the Competition and Consumer (Tobacco) Information Standard 2011 (which included expanding the size of the warning on the front of the pack from 30% to 75%). Given the timing of these changes, it is not possible to separately identify the effects of tobacco Plain Packaging from those of the updated and enlarged graphic health warnings without making restrictive assumptions. As such, my discussion of the effects of Plain Packaging encompasses the effects from both of these changes, which I refer to collectively as the "2012 Packaging Changes" (as is also the case with Dr Chipty's analysis in her report).

## II. EXECUTIVE SUMMARY

6. In this report I provide a comprehensive analysis of three key datasets from Australia, namely: 4 years of post-implementation RMSS data; 3 ½ years of post-implementation CITTS data; and the Australian Government commissioned NTPPTS data. My use of a longer post-implementation time frame for my analysis than in any previous study provides a stronger test of the impact of the 2012 Packaging Changes if, as some have suggested, the effect of the policy change would increase over time. Each of these datasets provides somewhat different perspectives, and no single dataset is complete in terms of addressing both smoking prevalence and various attitudinal responses to plain packs, or what are sometimes referred to as intermediate metrics. However, despite the different perspectives provided by these data, the implication of my analysis of the three datasets yields a consistent conclusion that there is no evidence of the 2012 Packaging Changes having any impact on reducing smoking prevalence rates or consumption amongst current smokers. There is also consistent evidence that the policy is associated with counterproductive effects on some of the intermediate or secondary measures that are relied upon in the Australian Government's Australian Post Implementation Review Report and by other proponents to promote Plain Packaging.[11] Chief among these potentially counterproductive effects is that there has been an increase in the belief that the warnings exaggerate the risks. Other impacts, such as the effects on quitting behavior and smoking rates, are more mixed. On balance, these results undermine any conclusion that the 2012 Packaging Changes have had a net beneficial effect. In particular:

[11] See e.g. World Health Organization, Regional Office for Europe, (2014) "Evidence Brief Plain packaging of tobacco products: measures to decrease smoking initiation and increase cessation"; and McNeill A, Gravely S , Hitchman SC, Bauld L, Hammond D, Hartmann-Boyce J. "Tobacco packaging design for reducing tobacco use". Cochrane Database of Systematic Reviews 2017, Issue 4. Art. No.: CD011244. DOI: 10.1002/14651858.CD011244.pub2 .

a. My analysis of the RMSS data, which includes 15 additional months of data in the post-2012 Packaging Changes period than was considered in the report of Dr. Chipty, and 3 years of additional data in the post-2012 Packaging Changes period than was addressed in Diethelm and Farley (2015), found that the estimated statistical association of the 2012 Packaging Changes with smoking prevalence rates is zero. Instead, my analysis of the RMSS data found that the decline in smoking prevalence rates in Australia is a continuation of past nonlinear time trends, overall economic trends such as the general Australian consumer price index, and influences such as rising cigarette prices, and is not significantly related to the adoption of the 2012 Packaging Changes. The only sound conclusion based on this evidence is that the 2012 Packaging Changes are not associated with any change in smoking prevalence rates.

b. An evaluation of the CITTS and NTPPTS data relating to actual cigarette consumption behavior in Australia indicates that the 2012 Packaging Changes have not been associated with a decrease in smoking behaviors amongst current smokers. The results for the CITTS sample are mixed, with no clear cut evidence of efficacy. The number of cigarettes smoked per day experienced a statistically significant increase of about one cigarette. There has also been a change in the distribution of smoking activity. More respondents report that they smoke daily, fewer report that they smoke at least weekly (not daily), fewer report that they smoke less often than weekly, and a statistically insignificant larger number report that they currently smoke not at all, though they did smoke in the last year. Within the NTPPTS sample, there is no statistically significant change in the

number of cigarettes smoked per day.[12] My analysis of the CITTS data includes a longer time period than in any published study as it extends through June 2016, which includes an additional 37 months of data beyond that considered in Dunlop et al. (2014).[13]

c. There is also consistent evidence from the CITTS and NTPPTS data indicating an unfavorable association of the 2012 Packaging Changes with a number of so called intermediary metrics (e.g., increasing the efficacy of health warnings) even setting aside issues pertaining to the efficacy of these intermediate variables in predicting actual smoking behaviors. For example, my analysis of the CITTS data shows that after the implementation of 2012 Packaging Changes in Australia:

i. respondents rate it significantly more difficult to quit both in terms of how difficult it would be to quit and how difficult they thought it would be to quit, and respondents are significantly less confident that they can quit, which is an impact that could arise if the policy made consumers think that quitting would be a more formidable challenge; and

ii. there is a statistically significant 16% increase in whether respondents believe that the graphic warning labels policy exaggerate the risk of smoking, a statistically significant 7% increase in beliefs that the government pesters people too much about smoking risks, a statistically

[12] I note that consistent with my analysis, Scollo et al. (2015), which is the only published study of the NTPPTS data that discusses the data on actual consumption behavior, also found that the 2012 Packaging Changes had no impact on consumption: see Michelle Scollo, Meghan Zacher, Kerri Coomber, Megan Bayly, and Melanie Wakefield, "Changes in Use of Types of Tobacco Products by Pack Sizes and Price Segments, Prices Paid and Consumption Following the Introduction of Plain Packaging in Australia," *Tobacco Control* 2015;24:ii66-ii75.

[13] Sally M. Dunlop, Timothy Dobbins, Jane M. Young, Donna Perez, and David C. Currow, "Impact of Australia's Introduction of Tobacco Plain Packs on Adult Smokers' Pack-Related Perceptions and Responses: Results from a Continuous Tracking Survey", *BMJ Open* 2014; 4(12): e005836;

significant 5% increase in beliefs that the health effects are exaggerated, and a statistically significant 3% increase in the belief that smoking is only harmful to heavy smokers. These result could arise from defensive processes and increased reactance activated by the the 2012 Packaging Changes, leading to an increased degree of rejection of the graphic warnings message.

d. My analysis of the NTPPTS data also shows that after the implementation of the 2012 Packaging Changes in Australia:

i. respondents were less likely to think about quitting either once or once every few days over the previous week, less likely to stub out many times after the policy, and were less likely to stop many times upon having the urge to smoke;

ii. there was a decrease in the number of respondents who intend to quit smoking in the next month, and a decrease in the number of respondents who stub out their cigarette many times after thinking about the harms of smoking; and

iii. there is no statistically significant impact on beliefs regarding the harmfulness of cigarettes; zero effects with respect to all categories of responses regarding whether the person thinks about the money spent on cigarettes; and an increase in the agreement that the dangers are exaggerated.

7. The evidence of a lack of impact of the of the 2012 Packaging Changes in Australia and of a number of potentially counterproductive effects is not unexpected given that

consumers are informed of the risks of smoking and the 2012 Packaging Changes do not provide any new information to consumers. An assumption that making the warnings larger and more prominent will increase their effectiveness is misplaced. There is no empirical evidence that "shouting" works in increasing behavioral compliance in this context where no new information is being provided. The evidence of negative outcomes is also consistent with research that demonstrates that fear-based warnings may in fact elicit responses that are the opposite of their intended effect.

8. In this report, I also evaluate and provide a critique of previous analysis of the Australian RMSS data presented in the report by Dr. Tasneem Chipty and in Diethelm and Farley (2015):

   a. The report by Dr. Tasneem Chipty was commissioned by the Australian Department of Health to assess the impact of Plain Packaging on smoking prevalence in Australia, and is the only econometric analysis of data that seeks to identify the actual effect of the 2012 Packaging Changes on smoking that is relied on in the Australian Post Implementation Report. As explained below, I have identified several flaws in in Dr. Chipty's approach that render it unreliable, namely:

      i. the use of overlapping indicator variables which create confounding effects, meaning that any conclusions drawn from Dr. Chipty's analysis are highly speculative;

      ii. the use of a linear time trend when the time trend is nonlinear. Dr. Chipty's procedure violates basic principles of statistical analysis since she reported no statistical tests of the use of a linear trend as opposed to a

nonlinear trend. Capturing any nonlinear relationship with a linear trend line, as Dr. Chipty does, leads to an unexplained "policy impact" that is spurious, as it is not an effect of the policy but instead reflects an underlying nonlinear trend; and

iii. the use of indicator variables only for the major tax increases that occurred in Australia, which fails to recognize the continuous nature of excise tax levels and generates a source of error in the treatment of taxes; and

iv. the failure to include a cigarette price variable in her model which is the most important variable in models of the economic demand for any consumer product.

As a result of these shortcomings, the report of Dr Chipty provides no sound evidence in support of the efficacy of plain packs policies**. The two most important flaws in her study were the failure to consider the nonlinearity of the temporal trend in smoking prevalence rates and the omission of cigarette prices from the model.**

v. Three principal results from the RMSS data analysis are apparent in both the analysis of the extended dataset that I used, as well as in my analysis of the shorter time period considered in Dr. Chipty's report:

- Properly recognizing that the temporal trend is nonlinear rather than linear (as Dr. Chipty wrongly assumes) alone accounts for the downward trend in smoking rates;
- Even with only a linear trend, reasonable specifications of the model using either overall consumer prices or continuous measures

of the recommended retail price of cigarettes rather than the crude excise tax indicator variables approach used by Chipty eliminates the statistical significance of the 2012 Packaging Changes variable. It is only by ignoring both the nonlinearity of the smoking prevalence time trend and the role of prices, as Dr. Chipty does, that it is possible to generate non-zero statistically significant estimates of the 2012 Packaging Changes variable; and

- Third, even if there were a purported association of the 2012 Packaging Changes with smoking prevalence based on Dr. Chipty's analysis, one should be skeptical of the import of these results given that her statistical analysis includes four overlapping indictor variables for the 2010 to 2015 period. Given her statistical format, it is difficult to disentangle the effect of the multiple policy shifts that occurred around the 2012 period. Attributing the lower smoking prevalence rates to the 2012 Packaging Changes as opposed to the excise tax increases both before and after the advent of the 2012 Packaging Changes policy is not warranted.

vi. Properly specified multivariate regression analyses that corrects for the flaws in Dr. Chipty's analysis demonstrates that the estimated effect of the 2012 Packaging Changes on the smoking prevalence rate cannot be distinguished statistically from zero. As noted above, I also extended Dr. Chipty's data period with an additional 15 months of data through to December 2016 and found that the impact of the 2012 Packaging Changes

on smoking prevalence rates cannot be distinguished statistically from zero for this longer time period as well.

b. The article by Diethelm and Farley (2015) is identified as the only published study that assesses the impact of Plain Packaging on smoking prevalence, in a recent Cochrane review of the plain packing literature that was published in April 2017 (the "Cochrane Review").[14] However, as I explain below, the article lacks scientific validity for several reasons:

i. The authors had no original data, but instead relied on estimates of monthly averages inferred from a figure in a working paper by Kaul and Wolf.[15] As a result, their sample size for their analysis only included 156 imputed monthly average figures, not the more than 700.000 individual observations in the Kaul & Wolf sample.[16] While the authors express concern about the possible error in imputing data based on the chart in Kaul and Wolf, the more important limitation is that the aggregation of the data by month reduces the informational content of the data and prevents the ability to match any data to particular respondents;

ii. Because of this reliance on monthly average data the authors have no information by individual respondent and consequently their analysis includes no controls in the model for individual characteristics such as

[14] McNeill, A., Gravely, S., Hitchman, S.C., Bauld, L., Hammond, D., and Hartmann-Boyce, J., "Tobacco Packaging Design for Reducing Tobacco Use," Cochrane Database of Systematic Reviews 2017, Issue 4, Art. No.: CD011244.

[15] Kaul, A. and Wolf, M. "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis," University of Zurich Department of Economics Working Paper, June 2014.

[16] I note that the Diethelm and Farley (2015) sample size is wrongly listed as 700,000 on p. 4 of the Cochrane Review.

age, gender, education, income level, and region, and changes in the sample composition that may have occurred over time.

iii. In addition to ignoring all demographic variables, the Diethelm and Farley (2015) article also omitted other key determinants of smoking prevalence rates. Cigarette prices are not included in the model. Excise tax rates are ignored except in terms of a single tax shift. Also, the nonlinear nature of the smoking prevalence rates before the advent of plain packaging is not taken into account.[17]

iv. The net impact of these flaws is that this study lacks any scientific credibility. The deficiencies I cited are not minor limitations nor matters of a difference of opinion, but are fundamental problems that make it inappropriate to rely on their study.

v. I note that the Cochrane Review graded the quality of the Diethelm and Farley (2015) paper as "low" (p.4), which is an assessment I believe nevertheless actually overstates the quality of the paper for the reasons stated above. Had the Cochrane Review also taken into account the factors I cite above, the article's value would be below the rating of "low," as it should not be regarded as having any scientific merit at all.

9. My examination of the outputs of each of the CITTS and NTPPTS datasets also indicates that the published articles analyzing these data are disturbing from the standpoint of academic integrity and are highly misleading. Rather than provide an unbiased assessment of the survey results, the studies present selected findings that purport to

[17] Diethelm and Farley (2015) faulted the study by Kaul and Wolf, which discarded the first 42 months of observations because they were not consistent with a linear trend. However, Diethelm and Farley (2015) do not present any statistical tests supporting the validity of a linear trend.

demonstrate the efficacy of the 2012 Packaging Changes policy which a more thorough analysis of the data shows is misleading. In particular, these studies have ignored substantial evidence from the same Australian datasets they purport to analyze; which evidence is consistent with a lack of efficacy of the 2012 Packaging Changes and underscores the point that the post-implementation publications analyzing these data have selectively and misleadingly presented the results they do present. Viewed in their entirety, the datasets consistently indicate that the 2012 Packaging Changes are not associated with any reduction in smoking behaviors. Empirical assessments are biased if a researcher only cites the results that portray a policy in a positive light and fails to report the evidence that indicates not only a lack of a favorable impact, but also rather important counterproductive effects. A comprehensive analysis of a broader set of questions in the CITTS and NTPPTS datasets leads to the conclusion that on balance the 2012 Packaging Changes policy is not working.

10. The fact that these articles are peer reviewed does not provide any assurance that the analyses and conclusions of the papers are valid. I have served for three decades as the founding editor of a peer-reviewed journal and have been on the editorial boards of 20 other peer-reviewed journals. Peer review only means that one or more persons in the field has reviewed the article and has recommended publication of it. The peer reviewers do not generally have access to the data used in the article to replicate the study. Reviewers typically only read the article to assess whether the methodology and findings appear to be sound and novel contributions. Other researchers who have access to the original data often can undertake a more thorough analysis than in a peer review, as I have done with the data that I have reviewed.

11. Similar to my review of the data, the only consistent evidence that the recent Cochrane Review of the Plain Packaging literature found was that Plain Packaging was associated with a decrease in the appeal of the pack. However, the responses to these questions could be a result of the increase in the size of the warning to 75% that result in the packs being dominated by graphic health warnings, rather than Plain Packaging. Indeed the Cochrane Review highlights the high risk of confounding in these studies given that Plain Packaging was introduced alongside enhanced health warnings in Australia making it difficult to isolate the effects of Plain Packaging. For studies that focused on the effects of Plain Packaging on actual behavioral outcomes, including smoking prevalence and consumption, the Cochrane Review concluded that the confidence in the findings was "limited, due to the nature of the evidence available" and that the evidence was "mixed." The Cochrane Review also noted that: "[n]o studies assessed uptake, cessation, or relapse prevention"(p. 2). The results of many of the studies on other intermediate outcomes were also limited and mixed so that there is no consistent evidence of Plain Packaging being effective across a large number of variables. The Cochrane Review concludes that "[t]he available evidence suggests that standardised packaging may reduce smoking prevalence" (p. 2), which itself doesn't demonstrate the efficacy of Plain Packaging. In addition, based on my review of the actual data emanating from Australia and critical analysis of the published papers on this data, which the Cochrane Review did not undertake, the overwhelming evidence across all the datasets is not consistent with the 2012 Packaging Changes being effective in reducing smoking, while there is also evidence consistent with the policy being counterproductive on many of the intermediate or secondary measures that are relied upon to promote Plain Packaging.

12. The Australian Government Post-Implementation Review Tobacco Plain Packaging 2016 report (the "PIR") provided an inadequate and incorrect assessment of the effect of the 2012 Packaging Changes on smoking. The PIR's only statistical evidence of the effect of the 2012 Packaging Changes is based on the flawed report by Dr. Chipty. What is also striking is that the PIR did not review the implications of the NTPPTS and CITTS data with respect to smoking prevalence and consumption. The PIR merely relies on published papers without any critique or review of those papers. Based on my review of the papers and the underlying NTPPTS and CITTS datasets, I conclude that they cannot be relied upon. There is not a sound basis for the PIR's conclusion (p. 4): "[i]n light of all this evidence, the PIR concludes that tobacco plain packaging is achieving its aim of improving public health in Australia and is expected to have substantial public health outcomes in the future." The PIR's reference to "all this evidence" is especially inappropriate because the cited studies did not report all the evidence from the NTPPTS and CITTS datasets, but only the selected results that provide the most favorable perspective on the performance of plain packs. In addition, as noted above my extended analysis of the RMSS data and the CITTS data which is the most extensive data analysis undertaken to date (and includes 15 months of additional data to the analysis undertaken by Dr Chipty) confirms that Plain Packaging has not been effective, as the statistical association of the 2012 Packaging Changes with smoking prevalence rates cannot be distinguished from zero. This result further demonstrates that the conclusion reached in the PIR is unjustified.

## III. ROY MORGAN RESEARCH DATA

13. The most extensive set of individual survey data on smoking prevalence in Australia are the RMSS data from Roy Morgan Research. This independent firm employs a large nationally representative Australian sample using cross-sectional surveys to generate survey data on individuals aged 14 and over regarding their smoking status, where interviewers are dispatched weekly and all areas are covered monthly.[18] The data have been used in previous peer-reviewed published research to obtain estimates of smoking prevalence in Australia.[19]

14. Previous reports have provided analyses of the effect of Plain Packaging on smoking prevalence in Australia using the RMSS data, including:

    a. A non-peer-reviewed report prepared for the Australian Department of Health by Dr. Tasneem Chipty, which analyzed the RMSS data from January 2001 to September 2015, and concluded based on a regression analysis that during the period after the implementation of the 2012 Packaging Changes in Australia through to September 2015, smoking prevalence rates declined by 0.55 percentage points relative to what the prevalence would have been without the 2012 Packaging Changes;[20] and

    b. Diethelm and Farley (2015) which assessed the effect of Plain Packaging on smoking prevalence in Australia using the RMSS data for adults (aged 18+) for

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[18] For details of how Roy Morgan Research collects the RMSS data see Roy Morgan Research. "How we collect and process Single Source data in Australia". Available from: http://www.roymorgan.com/products/single-source/single-source-fact-sheets, accessed 2 May 2017.

[19] See Wakefield MA, Durkin S, Spittal MJ, Siahpush M, Scollo M, Simpson JA, et al. "Impact of tobacco control policies and mass media campaigns on monthly adult smoking prevalence" Am J Public Health. 2008;98:1443-50. doi: 10.2105/AJPH.2007.128991; and Wakefield MA, Coomber K, Durkin SJ, Scollo M, et al. "Time series analysis of the impact of tobacco control policies on smoking prevalence among Australian adults," 2001-2011. Bull World Health Organ 2014; 92:413-422 doi: 10.2471/BLT.13.118448.

[20] Dr. Tasneem Chipty, "Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia," Report of Dr. Tasneem Chipty, January 24, 2016, supra at footnote 5.

the period from January 2001 to December 2013 (one year after mandatory full implementation of PP in Australia) and found a statistically significant reduction of smoking prevalence of 3.7% following the introduction of Plain Packaging in Australia. I note that the recently published Cochrane Review of the Plain Packaging literature notes that this paper is the only peer-reviewed published paper that assesses the impact of Plain Packaging on smoking prevalence in Australia.[21]

15. In this report I present an analysis of a larger Roy Morgan Research sample that includes a longer post-2012 Packaging Changes time period than that provided in Diethelm and Farley (2015), and in the report of Dr. Chipty. I also present analysis of the time period considered in Dr. Chipty's report to facilitate a comparison of the results. The starting date for my Roy Morgan Research data is January 2001, which is the same as that of Diethelm and Farley (2015) and Dr. Chipty's report. However, the data I analyze extend through December 2016, thus providing 3 years of additional data in the post-2012 Packaging Changes period than was addressed in Diethelm and Farley (2015) and 15 additional months of data in the post-2012 Packaging Changes period than was considered in the report of Dr. Chipty, making my analysis the most up to date available. According to Dr. Chipty, the inclusion of the new data should lead to even larger estimates of the effect of plain packs as she hypothesizes, "the benefits of the Packaging Changes will likely grow over time."[22]

A. Analysis of RMSS Data

[21] McNeill A, Gravely S , Hitchman SC, Bauld L, Hammond D, Hartmann-Boyce J. "Tobacco packaging design for reducing tobacco use". Cochrane Database of Systematic Reviews 2017, Issue 4. Art. No.: CD011244. DOI: 10.1002/14651858.CD011244.pub2.

[22] Chipty Report, p. 3.

16. Here I provide a detailed analysis of the RMSS data on smoking prevalence rates. The principal matter of interest is the effect of the 2012 Packaging Changes in Australia on smoking prevalence rates based on a regression analysis of whether the respondent is a smoker as a function of pertinent demographic and policy variables. My assessment of the RMSS data is patterned generally after that in the report of Dr Chipty. The table below lists the extensive set of demographic and locational variables from the RMSS data that I include in my multivariate regression analysis for which the detailed estimates appear in Appendix A. My variables address the same range of demographic influences as in Dr. Chipty's report, though there are a few minor differences. For example, I use continuous measures of age and income rather than a large series of categorical variables for different age and income categories.

Explanatory Variables Used in Regressions

| **Variable** | **Mean** | **Std. Dev.** |
|---|---|---|
| Female | 0.5181 | 0.4997 |
| Marital status, single | 0.2422 | 0.4284 |
| Marital status, divorced | 0.0818 | 0.2741 |
| Marital status, widowed | 0.0781 | 0.2683 |
| Marital status, separated | 0.0370 | 0.1887 |
| Student | 0.0238 | 0.1525 |
| Years of education | 12.34 | 3.18 |
| Age | 47.46 | 19.30 |
| Non-adults (14-17) | 0.0575 | 0.2328 |
| Employed full time | 0.5524 | 0.4972 |
| Retired | 0.0111 | 0.1048 |
| Income (thousands) | 47.63 | 40.93 |
| Income, multiple household members | 0.4162 | 0.4929 |
| Bread winner | 0.6502 | 0.4769 |

| | | |
|---|---|---|
| Household size | 2.7263 | 1.3806 |
| Home owner | 0.6812 | 0.4660 |
| Victoria | 0.2300 | 0.4208 |
| Queensland | 0.1985 | 0.3988 |
| South Australia | 0.0780 | 0.2681 |
| Western Australia | 0.0950 | 0.2932 |
| Tasmania | 0.0481 | 0.2139 |
| Darwin-Alice Springs | 0.0101 | 0.1001 |
| Lives in capital city | 0.5812 | 0.4934 |

17. The principal differences between my analysis and Dr. Chipty's, as I discuss below, are with respect to the following matters. First, I include different measures of cigarette prices in the equation to account for the important economic dependence of smoking behavior on the cost of cigarettes. Second, my analysis accounts for the nonlinear trend in smoking prevalence rates and includes a statistical test of the importance of nonlinearity, whereas Dr Chipty assumes without any testing that the trend is linear. Thirdly, my analysis also accounts for the continuous changes in cigarette excise tax rates rather than focusing on the major increases alone. As I discuss below, if the analysis correctly includes either a measure of cigarette prices or a nonlinear trend, or both of these influences, then the estimated statistical association of the 2012 Packaging Changes with smoking prevalence rates is zero. The only sound conclusion based on this evidence is that the 2012 Packaging Changes are not associated with any change in smoking prevalence rates.

18. I begin with an analysis of the RMSS data time period used in Dr. Chipty's report and excluding October and November 2012 from the sample. As noted above, my variables address the same range of demographic influences as do Dr. Chipty's, with only a few

minor differences. In addition to these variables, I have constructed a series of policy-related variables based on the different time periods relating to the policies noted above. These include indicator variables for the 2006 graphic warnings policy and the 2012 Packaging Changes as well as measures of consumer prices and the recommended retail price of cigarettes. I capture the effect of the cost of cigarettes in several separate ways. First, I use indicator variables for the major excise tax eras indicated in the table above. However, as I discuss further below in my critique of the report of Dr. Chipty, this formulation ignores the continuous nature of excise tax changes and also ignores the level of the taxes. Second, instead of these indicator variables I include a variable for the level of excise taxes per pack, in real inflation-adjusted terms. This measure accounts for both the excise tax level embodied in the major excise tax increases and also recognizes the periodic updates of the excise taxes during the year. Third, as a measure of the cost of cigarettes I have used two different measures of the total cigarette prices, not simply the excise tax component. The first cost variable is the overall consumer price index (CPI), which is a measure of general price trends in the economy, not just the cost of cigarettes. I also use a more cigarette-specific price measure, which is the recommended retail price per pack for Craven Cork Tip 20s cigarettes. This data is provided in Scollo, and Winstanley, "Tobacco in Australia: Facts and Issues," where the authors explain that Craven is a longstanding brand in Australia and one of a handful of brands available in 1940 that is still available in 2016.[23] Scollo, and Winstanley also provide recommended

[23] See table 13.3.1 in Section 13.3 in Scollo, MM and Winstanley, MH. "Tobacco in Australia: Facts and issues". Melbourne: Cancer Council Victoria; 2016. Available from www.TobaccoInAustralia.org.au. I recognize that the actual cost per pack may be different due to the influence of discounting. However, if discounting policies are consistent across time, the retail price will differ from the discounted price by a multiplicative constant, leaving the statistical significance of the estimated impact of prices unaffected. Even if discounting policies change over time, recommended retail prices will be strongly correlated with actual prices as evidenced by the negative effect of prices on smoking prevalence rates.

retail price data for Winfield 25s which they state is a popular Australian brand, and I obtained similar results using these data in results which are not reported here.

19. For simplicity I report here only the estimates for the 2012 Packaging Changes policy variable. Representative regression results for my full sample appear in Appendix A. The table below summarizes 10 different ways in which the model could be formulated—whether the model includes a linear or nonlinear trend and the formulation of the cigarette cost variables using indicator variables, the excise tax level, the overall consumer price index, the retail price per pack for Craven 20 cigarettes, and an instrumental variables (IV) version of the Craven 20 measure to account for the possible mutual dependence of cigarette prices and smoking prevalence.[24] In 8 of the 10 estimates reported below, it is not possible to reject the hypothesis that the coefficient for the 2012 Packaging Changes in the smoking prevalence rate equation is zero. The estimated coefficient is statistically indistinguishable from zero for all models including a nonlinear time trend or either a linear or nonlinear time trend but also including the consumer price index, the Craven 20 price level, or the IV version of the Craven 20 prices. It is only by ignoring both the nonlinearity of the smoking prevalence trend and the role of prices, as Dr. Chipty does, that it is possible to generate non-zero statistically significant 2012 Packaging Changes coefficient. Given the strong correlation of the nonlinear trend variable and the nonlinear trend in cigarette prices, including both these variables is not needed to eliminate the statistical significance of the 2012 Packaging Changes. Thus, the only two estimates below that can be distinguished from zero assume a linear time trend and use either indicator variables or the cigarette excise tax as a proxy for cigarette prices, which as explained below is unjustified.

[24] The instruments used to predict the Craven 20 price are the consumer price index and the excise tax levels.

Estimates of the 2012 Packaging Changes Coefficient for Equations Using the Chipty Sample

| | 2012 Packaging Changes Variable | |
|---|---|---|
| Equation characteristics | Coefficient | Standard Error |
| Tax policy indicators and linear time trend | –0.0062 *** | 0.0021 |
| Tax policy indicators and nonlinear time trend | –0.0029 | 0.0026 |
| Cigarette tax levels and linear time trend | –0.0050 *** | 0.0015 |
| Cigarette tax levels and nonlinear time trend | –0.0012 | 0.0024 |
| Consumer price index and linear time trend | –0.0026 | 0.0022 |
| Consumer price index and nonlinear time trend | –0.0004 | 0.0023 |
| Cost per pack and linear time trend | –0.0027 | 0.0021 |
| Cost per pack and nonlinear time trend | –0.0006 | 0.0023 |
| IV cost per pack and linear time trend | –0.0024 | 0.0022 |
| IV cost per pack and nonlinear time trend | –0.0006 | 0.0023 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01

20. Similar results are found for the entire RMSS data time period extending through December 2016. The Roy Morgan Research sample that I use includes 857,355 observations from January 2001 through December 2016. Here I report results not excluding October and November 2016 from the sample and using December 2012 as the 2012 Packaging Changes starting date. As indicated in Appendix A, the results are similar when using October 1 as the starting date, December 1 as the starting date, or December 1 as the starting date but discarding the October and November 2012 data. As with the results above, the 2012 Packaging Changes variable is negative and statistically significant in only 2 of the 10 equations. However, in the other specifications, the 2012 Packaging Changes coefficient is substantially reduced and is never statistically significant. The estimated effect of the 2012 Packaging Changes is always indistinguishable from zero if the model includes a nonlinear trend term or includes a cost

measure based on the overall CPI, the recommended retail price of Craven 20 cigarettes, or an IV version of the Craven 20 variable.

Estimate of the 2012 Packaging Changes Coefficient for Equations Using the Full Sample

| | 2012 Packaging Changes Variable | |
|---|---|---|
| Equation characteristics | Coefficient | Standard Error |
| Tax policy indicators and linear time trend | –0.0061*** | (0.0021) |
| Tax policy indicators and nonlinear time trend | –0.0030 | (0.0026) |
| Cigarette tax levels and linear time trend | –0.0058*** | (0.0018) |
| Cigarette tax levels and nonlinear time trend | –0.0019 | (0.0023) |
| Consumer price index and linear time trend | –0.0029 | (0.0021) |
| Consumer price index and nonlinear time trend | –0.0013 | (0.0022) |
| Cost per pack and linear time trend | –0.0032 | (0.0021) |
| Cost per pack and nonlinear time trend | –0.0015 | (0.0022) |
| IV cost per pack and linear time trend | –0.0029 | (0.0021) |
| IV cost per pack and nonlinear time trend | –0.0015 | (0.0022) |

*Notes*: Significance levels: *0.10, **0.05, ***0.01

21. Using a Roy Morgan Research RMSS dataset that includes an additional 15 months of data not included in Dr. Chipty's report should have led to larger estimates of the effect of 2012 Packaging Changes if the impact of the policy is increasing over time, as Dr. Chipty hypothesizes. What I find instead is that the estimated effect is not distinguishable from zero if one correctly recognizes either the nonlinear nature of the time trend or the impact of cigarette prices on smoking prevalence rates.

B. Critique of Previous Analyses of RMSS Data

i. Report of Dr. Tasneem Chipty entitled "Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia" (24 January 2016).

22. The report of Dr. Chipty was commissioned by the Australian Department of Health and is the only econometric analysis of data that is relied on in the Australian Government's Post Implementation Review Report. I also understand that it has been cited by a number of other regulators and proponents of Plain Packaging to support claims that the policy has been successful in reducing smoking.[25]

23. The report focuses on the effect of policy changes in Australia on the probability that members of the RMSS sample report are smokers. As noted above, Dr. Chipty acknowledges that it is not possible to separately identify the effects of tobacco plain packaging from those of the updated and enlarged graphic health warnings which Australia implemented at the same time. As such, Dr. Chipty's analysis, as well as the analysis in my report, encompasses the estimated effects of Plain Packaging and the updated and enlarged graphic health warnings (which Dr. Chipty also refers to as the 2012 Packaging Changes). Dr. Chipty's multivariate regression analysis controls for demographic factors, a linear time trend, and various tax increases and other policy shifts.

24. The principal matter of interest for this analysis is the estimated effect of the 2012 Packaging Changes. Dr. Chipty's model captures this influence with an indicator variable that takes on a value of 1 from December 1, 2012 through 2015, and a value of zero otherwise. Her particular 2012 Packaging Changes variable excludes the transition period

[25] See e.g. U.S. National Cancer Institute and World Health Organization. *The Economics of Tobacco and Tobacco Control.* National Cancer Institute Tobacco Control Monograph 21. NIH Publication No. 16-CA-8029A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016.

of October and November 2012 during which plain packs began to appear in the Australian market, so that the variable has a value of 0 through September 2012, with a value of 1 starting in December and the months of October and November excluded from the analysis. In Appendix A, I report representative parallel results using an October 1 start date, a December 1 start date, or a December 1 start date but excluding the October and November transition period from the analysis altogether, as does Dr. Chipty. The results are similar in all these cases. Dr. Chipty's indicator variable for the 2012 Packaging Changes is intended to capture shifts in smoking rates with the advent of the 2012 Packaging Changes. Smoking behavior will, of course, also be affected by other factors such as the cost of cigarettes. Dr. Chipty's analysis seeks to isolate the effect of the 2012 Packaging Changes on smoking prevalence rates by including indicator variables for different excise tax eras, notably the increases in excise taxes in 2010, 2013, and 2014. Similar to the indicator variable for the 2012 Packaging Changes, these variables take on a value of 0 in the years before the excise tax increase and 1 in those years and thereafter. In my analysis above, I also present models that avoid this undesirable variable overlap by using continuous measures of prices and taxes.

25. The following table lists the different policy events affecting smoking. In Dr. Chipty's analysis each of the events leads to an indicator variable with a value of 0 before the event and 1 after the policy event. For Dr. Chipty's report, that ends with data from September 2015, the analysis includes four overlapping 0-1 indicator variables beginning in 2010: from 2010 through 2015 for excise taxes, from 2012 through 2015 for the 2012 Packaging Changes, from 2013 through 2015 for excise taxes, and from 2014 through 2015 for excise taxes. Given the overlapping nature of the construction of her variables

that fall just short of having an indicator for every year, any conclusions drawn from her analysis are highly speculative. Dr. Chipty's procedure is not wrong from a statistical analysis standpoint, but the use of multiple time period indicators provides very limited insight into the separate effects of the 2012 Packaging Changes policy. In particular, there is only a single year in which the 2012 Packaging Changes indicator variable's effect is not also confounded with other policy shifts. Moreover, any lag time in behavioral responses to policy changes due, for example, to the difficulty of quitting cigarettes, will tend to lead to smoking prevalence shifts from the earlier excise tax increases that extend over multiple periods, thus contaminating the purported effect associated with subsequent time period indicators.

Relevant Policy Changes During Period of Dr. Chipty's Analysis

| Year | Policy |
|---|---|
| 2006 | Graphic warning labels on cigarette packages (Jan. 1) |
| 2010 | Tax increase, 25% per pack (May) |
| 2012 | Plain packaging of cigarette packs and increase in graphic health warnings from 30% to 75% of the front of pack (Oct. 1 begin / Dec. 1 full) |
| 2013 | Tax increase, 12.5% per pack (Dec.) |
| 2014 | Tax increase, 12.5% per pack (Sept.) |

26. The policy change summary above and the chart below indicate the year overlaps and the difficulties they create. Excise tax increases in 2010 may have an impact in reducing smoking cessation rates in 2012, creating a confounded effect along with any impact of the 2012 Packaging Changes and the possibility of attributing an association with the 2012 Packaging Changes where there isn't one. Similarly, the influence of the 2012 Packaging Changes that is captured with an indicator variable starting in December 2012

spans a period that includes subsequent cigarette excise tax increases. The only year in which the 2012 Packaging Changes are introduced but no new excise tax measure is introduced is 2012.[26] The overlapping nature of Dr Chipty's indicator variables leads to results that suggest statistically that the analysis may be capturing general time trends due to the impact of excise taxes rather than effects correlated with the role of the 2012 Packaging Changes.

Dr. Chipty's Indicator Variables Specification

| | Year | | | | | | |
|---|---|---|---|---|---|---|---|
| Policy | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
| Excise Tax 2010 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| 2012 Packaging Changes | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| Excise Tax 2013 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| Excise Tax 2014 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |

27. Dr. Chipty's use of indicator variables for the major tax increases is also a crude empirical approach that generates a source of error in the treatment of taxes. The reliance on the indicator variables fails to recognize the continuous nature of excise tax levels, which are updated periodically for inflation. From 2001 through September 2015 (the period of Dr Chipty's analysis), cigarette excise tax levels in Australia had 32 different values.[27] My excise tax variable accounts for the level of excise taxes throughout my

[26] More specifically, if the full implementation of the 2012 Packaging Changes was in December 2012, and the 2013 excise tax was introduced in December 2013, the time period in which the 2012 Packaging Changes alone is the incremental change is from December 2012 to November 2013. My analysis accounts for the monthly policy changes, but for simplicity, the chart above focuses on years.

[27] See table 13.2.3 of Scollo, M, Bayly, M. 13.2 "Tobacco taxes in Australia". In Scollo, MM and Winstanley, MH [editors]. "Tobacco in Australia: Facts and issues". Melbourne: Cancer Council Victoria; 2016.

estimation period, more accurately characterizes the tax rate than simply identifying the major tax increase periods, and avoids the use of overlapping indicator variables.

28. The chart below also indicates the nature of Dr. Chipty's analysis and its fundamental shortcomings with respect to her analysis of temporal factors. As illustrated, there is a pronounced decline over time in smoking prevalence rates. Smoking prevalence rates over time may be affected by factors other than those explicitly captured by variables in a regression model. Progressive changes in public space smoking restrictions, differences across different population cohorts in attitudes toward smoking, and the rising role of vaping as an alternative to smoking are among the time-related variables that may not be accounted for in a regression model. To incorporate the role of omitted temporal factors, researchers may include variables reflecting the time period. However, there is no theoretical basis for assuming a particular temporal relationship as Dr. Chipty has done, as it might be linear or nonlinear. The proper form is an empirical question which Dr. Chipty doesn't consider. In estimates reported in Appendix A, I report multivariate regression equations including both time and time squared in the analysis.[28] The statistically significant coefficient on the time squared variable is the statistical test that shows that the temporal trend in smoking prevalence rates is consistent with the time trend being nonlinear. Contrary to Dr. Chipty's analysis, one can reject the hypothesis that the trend is linear.

29. Using data from the pre-2012 Packaging Changes period, I have fitted a nonlinear temporal relationship to the data indicated by the gray curve, focusing solely on the relationship between smoking propensities and time as well as time squared. The curve

[28] Thus, for example, for the first month of data in the RMSS sample the value of Time would be 1, in the second month it would be 2, the third month would be 3, etc. The value of Time squared is just the square of this value, or 1, 4, 9, etc.

fitting the pre-2012 Packaging Changes data generates the illustrated post-2012 Packaging Changes projections that track the overall trend nicely.[29] Thus, there is no discontinuous shift in the trajectory of smoking prevalence rates once one takes into account the nonlinear trend in smoking prevalence rates that already existed before the advent of the plain packs policy. My conclusion that there is no discontinuous shift in smoking prevalence rates that took place in 2012 is also consistent with findings by other researchers using a different statistical approach.[30]

30. A graphical analysis indicates the mistaken conclusions that will be generated by assuming that an underlying nonlinear trend is linear. Imposition of a linearity assumption when the underlying trend is nonlinear will always result in the projected values of smoking rates exceeding the actual future levels. This phenomenon can be illustrated using a variety of different time periods which, according to Dr. Chipty's logic, would indicate a shift in smoking prevalence rates, whereas in fact no shift has occurred, only a continuation of the underlying nonlinear trend.

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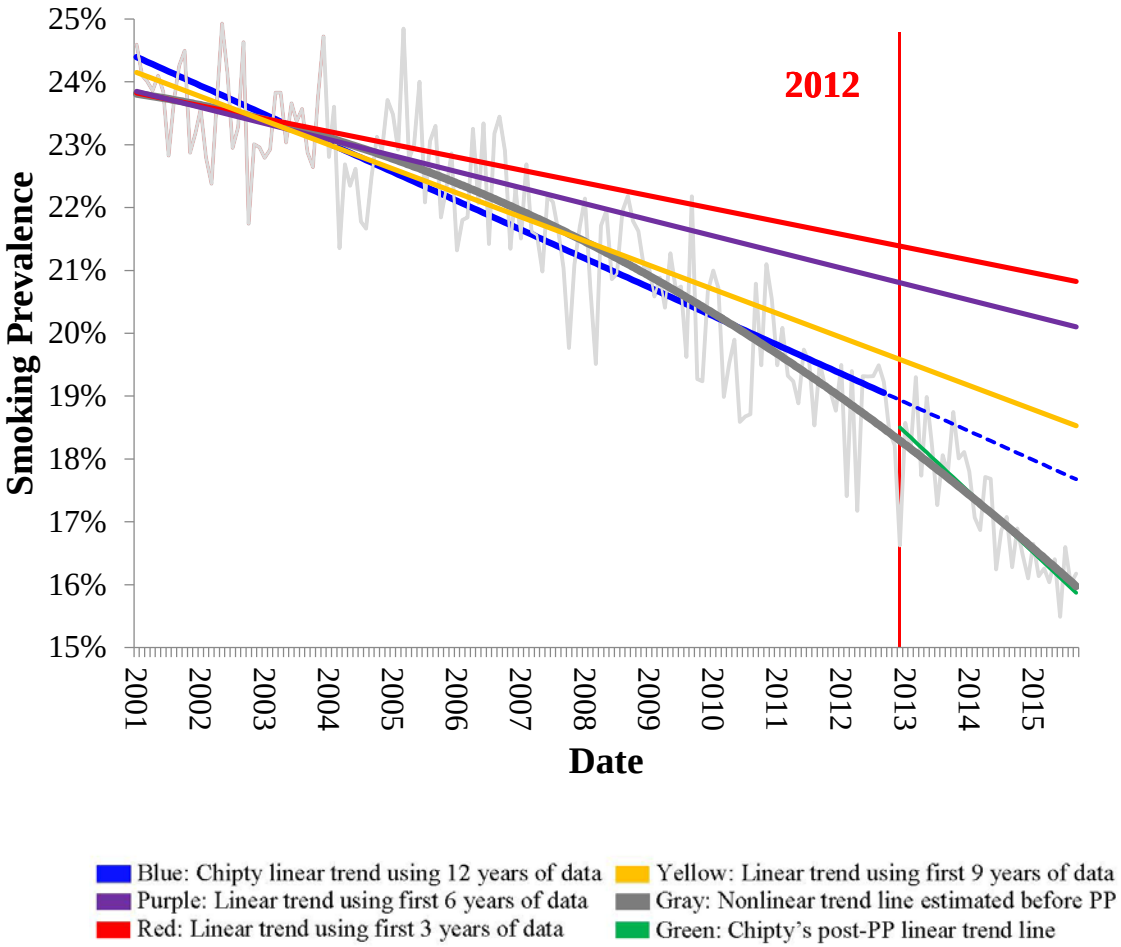
[29] The equation is a regression of the 0-1 smoking prevalence variable on a constant term, time in months, and time squared in months, where the smoking probability = 0.24 – 1.32E-4 time – 1.76E-6 time squared, where all coefficients are statistically significant at the 0.05 level or better.

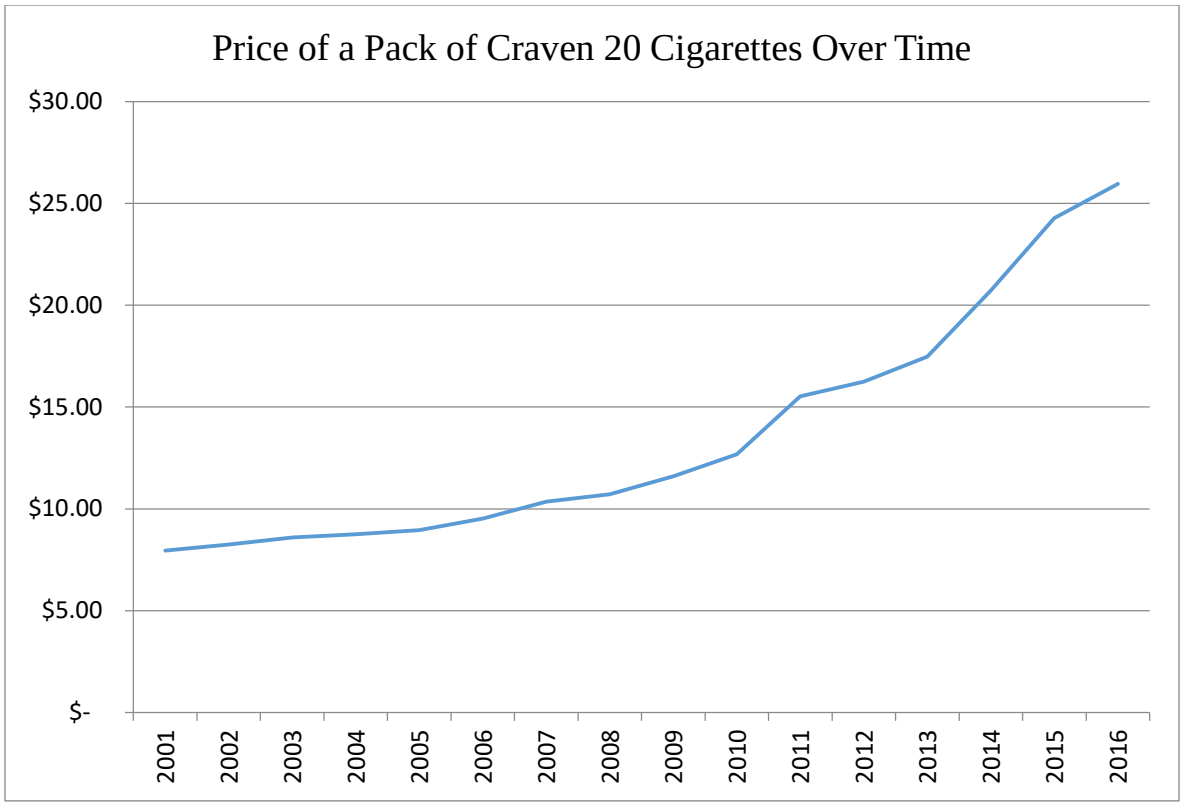
[30] Lilico, A. (2016). "Analysis of the Chipty Report's Conclusions Regarding Packaging Changes and Smoking Prevalence in Australia", August 30, 2016, available at http://www.jti.com/about-tobacco/key-regulatory-submissions/.




31. Dr. Chipty's analysis assumes a linear trend indicated by the blue line in the chart, which she estimated for the time period up to the 2012 Packaging Changes. As her analysis points out, this linear trend line does not predict the post- 2012 Packaging Changes trend, which exhibits an additional drop after the advent of the 2012 Packaging Changes. She then attributes the unexplained drop in smoking prevalence rates to the impact of the 2012 Packaging Changes. That there is a shift if one assumes that trends must be linear is illustrated by the green line, which is Dr. Chipty's linear trend line using only post-2012 Packaging Changes data. The blue line and the green line have clearly different slopes, indicating a purported drop in smoking prevalence rates associated with the 2012 Packaging Changes. However, one can generate other possible purported policy effects

for any time period in the chart since the underlying trend is nonlinear. Similar linear trend lines such as the red trend line based on the first 3 years of data indicate an unpredicted drop in smoking prevalence rates thereafter, as does the purple linear trend line based on the first 6 years of data, and the 9-year trend line in yellow. The "unexplained" departures from the trend lines occur because a linear trend line does not properly capture the nonlinear trend. Capturing any nonlinear relationship with a linear trend line as Dr. Chipty does, will lead to an unexplained subsequent apparent "policy impact" that is spurious, as it is not an effect associated with the policy but instead reflects an underlying nonlinear trend.

32. While there are multiple factors that could contribute to such a nonlinear trend such as progressive restrictions on public smoking and cohort effects as the population changes over time, an additional influence is the rising cost of cigarettes. The figure below indicates the recommended retail price trajectory for Craven 20 cigarettes, which has undergone a steep nonlinear increase, reflecting in part the influence of multiple boosts in the excise tax rate. The nonlinear nature of the price hikes is consistent with the nonlinear decline of smoking prevalence rates. Any increases in the non-monetary costs of smoking, such as the convenience costs arising from smoking restrictions, would reinforce such influences.




33. Three principal results from the RMSS data analysis are apparent in both the analysis of the extended dataset that I used as well as in my analysis of the shorter time period considered in Dr. Chipty's report. First, if one properly recognizes that the temporal trend is nonlinear rather than linear (i.e., by including a quadratic time trend term), that reformulation alone accounts for the downward trend in smoking rates without there being any additional downward shift associated with the 2012 Packaging Changes. Second, even with only a linear trend, reasonable specifications of the model using either overall consumer prices or continuous measures of the recommended retail price of cigarettes rather than the excise tax indicator variables approach used by Dr. Chipty eliminates the statistical significance of the 2012 Packaging Changes variable. Third, even if there were a purported association of the 2012 Packaging Changes with the

decline in smoking prevalence rates based on Dr. Chipty's analysis, one should be skeptical of the import of these results. Her statistical analysis ignores the multiple changes in excise tax rates and includes four overlapping indicator variables for the 2010 to 2015 period in which there is only a single year in which the 2012 Packaging Changes are introduced without any other new smoking policies also being introduced. Attributing the decline in smoking prevalence rates to the 2012 Packaging Changes as opposed to the excise tax increases, both before and after the advent of the 2012 Packaging Changes policy, is not warranted. While the final concern may reflect a difference in statistical approaches, the first two shortcomings are fundamental. Dr. Chipty's failure to consider the pivotal role of prices on smoking behavior and the underlying nonlinear trend in smoking prevalence rates have generated the mistaken conclusion that the 2012 Packaging Changes are associated with an unexplained drop in smoking prevalence rates.

ii. Diethelm and Farley (2015)[31]

34. The article by Diethelm and Farley (2015) analyzed the average monthly smoking prevalence rates in the RMSS data which they derive from a research paper by Kaul and Wolf.[32] They did not use any original RMSS data but instead relied on visual inspection of the figure in Kaul and Wolf to impute 156 monthly smoking prevalence rates. Because they have no individual respondent data, their analysis includes no demographic variables. As a result, changes in sample composition over time, such as the age and income level of respondents, are ignored. Similarly, there are no controls for different

[31] Pascal A Diethelm, Timothy M Farley, "Refuting tobacco-industry funded research: empirical data shows a decline in smoking prevalence following the introduction of plain packaging in Australia," Tob. Prev. Cessation 2015;1(November):6 http://dx.doi.org/10.18332/tpc/60650.

[32] Kaul, A. and Wolf, M. "The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis" University of Zurich Department of Economics Working Paper, June 2014.

Australian state territories so that the mix of the sample across states and any state-specific smoking-related policies are not taken into account and may be incorrectly attributed to the 2012 Packaging Changes. The only explanatory variables included in the regression analysis reported in the paper are a linear time trend, an indicator variable for the 2010 excise tax increase, an indicator variable for smoke-free policies, and a plain packaging indicator variable. Even setting aside the omitted demographic and regional variables, the equation is a very 'bare-bones' specification. The many other excise tax changes, cigarette prices, and the nonlinear smoking prevalence trend are all omitted. The recent Cochrane Review notes the nonlinearity in the smoking prevalence trend but claims that the "additional covariates" in Diethelm and Farley (2015) address the nonlinearity. This claim is simply not true since their specification includes only two policy indicator variables and no variables that capture the evident nonlinearity in the trend apart from these shifts.

35. The impact of the limitations and flaws in the Diethelm and Farley (2015) paper is that this study lacks any scientific credibility. The deficiencies I cite above are not minor limitations or matters of a difference of opinion, but are fundamental problems that make it inappropriate to rely on their study. The paper has no scientific merit at all.

## IV. IMPLICATIONS OF THE CITTS DATA

### A. Overview of the CITTS Data

36. The CITTS data that I analyze consists of cross-sectional telephone data utilizing a sample of 17,468 adult smokers and recent quitters (people who quit smoking in the past 12 months). The CITTS data (and the NTPPTS data) only include smokers and recent quitters, so they cannot be used to assess the effect of the 2012 Packaging Changes on smoking prevalence. However, these data provide valuable insights into smoking-related behaviors of smokers and recent quitters, which is clearly an important target group of the policy. The survey also includes a number of variables relating to the perceptions of the 2012 Packaging Changes by this group even setting aside issues pertaining to the efficacy of these 'intermediate' variables in predicting actual smoking behaviors. The CITTS is undertaken in New South Wales, which is the most populous state in Australia. Further details of this survey are provided in the paper by Dunlop et al. (2014).[33] The sample analyzed by Dunlop et al. focused on smokers interviewed between April 2006 and May 2013, which includes only six months of data post the implementation of PP in Australia. My sample through June 2016 adds an additional 37 months and 2,045 observations to the sample, which takes it through June 2016 (i.e., 3 1/2 years of data post the implementation of the 2012 Packaging Changes in Australia).[34] Accordingly, the analysis I present here is the most up to date analysis of this dataset.

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[33] Sally M. Dunlop, Timothy Dobbins, Jane M. Young, Donna Perez, and David C. Currow, "Impact of Australia's Introduction of Tobacco Plain Packs on Adult Smokers' Pack-Related Perceptions and Responses: Results from a Continuous Tracking Survey," *BMJ Open* 2014; 4(12): e005836;

[34] As noted above, I have previously addressed the CITTS data in reports that I submitted for British American Tobacco in October 2015 in UK legal proceedings in which the 2012 packaging change regulation was being challenged, and in November 2015 in relation to the Australian Government Department of Health Post-Implementation Review (PIR) of the Tobacco Plain Packaging Act 2011 (TPP). In this report, in addition to using a larger sample, I also undertake new analyses using more detailed

37. The 2012 Packaging Changes took full effect in Australia on December 1, 2012. October and November of that year were a transition period in which some packs began to conform to the 2012 packaging change format. To streamline the exposition below, I only report results in the main body of the report using the December 1, 2012 starting date for the 2012 Packaging Changes. Results reported in Appendix B indicate that the results are stable using other policy starting dates.

38. The sampling procedure for the CITTS survey changed in 2013, as recruitment of respondents changed to include mobile phone users instead of only landline users.[35] As a result, my analysis of the CITTS data draws on the findings using multiple regression analyses in which there is a statistical control for the mobile phone recruitments in the sample as well as detailed set of demographic variables.

39. Many of the CITTS data questions are in the form of qualitative Likert rating scales in which some measures are rated on a scale from 1 to 5 (strongly disagree, somewhat disagree, neither, somewhat agree, strongly agree), where 1 equals strongly disagree and 5 equals strongly agree. These qualitative scales do not provide a basis that permits a comparison either within or across people since the cut-off between these categories will vary across individuals and across questions so that the distinctions are not very meaningful. For example, there is no way of knowing whether person A's score of a 4 for pack attractiveness implies a lower or higher level of attractiveness than person B's score of 3. Similarly, we cannot tell if a drop of a score from 4 to 2 is twice the size as a decrease from 4 to 3. Accordingly, focusing on only one set of extreme responses, such as shifts in the "strongly agree" category, will distort the assessment of the implications

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controls than in my previous assessments. In my previous reports I controlled for cell phone usage and time trends, but the current report also includes controls for a detailed demographic variables.

35 Cancer Institute NSW's Tobacco Tracking Survey (CITTS) Research Plan 2013-2014 at page 11.

of the 2012 Packaging Changes. A more meaningful way to address this issue is by focusing on the pooled agreement responses ("strongly agree" and "agree") and pooled disagreement responses ("strongly disagree" and "disagree"). Thus, while I will report the distribution of the findings with respect to various statements regarding cigarettes, my emphasis will be on the pooled set of responses who indicate agreement in terms of either "strongly agree" or "agree." Similarly, I will pool the disagreement responses for whether the respondent indicates "strongly disagree" or "disagree" with the various statements.

40. I divide the survey questions into three groups. The first set of questions explores consumption-related questions pertaining to quit behavior and smoking. Whether the 2012 Packaging Changes are associated with actual smoking behaviors is the fundamental policy issue. The next set of questions consists of belief and smoking attitude questions. The overwhelming result is that there is no evidence that the 2012 Packaging Changes policy has succeeded in any of these dimensions. I then address the questions pertaining to pack appearance. These are the questions that have received the greatest emphasis in the published articles on the 2012 Packaging Changes, perhaps because they are most consistent with some authors' efforts to support the policy. However, the absence of any impact of the 2012 Packaging Changes on the belief and behavior responses suggests that even though the trademarks and the brands they represent have been removed from cigarette packaging, that change has not advanced more fundamental smoking policy objectives. Unlike Dunlop et al. (2014) that does not consider the broad set of survey questions in the CITTS data that I analyze here, the

tables below and in Appendix B provide a more comprehensive and balanced perspective on the implications of the data from the post-2012 Packaging Changes era.[36]

B. Smoking and Quit Behavior in the CITTS Data

41. The first set of regression results reported in Appendix B estimates the effect of the 2012 Packaging Changes with the number of cigarettes smoked, controlling for the other variables and the time trend variables listed in the tables. Tables B1 and B2 report similar results for different specifications of the policy time period. These regressions pertain to daily, weekly, and occasional smokers.[37] The table below reports only on the estimates of the 2012 Packaging Changes variable in a large series of regressions for both the full sample in the first column and excluding quitters in the second column. I exclude quitters in some instances both because the questions may not be pertinent to quitters and because it is also instructive to analyze the results for the current smoking population. Although only the 2012 Packaging Changes coefficients are reported, the regressions included the complete set of variables in the regressions reported in Appendix B. There is a statistically significant increase in the number of cigarettes smoked both for the sample overall and excluding quitters in the second column. Total cigarettes smoked rose after the advent of the 2012 Packaging Changes policy by 0.9 cigarettes per day overall, and by 1.4 cigarettes per day excluding quitters. That cigarettes per day increased even while

[36] Multiple regression analysis makes it possible to estimate statistically the effect of the PP requirements controlling for other factors, in particular, the shift in the sample recruitment to include mobile phone users and the existing trends in smoking-related attitudes and behaviors. The regression coefficients have direct interpretations. For 0-1 questions such as whether the respondent plans to quit in the next month, the estimates are probit regressions where the coefficients have been transformed to correspond to marginal effects. Probit regressions are appropriate when the dependent variable is dichotomous rather than continuous. The other equations are estimated using ordinary least squares regressions.

[37] Daily and weekly smokers are measured by self-reported number of cigarettes smoked per day. Monthly or less frequent smokers are deemed to smoke zero cigarettes per day.

including recent quitters indicates that the rise in cigarettes per day is not because the 2012 Packaging Changes reduced the smoking rates of those who had less intensive smoking histories, thus altering the mix of smokers. These results are consistent for each possible marker for policy implementation, either full implementation from December 1, 2012 as shown here, partial implementation from October 1, 2012, or full implementation excluding partial observations. The latter two results are included as Appendix Tables B1 and B2.

| Regressions, Reporting Only 2012 Packaging Changes Coefficient[38] | | |
|---|---|---|
| Variable Name | 2012 Packaging Changes | 2012 Packaging Changes Quitters Excluded |
| Number of cigarettes per day (OLS) | 0.8904*** | 1.4234*** |
| Plan to quit in the next month (yes/no) | 0.0095 | 0.0095 |
| Smoker: Daily | 0.0474*** | 0.0884*** |
| Smoker: At least weekly (not daily) | –0.0284*** | –0.0324*** |
| Smoker: Less often than weekly | –0.0496*** | –0.0574*** |
| Smoker: Not at all, but yes in last year | 0.0194* | . |
| How difficult would it be to quit (OLS) | 0.6523*** | 0.6523*** |
| How difficult did you think (OLS) | 0.7043** | . |
| How difficult last attempt (OLS) | 0.2080 | . |
| How confident that you can quit (OLS) | –0.5354*** | –0.5354*** |
| How confident that you can stay (OLS) | –0.2906 | . |
| GWL stop agree | 0.0149 | 0.0099 |
| GWL stop disagree | 0.0015 | 0.0100 |
| GWL worry agree | 0.0405** | 0.0405** |
| GWL worry disagree | –0.0296* | –0.0296* |
| GWL exaggerate agree | 0.1608*** | 0.1782*** |
| GWL exaggerate disagree | –0.1403*** | –0.1554*** |

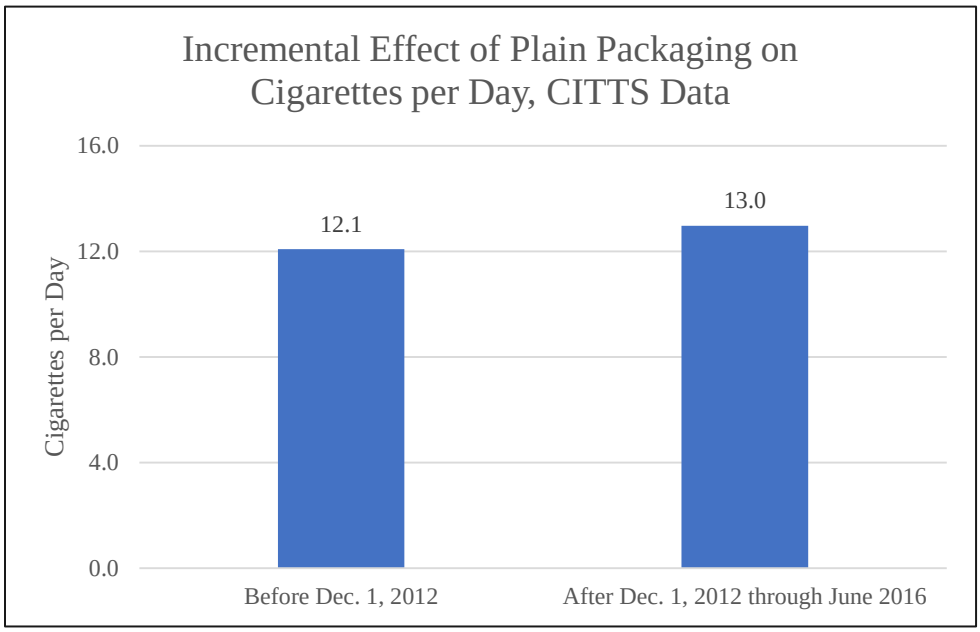
[38] Results are probit regressions reporting marginal effects, unless identified with (OLS), in which case ordinary least squares regressions.

| | | |
|---|---|---|
| Government pesters agree | 0.0746*** | 0.0832*** |
| Government pesters disagree | –0.0319* | –0.0441** |
| Health effects exaggerated agree | 0.0467*** | 0.0591*** |
| Health effects exaggerated disagree | –0.0080 | –0.0230 |
| Only harmful to heavy agree | 0.0308** | 0.0346** |
| Only harmful to heavy disagree | –0.0001 | 0.0012 |
| GWL hide pack agree | 0.1078*** | 0.1078*** |
| GWL hide pack disagree | –0.1022*** | –0.1022*** |
| GWL only thing notice agree | 0.0954*** | 0.0954*** |
| GWL only thing notice disagree | –0.0934*** | –0.0093*** |
| GWL notice of the warning yes/no | 0.0268*** | 0.0233*** |
| GWL don't look at warning agree | -0.0248 | –0.0248 |
| GWL don't look at warning disagree | 0.0258 | 0.0258 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01. GWL denotes graphic warning labels.

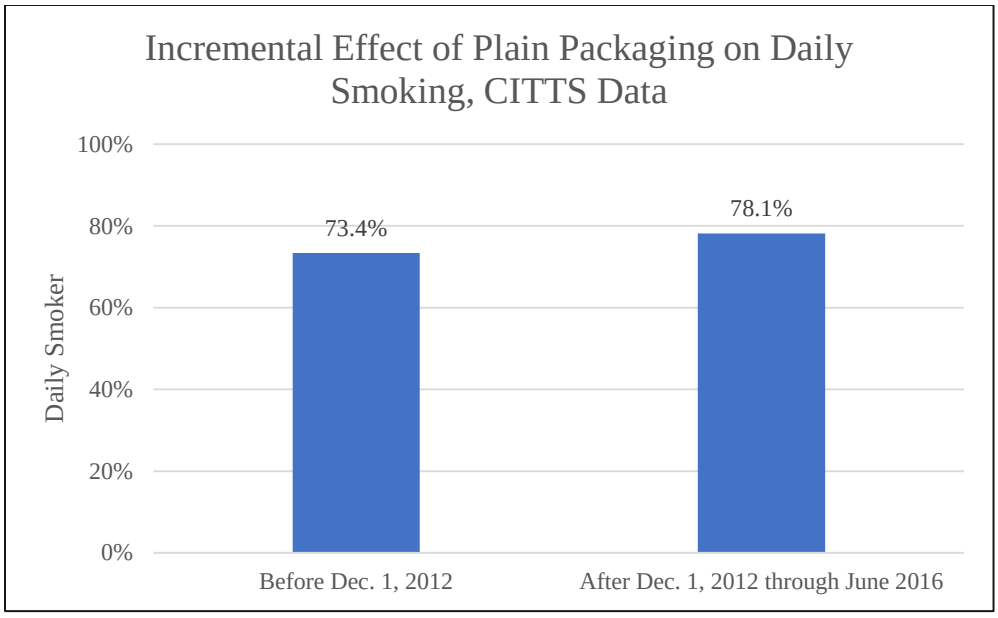
42. The change in consumption is illustrated in the figure below. The number of cigarettes smoked per day rises by a statistically significant amount of 0.9 cigarettes in the post-implementation period for the full sample and by 1.4 cigarettes per day excluding quitters. While these results are not pertinent to analyzing smoking prevalence due to the fact that the sample is restricted to smokers and recent quitters (within the past twelve months), they do indicate that within this population smoking intensity and consumption has not declined but on the contrary has increased. To calculate the post-implementation value, I added the incremental increase in the number of cigarettes smoked based on the 2012 Packaging Changes coefficient in the smoking probability regression. Thus, this and all subsequent discussions of the CITTS data control for a detailed set of variables and the impact of time trends.[39]

[39] To establish a parallel with studies of smoking prevalence rates, I include time trends in the analysis of the attitudinal variables, and they show a significant quadratic effect consistent with the RMSS analysis.



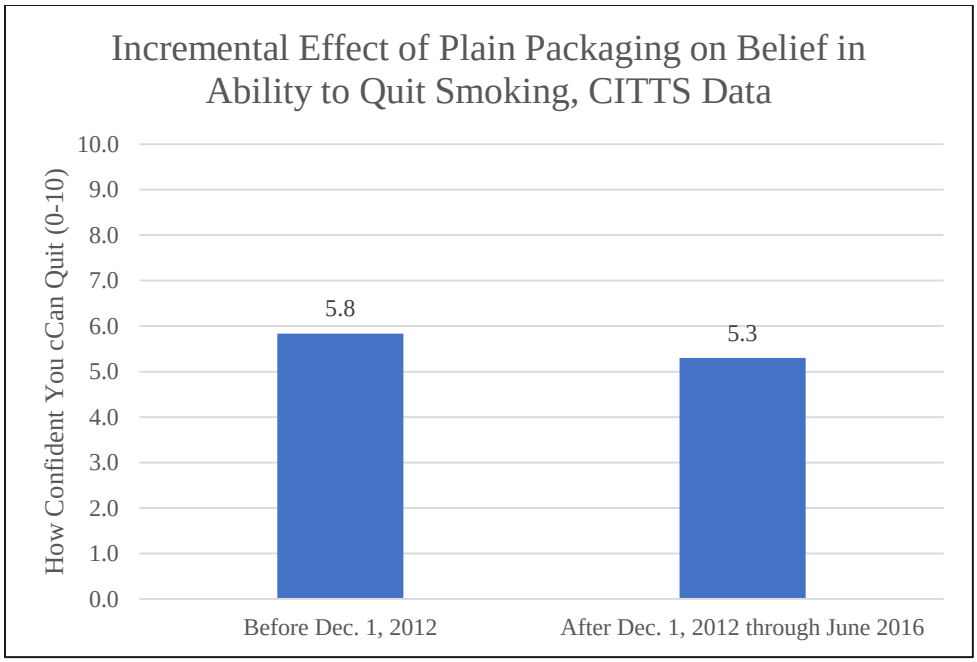

I note that this result is based on three and a half years of CITTS data after the implementation of the 2012 Packaging Changes in Australia.

43. The other smoking-related measures of interest pertain to smoking-related behaviors, and another set pertains to various attitudinal variables such as whether the respondent believes that graphic warning labels exaggerate the risk of smoking. All members of the CITTS sample were smokers or recent quitters. However, there is a shift in the mix of their smoking-related behaviors after the advent of the 2012 Packaging Changes. Whether the respondent is a daily smoker has risen by a statistically significant value of 5%, while there has been a statistically significant decline in the "at least weekly (not daily)" and "less often than weekly" smoking, reflecting an increase in the intensity of smoking behavior. The figure below illustrates the shift in daily smoking after the advent of the 2012 Packaging Changes policy. The baseline daily smoking rate in the period before December 1, 2012 is the mean value of daily smoking in that sample period.




44. The next series of questions I examine pertains to quit-related behaviors. There is no significant change in the proportion of respondents who plan to quit in the next month. Based on analysis of these measures, the 2012 Packaging Changes policy has not influenced these quit intentions.

45. This overall quit intention question was followed by a series of questions in which respondents rated the difficulty of quitting on a scale of 0 to 10. After the advent of the 2012 Packaging Changes policy, respondents rate it significantly more difficult to quit both in terms of how difficult it would be to quit and how difficult they thought it would be to quit. Respondents are significantly less confident that they can quit, as the average ratings before and after December 1, 2012 policy implementation date in the figure below indicate.



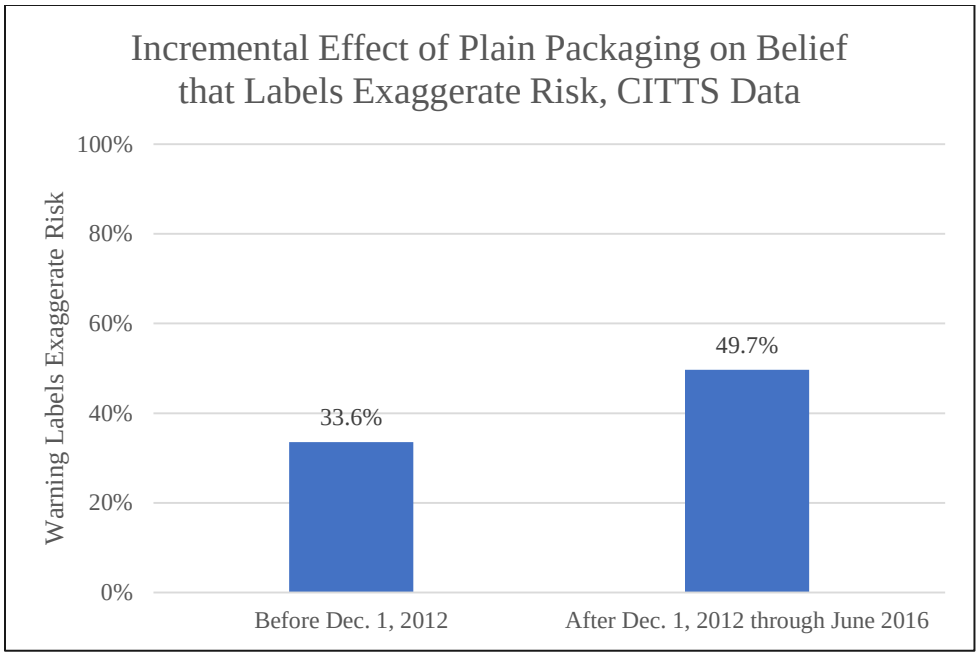

There were no statistically significant changes in the perceived difficulty of the last quit attempt or confidence that they can stay as quitters after the advent of the 2012 Packaging Changes. These outcomes indicate increased pessimism with regards to the possibility of quitting smoking after the advent of the 2012 Packaging Changes.

46. Dunlop et al. (2014) examine the CITTS data with respect to smoking emotions and pack perceptions, but do not examine the effects on behavior. They conclude: "[f]urther research should extend this study by considering any relationship between smokers' responses to their plain packaging packs and changes in smoking behaviours…."[40] My analysis of the CITTS data considered the behaviors that Dunlop et al. (2014) did not explore, both with respect to cigarette consumption and quit behavior. All statistically significant effects that I found are the opposite of what one would expect if the 2012 Packaging Changes policy was achieving its intended policy objective.

[40] Dunlop et al. (2014), *supra*, at 6.

C. Risk Beliefs and Smoking Attitudes in the CITTS Data

47. The next series of questions pertains to a series of attitudinal variables of the type considered by Dunlop et al. (2014). However, rather than focusing on the extreme responses of those who "strongly agree" or "strongly disagree," I pool the two "agree" response categories and the two "disagree" response categories. The effect of the 2012 Packaging Changes on these attitudinal variables is mixed and on balance do not indicate a shift in attitudes consistent with a beneficial effect of the 2012 Packaging Changes policies. Consider the following effects, all of which are based on the regression analysis controlling for demographic factors and other influential covariates. There is a statistically significant 16% increase in whether respondents believe that the graphic warning labels policy exaggerate the risk of smoking, a statistically significant 7% increase in beliefs that the government pesters people too much about smoking risks, a statistically significant 5% increase in beliefs that the health effects are exaggerated, and a statistically significant 3% increase in the belief that smoking is only harmful to heavy smokers. There is also a significant 4% increase in graphic warning labels making them worry more when they get a cigarette out to smoke. The largest perceptional shift in the post-implementation period is for whether respondents believe that the graphic warning labels policy exaggerates the risk, and this shift is illustrated in the figure below.




48. The overriding implication of these findings is that the 2012 Packaging Changes policy is associated with no beneficial impact on risk beliefs, coupled with a substantially increased degree of rejection of the graphic health warnings message. Other pertinent policy performance metrics, such as the number of cigarettes smoked per day, daily smoking behavior, and the perceived ability to quit smoking, show no net beneficial effect and actually show modest impacts that are counterproductive to the intended objective.

D. Perceptions of Pack Appearance in the CITTS Data

49. The final set of regression estimates focuses on the series of questions that pertain to pack appearance, which clearly has not been enhanced by the advent of the 2012 Packaging Changes. However, shifts in views toward pack appearance and associated changes in warnings are not associated with increased risk beliefs or behavioral changes, as documented above.

50. The percentage of those who agree that they would hide the cigarette pack rose by a statistically significant value of 11%. There consequently has been some increase in the tendency to hide the pack, which will also affect whether the respondent or others can view the graphic health warning.

51. The percentage of those who viewed the warning as the only thing they saw on the package rose by a statistically significant value of 10%. There was also a statistically significant 3% increase in those who notice the warning. However, since there is very little else on the pack that respondents can report seeing after the advent of 75% warnings on the front of packs, these results are not surprising and could be a result of the increase in the size of the warning to 75% rather than Plain Packaging. That Plain Packaging removed trademarks and branding from cigarette packaging is apparent. However, the responses to these questions largely characterize what the policy has done rather than indicating any effect on risk beliefs, smoking cessation, or decreased cigarette consumption.

E. Critique of Literature using CITTS Data

52. Dunlop et al. (2014) utilize the CITTS data comparing various pre-2012 Packaging Changes periods from April 2006 to 2012 to the post-2012 Packaging Changes period through to May 2013 (which is shorter than the period of the dataset that I present above which goes through to June 2016). Although the responses considered gradations of qualitative scores on a five point scale, the article by Dunlop et al. (2014) reports only the results for the most extreme category of whether the respondent indicates “strongly agree” with a favorable aspect of the 2012 Packaging Changes, such as increased

emotional response, or "strongly disagree" with an aspect that the 2012 Packaging Changes policy is intended to diminish, such as pack attractiveness. As my analysis of the CITTS data presented above indicates, that approach is an incomplete and misleading characterization of the data. Focusing on the responses at one extreme end of the spectrum ignores the countervailing movements at the other extreme for that question. In addition, pooling the two "agree" responses and the two "disagree" responses eliminates the apparent effects shown in Dunlop et al. (2014) by focusing only on the "strongly agree" or only on the "strongly disagree" responses. Because there is no objective reference point to distinguish degrees of agreement or disagreement, respondents may differ as to what it means to only agree (disagree) or strongly agree (strongly disagree). To establish a categorization that does not combine responses that may have quite different meanings across respondents, I combine the two agree categories in one group and the two disagree categories in a second group. I also examine many questions that Dunlop et al. (2014) ignored. By not cherry picking the data to focus only on those questions that appear to provide evidence favorable to the 2012 Packaging Changes, we can obtain a more balanced policy perspective. My more comprehensive exploration of the CITTS survey results above indicates quite different implications of the CITTS data. The implication of the findings from my analysis is that the 2012 Packaging Changes have been counterproductive in a number of respects, including that they are associated with an increased belief that the warnings exaggerate the risk, a decreased belief in respondents' ability to stop smoking, and a slight increase in smoking behaviors.

## V. IMPLICATIONS OF THE NTPPTS DATA

### A. Overview of the NTPPTS Data

53. The NTPPTS data is a national telephone adult smoker survey from which I analyze 10,308 observations from April 2012 to March 2014.[41] Further details of this survey are provided in the paper by Wakefield et al. (2015).[42] Because the pre-implementation time period covered was shorter than for the CITTS data and the sampling procedure did not change over time as was the case with the CITTS data, I do not include a time trend variable in the regression analysis. Similar to the CITTS, many of the NTPPTS questions are in the form of qualitative Likert rating scales, although a different scale is used where the survey posed statements and asked which of the following four levels of agreement the respondent had to the statement: not at all; a little; somewhat; and much. The results for the NTPPTS data are reported in Appendix C.

### B. Smoking and Quit Behavior in the NTPPTS Data

54. The first set of regression results reported in Appendix C assesses the estimate of the 2012 Packaging Changes variable in analyses of the number of cigarettes smoked for the NTPPTS sample. Controlling for other factors, the number of cigarettes smoked per day has increased by 0.1 cigarettes, which falls short of statistical significance, providing no support for the effectiveness of the policy. Tables in Appendix C report similar results for other specifications of the starting date of the 2012 Packaging Changes time period.

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41 The data collected in the National Tobacco Plain Packaging Monthly Tracking Survey is available on request from the Australian Department of Health, see http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-plain-packaging-evaluation#%5B%3Ch2%3E%5DNational%20Monthly%20Tobacco%20Pl

42 Melanie Wakefield, et al., "Australian Adult Smokers' Responses to Plain Packaging after Larger Graphic Health Warnings 1 Year after Implementation: Results from a National Cross-Sectional Tracking Survey", *Tobacco Control* 2015; 24:ii17-ii25.

| 2012 Packaging Changes Estimates in Regression Predicting Number of Cigarettes Per Day Smoked[43] | | |
|---|---|---|
| | Coefficient | Standard Error |
| Plain packaging policy (Dec. 1, 2012) | 0.1198 | 0.2029 |

*Notes*: The 2012 Packaging Changes variable is not statistically significant at the 0.10, 0.05, or 0.01 levels.

55. I note that consistent with my analysis, Scollo et al. (2015),[44] which is the only published study of the NTPPTS data that discusses the data on actual consumption behavior, also found that the 2012 Packaging Changes had no impact on consumption. The authors state the following regarding the impact of the implementation of the 2012 Packaging Changes (which they called PP for "plain packs") in Australia:

> "Among daily cigarette smokers, there was no change in consumption between pre-PP and the transition phase or PP year 1 period…Nor was any change detected when mean daily consumption was analysed among regular smokers…Mean daily consumption also did not change from the pre-PP to subsequent two phases among current smokers…Furthermore consumption did not change from pre-PP to the subsequent two phases among current smokers of brands of any market segment…"[45].

56. The other questions analyzed in the table below regarding smoking cessation related behaviors and thoughts about quitting also indicate almost a complete lack of any statistically significant effects relating to advancing the policy objectives of the 2012

[43] Regressions also include variables identifying whether data for demographic variables are missing. Missing data coded as zero. See Appendix C for fuller regression results.

[44] Michelle Scollo, Meghan Zacher, Kerri Coomber, Megan Bayly, and Melanie Wakefield, "Changes in Use of Types of Tobacco Products by Pack Sizes and Price Segments, Prices Paid and Consumption Following the Introduction of Plain Packaging in Australia," *Tobacco Control* 2015;24:ii66-ii75.

[45] *Ibid*, at 10, ii73; see also McNeill A, Gravely S , Hitchman SC, Bauld L, Hammond D, Hartmann-Boyce J. "Tobacco packaging design for reducing tobacco use" Cochrane Database of Systematic Reviews 2017, at p 20.

Packaging Changes. To the contrary, post-policy respondents were less likely to think about quitting either once or once every few days over the previous week, less likely to stub out many times after the policy, and similarly were less likely to stop many times upon having the urge to smoke.

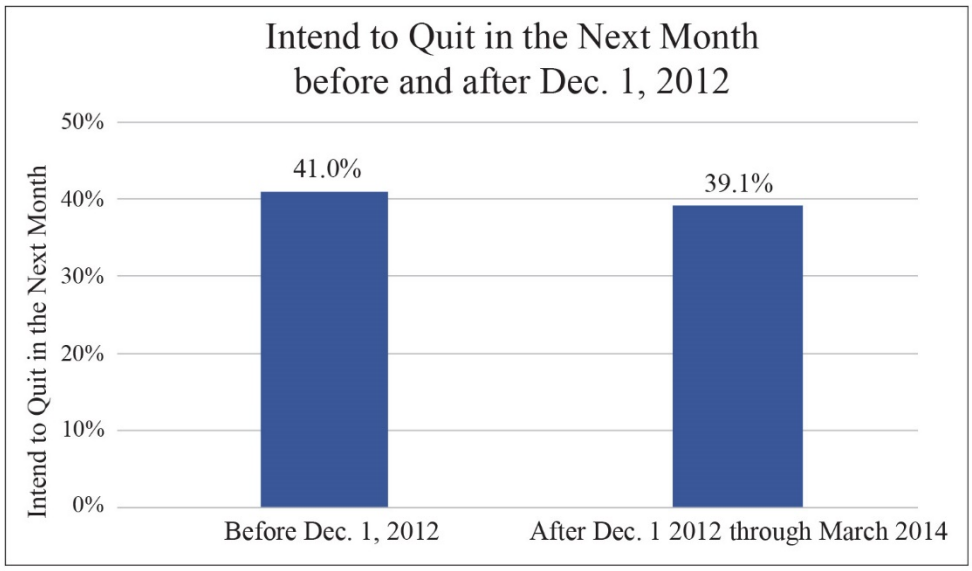
NTPPTS Data: Regressions for Consumption with December 1 Break Point, Reporting Only 2012 Packaging Changes Coefficient

| **Variable Name** | **2012 Packaging Changes** |
|---|---|
| Cigarettes per day (OLS) | 0.1198 |
| How important quitting for good (0-10) (OLS) | –0.0798 |
| How important quitting for good (0) | 0.0048 |
| How important quitting for good (10) | 0.0063 |
| Intend to quit in next month | –0.0195 * |
| Think quitting past week not at all | 0.0173 * |
| Think quitting past week once | –0.0186 ** |
| Think quitting past week once every few days | –0.0210 ** |
| Think quitting past week once per day | 0.0046 |
| Think quitting past week several times per day | 0.0172 |
| Have you ever attempted quitting smoking | –0.0131 |
| How long ago last quit attempt (days) (OLS) | 3.4713 |
| Stub out when thought harms never | 0.0168 |
| Stub out when thought harms once or twice | 0.0112 |
| Stub out when thought harms several times | 0.0004 |
| Stub out when thought harms many times | –0.0282 *** |
| Stop when had urge to smoke never | 0.0145 |
| Stop when had urge to smoke once or twice | –0.0036 |
| Stop when had urge to smoke several times | 0.0112 |
| Stop when had urge to smoke many times | –0.0223 *** |

*Notes*: Probit regressions reporting marginal effects unless noted by (OLS), indicating ordinary least squares; Significance levels: *0.10, **0.05, ***0.01. Regressions include all other variables listed in Table C1.

57. A series of questions focused on different aspects of smoking cessation behaviors. Rating the importance of quitting for good on a 10-point scale, there is a statistically insignificant decline of this score from 7.4 to 7.3.

58. Whether the respondent intends to quit smoking in the next month exhibits a 2% decrease in intentions to quit that is significant at the 0.10 level but not the 0.05 level, shown in the figure below. This effect is the opposite of what one would expect if the 2012 Packaging Changes policy fostered quit behavior.




59. In terms of how much the respondent thought about quitting in the past week, there is also a change that is opposite of presumed policy goals. The categories of "not at all" reflects an increase, though one that does not meet the 0.05 statistical level. There are also small but statistically significant decreases in two categories for thoughts of quitting ("once" and "once every few days"). Overall, the responses to this question are consistent with stable or even decreased quit intentions after the advent of the 2012 Packaging Changes.

60. The fraction of respondents who have ever attempted to quit smoking is unchanged between the periods before and after the advent of the 2012 Packaging Changes policy.

61. There is also no statistically significant difference in the number of days since the respondent's last quit attempt, with this value having risen from 142 days to 146 days.

62. The next question reported in the table pertains to whether the smoker stubs out the cigarette after thinking about the harms. The only statistically significant changes indicate a decrease in this behavior. There is a 3% decrease in those who stub out their cigarette many times for this reason. This result is the opposite of the policy goals of the 2012 Packaging Changes.

63. Choosing to stop smoking when the respondent has the urge to smoke elicits similar responses to stubbing out before and after the introduction of the 2012 Packaging Changes requirements. The only statistically significant difference is for people who would stop "many times," with this value declining by 2% which is the opposite of the policy goals of the 2012 Packaging Changes.

C. Risk Beliefs and Smoking Attitudes in the NTPPTS Data

64. The next table summarizes the series of risk belief and smoking attitude questions. A broad overview of the statistical significance of the differences before and after the 2012 Packaging Changes indicates that, with a few exceptions, there are no statistically significant differences in the responses to the risk belief and preference questions before and after the 2012 Packaging Changes were enacted. Below I discuss each of the specific questions and their implications, but this lack of significance is the general outcome from these data.

NTPPTS Data: Regressions for Risk Beliefs and Preferences with December 1 Break Point, Reporting Only 2012 Packaging Changes Coefficient

| Variable Name | 2012 Packaging Changes |
|---|---|
| Trouble believe harmful agree | 0.0017 |
| Trouble believe harmful disagree | 0.0049 |
| Trouble believe harmful strongly agree | 0.0027 |
| Trouble believe harmful agree | –0.0005 |
| Trouble believe harmful neither | –0.0059 |
| Trouble believe harmful disagree | 0.0236 ** |
| Trouble believe harmful strongly disagree | –0.0191 |
| GWL motivate quit not at all | –0.0437 *** |
| GWL motivate quit a little | 0.0019 |
| GWL motivate quit somewhat | 0.0131 ** |
| GWL motivate quit much | 0.0282 *** |
| Harmfulness vs. year ago lower | –0.0005 |
| Harmfulness vs. year ago same | –0.0040 |
| Harmfulness vs. year ago higher | 0.0045 |
| Smoking affect own health not at all | 0.0094 |
| Smoking affect own health a little | 0.0031 |
| Smoking affect own health somewhat | –0.0091 |
| Smoking affect own health very | –0.0033 |
| Smoking affect own health extremely | 0.0003 |
| Lung cancer only old agree | –0.0031 |
| Lung cancer only old disagree | 0.0044 |
| Lung cancer old strongly agree | –0.0038 |
| Lung cancer old agree | 0.0014 |
| Lung cancer old neither | –0.0014 |
| Lung cancer old disagree | –0.0108 |
| Lung cancer old strongly disagree | 0.0163 |
| Think about enjoy smoking never | 0.0060 |
| Think about enjoy smoking once or twice | –0.0108 |
| Think about enjoy smoking several | 0.0025 |
| Think about enjoy smoking many | 0.0020 |
| Think about money spent never | 0.0067 |
| Think about money spent once or twice | –0.0038 |
| Think about money spent several | –0.0085 |
| Think about money spent many | 0.0058 |
| Dangers exaggerated agree | 0.0203 ** |
| Dangers exaggerated disagree | –0.0254 ** |
| Dangers exaggerated strongly agree | 0.0175 *** |
| Dangers exaggerated agree | 0.0032 |
| Dangers exaggerated neither | 0.0053 |
| Dangers exaggerated disagree | –0.0171 * |
| Dangers exaggerated strongly disagree | –0.0069 |

*Notes*: Probit regressions reporting marginal effects; significance levels: *0.10, **0.05, ***0.01. Regressions include all other variables listed in Table C1.

65. There is no statistically significant change in the percentage of respondents who agree that they have trouble believing their current brand is harmful. There is also very little change in the levels of agreement or disagreement responses, though one change indicates a 2% increase among those who disagree.

66. The question regarding the respondent's motivation to quit is of a different form than many of the CITTS questions in that it does not ask whether the respondent agrees or disagrees with a particular statement. Instead, the quit intentions questions relate to how motivated respondents are to quit. The survey asks if the respondent's motivation to quit is not at all, a little, somewhat, or much. There is a statistically significant 4% decrease in those who indicate "not at all" to whether graphic health warnings have increased their motivation to quit in the past month. While there is no statistically significant change to those who indicate "a little" to whether graphic health warnings have increased their motivation to quit in the past month, there is a statistically significant 1% and 2% respective increases in responses indicating that the graphic health warnings did increase their motivation to quit by "somewhat" and "much." The results indicate some small increases in stated motivations to quit. With respect to the respondents' belief regarding the harmfulness of cigarettes compared to their beliefs a year ago, there is no statistically significant effect for any of the response categories. The responses are consistent with a zero association with the 2012 Packaging Changes.

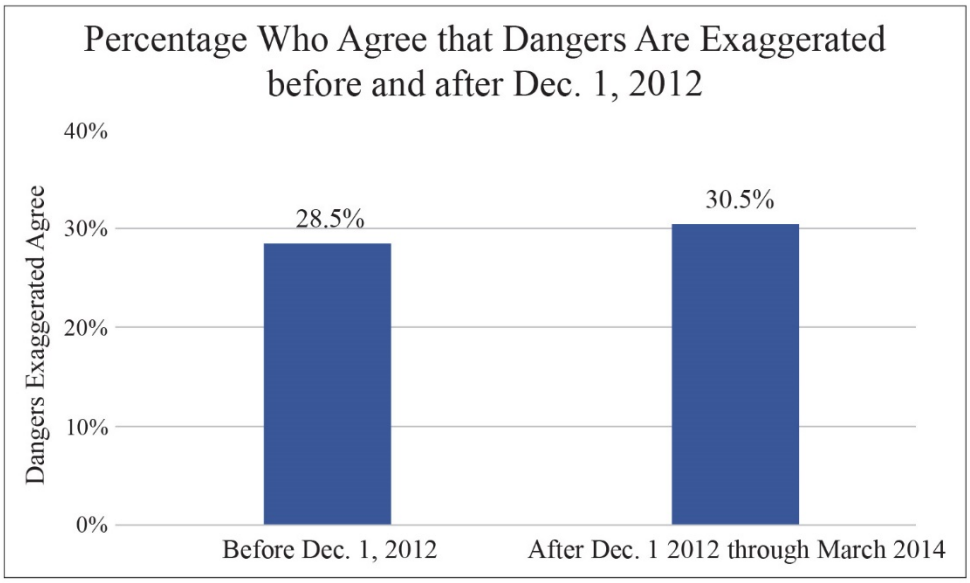
67. The next set of questions reported in this table pertains to whether the respondent believes that smoking affects their own health, thus personalizing the risk assessment. Here again, no response exhibits change due to policy implementation.

68. The next two sets of questions, measuring perceptions of lung cancer risk, also show no significant shifts due to policy change.

69. There are also no evident effects with respect to all categories of responses regarding thoughts about enjoying cigarettes. None of the differences are statistically significant.

70. There are also zero significant changes with respect to all categories of responses regarding whether the person thinks about the money spent on cigarettes. None of the differences before and after the 2012 Packaging Changes policies are statistically significant.

71. Beliefs with respect to whether the dangers of cigarettes have been exaggerated do exhibit statistically significant changes. There is a 2% increase in the agreement that the dangers are exaggerated, as is indicated in the figure below. Consumers' belief that the risks are exaggerated is a survey response that indicates that the warnings policy is not credible. If, as a result, consumers dismiss the warnings as being excessively alarmist, they may be dismissed as being uninformative. Similarly, there is a 3% decrease in the level of disagreement as fewer respondents disagree with the proposition that the risks of smoking are exaggerated. These changes both reflect potentially counterproductive results as there is evidence of increased opposition to the 2012 Packaging Changes policy. The statistically significant shifts are restricted to the extreme responses of "strongly agree" and the less pronounced "disagree" category. These various outcomes suggest some resistance or even cynicism towards the new policy.




D. Perceptions of Pack Appearance in the NTPPTS Data

72. The results in the final NTPPTS table regarding changes in responses with respect to cigarette pack appearance exhibit statistically significant shifts in almost every instance. These shifts are consistent with what one would expect based on changes in the pack after the introduction of 75% warnings on the front of packs in Australia which results in the packs being dominated by graphic health warnings.

73. The results indicate that the post-2012 Packaging Changes cigarettes are being perceived as similar to generic and lower priced brands, but coupled with the findings in the previous two tables, this shift has not translated into any discernible changes in on risk beliefs or behavior (if anything, respondents are smoking more). Consideration of the smoking risk belief questions tells quite a different story than considering only packaging appearance effects.

| NTPPTS Data: Regressions for Pack Appearance with December 1 Break Point, Reporting Only 2012 Packaging Changes Coefficient | |
|---|---|
| **Variable Name** | **2012 Packaging Changes** |
| Quality vs. year ago lower | 0.1160 *** |
| Quality vs. year ago same | –0.0883 *** |
| Quality vs. year ago higher | –0.0266 *** |
| Satisfaction vs. year ago lower | 0.0743 *** |
| Satisfaction vs. year ago same | –0.0445 *** |
| Satisfaction vs. year ago higher | –0.0284 *** |
| Value for money vs. year ago lower | 0.0830 *** |
| Value for money vs. year ago same | –0.0497 *** |
| Value for money vs. year ago higher | –0.0321 *** |
| Pack appeal vs. year ago lower | 0.3835 *** |
| Pack appeal vs. year ago same | –0.3831 *** |
| Pack appeal vs. year ago higher | –0.0017 |

*Notes*: Probit regressions reporting marginal effects; significance levels: *0.10, **0.05, ***0.01. Regressions include all other variables listed in Table C1.

74. The implications of the NTPPTS data reinforce the findings based on the CITTS data and the RMSS data. Survey evidence regarding smoking behavior, perceived risks of smoking, and smoking attitudes are not consistent with the 2012 Packaging Changes being significantly associated with fostering the avowed policy objectives. The only consistent findings are with respect to package appearance, which could be a result of the increase in the size of the graphic health warnings to 75% that result in the packs being dominated by graphic health warnings, rather than Plain Packaging. Stripping away everything from the pack other than the warning and the name of the product does not translate into higher risk beliefs, reduced smoking, or quit-related behaviors. The quit results are at best mixed, with no effect on quit attempts and a statistically insignificant decrease in those who intend to quit in the next month. Statistically significant impacts included a decrease in those who thought about quitting in the past week, a decrease in those who stubbed out when they thought about the harms many times, and a decrease in stopping smoking when they had the urge to smoke many times. At the very least, these

results indicate that there is no evidence of any beneficial policy effects on these performance dimensions.

75. The evidence of a lack of impact of the 2012 Packaging Changes in Australia and of a number of potentially counterproductive effects is not unexpected. There is substantial evidence in Australia that people are not only aware of the risks of smoking but also personalize the risks to themselves.[46] In this environment, there is no beneficial role for increased warnings where they are not providing any new information, as is the case with the 2012 Packaging Changes. Bolder warnings do not convey unknown information and telling people something that they already know in **bold** letters or **LARGE TYPE FACE** or with increased graphics does not change that. There is no empirical evidence that "shouting" works in increasing behavioral compliance in this context, and it can have the opposite effect.

76. The evidence of the 2012 Packaging Changes having negative outcomes is also consistent with research that demonstrates that fear-based warnings may in fact elicit responses that are the opposite of their intended effect. For example, a meta-analysis of studies that measure the impact of threatening communications on behavior found that: "… (1) there are very few studies that could theoretically have supported the use of threatening communications; and (2) those studies that do exist do not support the wide application of threatening communications. Instead, they indicate that using threatening communication is at best ineffective, and at worst causes health-defeating behaviour, unless the intervention contains an element that effectively enhances response efficacy and

[46] See e,g. P. Shanahan and D. Elliott, *Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008*. Australian Government Department of Health and Ageing, Canberra (2009); Tobacco in Australia: Facts and Issues (3rd ed., M. M. Scollo and M. H. Winstanley, eds., Melbourne: Cancer Council Victoria, 2008), available at http://www.tobaccoinaustralia.org.au.

(especially) self-efficacy." The authors concluded that: "… warning labels on packs of cigarettes seem ill-advised. They may in fact increase smoking among smokers who derive self-esteem from their identity as a smoker."[47] A recent study by LaVoie et al. (2015) also found results that suggest the using graphic health warnings on cigarette packaging enhances freedom threat perceptions, reactance, and perceived source domineeringness. They conclude: "These results indicate that utilizing graphic images on tobacco packaging might not be as effective as some practitioners had originally hoped. In fact, the messages designed to deter smoking behaviors ignite freedom threat appraisal, which precedes reactance and, in turn, elevates source domineeringness. Each of these outcomes is counterproductive to this antitobacco strategy."[48]

E. Critique of Literature using NTPPTS Data

77. Wakefield et al. (2015),[49] focuses on components of the NTPPTS pertaining to matters such as decreased pack appeal. Unlike my analysis of the NTPPTS data, the article does not consider any of the cigarette consumption metrics in the NTPPTS data, such as the number of cigarettes smoked per day. However, even with respect to the variables considered, the data presented in Wakefield et al. (2015) do not provide consistent evidence that is suggestive of a positive influence of the 2012 Packaging Changes. For example, beliefs in the level of harmfulness of cigarettes are insignificantly lower after

[47] Gjalt-Jorn Ygram Peters, Robert A.C. Ruiter & Gerjo Kok (2012): Threatening communication: a critical re-analysis and a revised meta-analytic test of fear appeal theory, Health Psychology Review, DOI:10.1080/17437199.2012.703527.

[48] LaVoie et al (2015), Are Graphic Cigarette Warning Labels an Effective Message Strategy? A Test of Psychological Reactance Theory and Source Appraisal, Communication Research, DOI: 10.1177/0093650215609669.

[49] Melanie Wakefield, Kerri Coomber, Meghan Zacher, Sarah Durkin, Emily Brennan, and Michelle Scollo, "Australian Adult Smokers' Responses to Plain Packaging with Larger Graphic Health Warnings 1 Year after Implementation: Results from a National Cross-Sectional Tracking Survey," Tobacco Control 2015;24:ii17-ii25. doi:10.1136/tobaccocontrol- 2014-052050.

the 2012 Packaging Changes (24.2 pre-changes and 23.4 post-changes for the unadjusted results, and 23.8 pre-changes adjusted and 23.6 post-changes for adjusted results). There were also no statistically significant differences in perceived exaggeration of harms, perceived differences in taste of different brands, or the belief that variants do not differ in strength at one-year post-2012 Packaging Changes compared to pre-2012 Packaging Changes. In addition, as my detailed review of the NTPPTS data presented above indicates, there are numerous outcomes from the NTPPTS data that go against claims that the 2012 Packaging Changes have been effective and which are not reported in Wakefield et al. (2015). Unbiased assessments of the data require that one not select isolated components of questions, but instead consider the implications of the full set of responses. Failure to consider the full range of pertinent behavioral questions provides a distorted perspective that makes it impossible to draw accurate conclusions about the impact of the 2012 Packaging Changes. My analysis shows that the NTPPTS data do not provide consistent support for the 2012 Packaging Changes being associated with even these non-behavioral variables, leaving aside the questionable relevance of these variables for examining the effect of the 2012 Packaging Changes on actual smoking behavior. Wakefield et al. purport to find strong evidence that "the specific objectives of plain packaging were achieved," but this conclusion is based on mixed outcomes and an incomplete analysis of the data. A proper analysis of the NTPPTS does not support the 2012 Packaging Changes as having been effective and indeed shows that the 2012 Packaging Changes have been counterproductive in many respects, not the least of which is that there is no evidence that the 2012 Packaging Changes are associated with a reduction in smoking behavior, which is the objective of the policy.

## VI. ANALYSIS OF COHORT-BASED NTPPTS STUDIES

78. The NTPPTS survey also includes a cohort component in which a subsample of the NTPPTS was re-interviewed at different times in the year following the implementation of the 2012 Packaging Changes. By tracking individuals over time, these data could potentially provide insight into how the 2012 Packaging Changes influenced behavior. Thus, to take advantage of the cohort aspect of the data the researcher should examine whether there was a change in behavior or smoking attitudes before and after the 2012 Packaging Changes. However, as I will demonstrate below, the published studies using the cohort sample have not always utilized the cohort aspect of the data to examine within person changes in behavior. The cohort aspect is sometimes ignored as there is no exploration of changes. Rather the article simply inquires whether respondents who happen to be members of the cohort subsample gave particular survey responses. Thus, whether a person was in the cohort subsample or not is sometimes irrelevant to the statistical analysis. And, more importantly, when they do analyze the changes in behavior of members of the cohort subsample, they have ignored the biases in terms of which sample members agreed to be re-interviewed. The differences in the baseline sample and those who were re-interviewed are so stark that the cohort analysis is fundamentally flawed.

79. The Durkin et al. (2015)[50] study used the cohort subsample of the NTPPTS data to examine both variables related to quitting and several smoking-related behaviors. I note

[50] Sarah Durkin, Emily Brennan, Kerri Coomber, Meghan Zacher, Michelle Scollo, and Melanie Wakefield, "Short-Term Changes in Quitting-Related Cognitions and Behaviours after the Implementation of Plain Packaging with Larger Health Warnings: Findings from a National Cohort Study with Australian Adult Smokers," Tobacco Control 2015;24:ii26-ii32. doi:10.1136/tobaccocontrol-2014-052058

that the discussed data only concerned perceptions and intentions rather than actual behavioral data. In addition, for many of the measures considered in Durkin et al. (2015) there is not a statistically significant change between the pre-2012 Packaging Changes period and the post-2012 Packaging Changes period. The response categories that exhibited no statistically significant changes in the post-implementation period (i.e., zero effects) include: daily thoughts about quitting in the past week, intend to quit next month, firm date to quit next month, and stopped smoking several or many times in past month. Accordingly, the NTPPTS data do not support the conclusion that Plain Packaging contributed to increasing quitting cognitions and intentions. This is even clear from the results reflected in the study by Durkin et al. (2015).

80. The Durkin et al. (2015) article uses 4 cohorts of adult cigarette smokers sourced from the NTPPTS sample surveyed before the 2012 Packaging Changes, followed up approximately 1 month after their baseline interview. Logistic regression analyses compared changes in selected quitting-related outcomes over this 1-month follow-up period for the cohorts surveyed before the policy change, over the period of transition to the policy change, and during the first year of the policy change. These periods are labelled pre-Packaging Changes, early transition, late transition, and Packaging Changes year 1. Given the short time frame that is involved as well as the failure to account for any longer term trends, it is likely that any observed effects are spurious. If, however, there are any meaningful statistically significant impacts, one would expect there to be a consistently rising pattern of changes between the pre-Packaging Changes period and the post-Packaging Changes period.

81. The Durkin et al. (2015) article examined seven different variables. Several of the response categories do not indicate any statistically significant differences, and those that did typically exhibited mixed patterns. The “daily thoughts about quitting” variable exhibited no changes based on either the unadjusted or adjusted (for baseline values and covariates) model. The “intend to quit” measure is higher in the late transition but not in either the early transition or the Packaging Changes year 1 results. The “firm date to quit in next month” variable exhibits no significant differences from the baseline value. The “concealed or covered pack several or many times in past month” variable exhibits a rising pattern in the adjusted results, but rises and then declines in the unadjusted results. This seems to be the strongest effect that was observed. The measure “stubbed out several or many times in past month” is unchanged in the unadjusted results but has one significant difference (for the Packaging Changes year 1) in the adjusted results. The variable “stopped from smoking several or more times in past month” rises in the early transition and declines back to the baseline level in the late transition and in the Packaging Changes year 1 so that either the result is an aberration or the estimated effect is ephemeral. Similarly, “attempt to quit in past month” exhibits no clear trend, with significantly lower values in the unadjusted results in the late transition, and significantly higher values in the unadjusted results in the early transition and Packaging Changes year 1. Accordingly, the NTPPTS data do not support the conclusion that the 2012 Packaging Changes are associated with increased quitting cognitions and intentions. This is even clear from the results reflected in the study by Durkin et al. (2015).

82. Brennan et al. (2015)[51] use the NTPPTS cohort data to explore correlations of the quit attempt variables with the attitudinal variables. However, the article focuses only on those interviewed one month after the baseline period so that in that short time frame there is unlikely to be any meaningful change in smoking behavior. The cohort aspect of the study is largely irrelevant since the authors never analyze any changes in quit related behaviors or changes in the various perception variables. Rather the focus of the article is on correlations of levels of the variable. In particular, do people who express various anti-smoking perceptions such as "dislikes pack" in the baseline period also express various quit-related behaviors in the follow up survey? Even if there were such influences, they have no bearing on whether there were any changes in behavior or perceptions since the article does not address changes of any kind.

83. In addition, the researchers also found very little in the way of statistically significant correlations between baseline impressions and the follow-up answers. For example, the following measures examined by Brennan et al. (2015) did not have a significant association with quit attempts, much less actual quit behavior: dislikes pack, lower pack appeal, lower quality, lower satisfaction, lower value for money, notices graphic health warnings first when looking at pack, does not believe dangers of smoking are exaggerated, and concealed pack in past month. This article focuses on subjective impressions that have no validated link with actual smoking decisions and never analyzes changes in the variables before and after the implementation of the 2012 Packaging Changes. One cannot infer any causality from the correlations presented. Even the

[51] Emily Brennan, Sarah Durkin, Kerri Coomber, Meghan Zacher, Michelle Scollo, and Melanie Wakefield, "Are Quitting- Related Cognitions and Behaviours Predicted by Proximal Responses to Plain Packaging with Larger Health Warnings? Findings from a National Cohort Study with Australian Adult Smokers," *Tobacco Control* 2015;24:ii33–ii41.doi:10.1136/tobaccocontrol-2014-052057., at 23.

number of insignificant correlations (i.e., those not distinguishable from zero) outnumbered the number of significant correlations by two to one. The affirmative conclusions of this article are misplaced. Given the design of the study, it has no bearing whatsoever on whether the 2012 Packaging Changes have been effective.

84. Both the Durkin et al. (2015) and the Brennan et al. (2015) articles also failed to account for sample selection effects in terms of who agreed to be re-contacted for a follow-up survey. The Durkin et al. (2015) study indicates that 95% agreed to be contacted and of these 83% were successfully contacted, and the data reflect a follow-up participation rate of 79%. There could be important sample selection biases if the characteristics of those who participated in the follow-up survey differ significantly from those who did not. The authors never address this issue, but using information from the NTPPTS regarding who participated in the cohort and who did not we are able to test for such differences and have identified some statistically significant gaps.

85. The table below lists a series of sample characteristic variables and gives their value for both the pre-2012 Packaging Changes period and the post implementation sample. As the table indicates, there are 8 statistically significant differences in the sample characteristics at the 0.05 level or better, as coefficients not statistically significant at the 0.10 level or better are denoted by “ns.” Among the many notable demographic differences is that those who participated in the follow-up survey are 4 years older and 8 percent more likely to have a landline in the home.

| NTPPTS Data: Personal Characteristics by Follow-up Participation | | | | |
|---|---|---|---|---|
| Variable Name | No Follow | Yes Follow | t-statistic | Significance |
| Age | 39.61 | 43.58 | –11.6014 | *** |
| Female | 0.4471 | 0.4626 | –1.2809 | ns |
| Years of education | 13.17 | 13.07 | 1.5350 | ns |
| Income, low | 0.2204 | 0.2385 | –1.5419 | ns |
| Income, medium | 0.4932 | 0.5053 | –0.8767 | ns |
| Income, high | 0.2863 | 0.2562 | 2.4846 | ** |
| Original peoples | 0.0433 | 0.0358 | 1.6201 | ns |
| English primary language | 0.8795 | 0.9391 | –9.4465 | *** |
| Phone: land line in home | 0.7033 | 0.7759 | –6.9946 | *** |
| Phone: mobile line in home | 0.9315 | 0.9260 | 0.8783 | ns |
| Hours of television per day | 2.3513 | 2.6958 | –5.2806 | *** |
| New South Wales | 0.3282 | 0.2948 | 2.9942 | *** |
| Victoria | 0.2494 | 0.2653 | –1.4927 | ns |
| Queensland | 0.2000 | 0.2089 | –0.9021 | ns |
| South Australia | 0.0587 | 0.0817 | –3.5543 | *** |
| Western Australia | 0.1175 | 0.0960 | 2.9398 | *** |
| Tasmania | 0.0186 | 0.0241 | –1.5084 | ns |
| Northern Territory | 0.0140 | 0.0116 | 0.8842 | ns |
| Australian Capital Territory | 0.0135 | 0.0174 | –1.2506 | ns |
| Capital city | 0.6567 | 0.6370 | 1.6760 | * |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

86. In addition to significant differences in respondent personal characteristics between the entire sample of participants in the original survey and those who participated in the follow-up survey, further problems are apparent between the two groups on the basis of their answers to the questions related to cigarettes in the original survey. The tables below show 8 statistically significant differences (at the 0.05 significance level) between

the two groups. Follow-up survey participants smoke 1.5 more cigarettes per day and are 6 percent more likely to have attempted to quit smoking.

Consumption by Follow-up Participation

| Variable Name | No Follow | Yes Follow | t-statistic | Signifi-cance |
|---|---|---|---|---|
| Cigarettes per day | 13.09 | 14.65 | –6.1623 | *** |
| How important quitting for good (0-10) | 7.0931 | 7.3335 | –3.2386 | ** |
| How important quitting for good (0) | 0.0766 | 0.0612 | 2.5645 | ** |
| How important quitting for good (10) | 0.3868 | 0.4028 | –1.3402 | ns |
| Intend to quit in next month | 0.4149 | 0.3881 | 2.0158 | ** |
| Think quitting past week not at all | 0.2194 | 0.2510 | –2.7967 | *** |
| Think quitting past week once | 0.1323 | 0.1442 | –1.2956 | ns |
| Think quitting past week once every few days | 0.1835 | 0.1932 | –0.9463 | ns |
| Think quitting past week once per day | 0.0822 | 0.0838 | –0.2198 | ns |
| Think quitting past week several times per day | 0.3823 | 0.3279 | 4.4093 | *** |
| Have you ever attempted quitting smoking | 0.7477 | 0.8116 | –6.0959 | *** |
| How long ago last quit attempt (days) | 150.4 | 143.7 | 1.3049 | ns |
| Stub out when thought harms never | 0.5413 | 0.5670 | –1.9687 | ** |
| Stub out when thought harms once or twice | 0.1872 | 0.1682 | 1.9144 | * |
| Stub out when thought harms several times | 0.1458 | 0.1507 | –0.5171 | ns |
| Stub out when thought harms many times | 0.1257 | 0.1142 | 1.3664 | ns |
| Stop when had urge to smoke never | 0.3324 | 0.3128 | 1.5992 | ns |
| Stop when had urge to smoke once or twice | 0.2566 | 0.2691 | –1.0785 | ns |
| Stop when had urge to smoke several times | 0.2767 | 0.2758 | 0.0782 | ns |
| Stop when had urge to smoke many times | 0.1343 | 0.1422 | –0.8694 | ns |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

Thus, consumption-related variables show many significant differences between the original survey sample and the sample that participated in the follow-up survey. Variables ranging from rate of consumption, attitudes or attempts of quitting, and stub-out behavior are significantly different. These various differences in turn lead to pronounced differences in risk beliefs and preferences. There are 24 variables pertaining

to risk beliefs and preferences that display statistically significant differences between the sample that did not participate in the follow-up and the follow-up group.

| Risk Beliefs and Preferences by Follow-up Participation | | | | |
|---|---|---|---|---|
| Variable Name | No Follow | Yes Follow | t-statistic | Significance |
| Trouble believe harmful agree | 0.3305 | 0.2728 | 4.2738 | *** |
| Trouble believe harmful disagree | 0.6294 | 0.6907 | –4.3919 | *** |
| Trouble believe harmful strongly agree | 0.1183 | 0.0970 | 2.3586 | ** |
| Trouble believe harmful agree | 0.2122 | 0.1758 | 3.1418 | *** |
| Trouble believe harmful neither | 0.0401 | 0.0365 | 0.6503 | ns |
| Trouble believe harmful disagree | 0.2710 | 0.2534 | 1.3419 | ns |
| Trouble believe harmful strongly disagree | 0.3584 | 0.4373 | –5.3466 | *** |
| GWL motivate quit not at all | 0.5325 | 0.5770 | –3.6652 | *** |
| GWL motivate quit a little | 0.2010 | 0.1955 | 0.5595 | ns |
| GWL motivate quit somewhat | 0.1088 | 0.1084 | 0.0555 | ns |
| GWL motivate quit much | 0.1577 | 0.1192 | 4.7325 | *** |
| Harmfulness vs. year ago higher | 0.2530 | 0.2192 | 2.9993 | *** |
| Harmfulness vs. year ago lower | 0.0568 | 0.0402 | 3.0178 | *** |
| Harmfulness vs. year ago same | 0.6902 | 0.7406 | –4.2184 | *** |
| Smoking affect own health not at all | 0.1536 | 0.1145 | 4.9051 | *** |
| Smoking affect own health a little | 0.2691 | 0.2563 | 1.2016 | ns |
| Smoking affect own health somewhat | 0.2691 | 0.2989 | –2.6863 | *** |
| Smoking affect own health very | 0.1871 | 0.1976 | –1.0883 | ns |
| Smoking affect own health extremely | 0.1211 | 0.1328 | –1.4246 | ns |
| Lung cancer only old agree | 0.1219 | 0.0682 | 8.1079 | *** |
| Lung cancer only old disagree | 0.8661 | 0.9184 | –7.3617 | *** |
| Lung cancer old strongly agree | 0.0461 | 0.0268 | 4.5336 | *** |
| Lung cancer old agree | 0.0759 | 0.0414 | 6.5364 | *** |
| Lung cancer old neither | 0.0120 | 0.0134 | –0.5041 | ns |
| Lung cancer old disagree | 0.3932 | 0.3860 | 0.6004 | ns |
| Lung cancer old strongly disagree | 0.4729 | 0.5324 | –4.8478 | *** |
| Think about enjoy smoking never | 0.3555 | 0.3299 | 2.2115 | ** |
| Think about enjoy smoking once or twice | 0.2981 | 0.3088 | –0.9541 | ns |
| Think about enjoy smoking several | 0.1955 | 0.2039 | –0.8458 | ns |
| Think about enjoy smoking many | 0.1509 | 0.1574 | –0.7280 | ns |
| Think about money spent never | 0.2289 | 0.1913 | 3.8592 | *** |
| Think about money spent once or twice | 0.1787 | 0.1759 | 0.2964 | ns |
| Think about money spent several | 0.2057 | 0.2129 | –0.7249 | ns |
| Think about money spent many | 0.3867 | 0.4199 | –2.7567 | *** |
| Dangers exaggerated agree | 0.3321 | 0.2905 | 3.7035 | *** |
| Dangers exaggerated disagree | 0.6187 | 0.6691 | –4.3340 | *** |
| Dangers exaggerated strongly agree | 0.1190 | 0.1042 | 1.9447 | * |

| | | | | |
|---|---|---|---|---|
| Dangers exaggerated agree | 0.2131 | 0.1863 | 2.7767 | *** |
| Dangers exaggerated neither | 0.0492 | 0.0404 | 1.7831 | * |
| Dangers exaggerated disagree | 0.3053 | 0.3075 | –0.1950 | ns |
| Dangers exaggerated strongly disagree | 0.3134 | 0.3616 | –4.1147 | *** |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

Risk belief variables show significant differences in literally every measured category between the full sample and the follow-up participants. This is also true of the pack appearance, shown below. There are 5 pack appearance variables that differ significantly including the pack appeal variable as the follow-up group consists disproportionately of those who answer negatively to whether the pack appeal is higher than a year ago.

Pack Appearance by Follow-up Participation

| Variable Name | No Follow | Yes Follow | t-statistic | Significance |
|---|---|---|---|---|
| Quality vs. year ago lower | 0.2165 | 0.2217 | –0.4719 | ns |
| Quality vs. year ago same | 0.7106 | 0.7248 | –1.1868 | ns |
| Quality vs. year ago higher | 0.0729 | 0.0535 | 3.1239 | *** |
| Satisfaction vs. year ago lower | 0.1649 | 0.1763 | –1.1253 | ns |
| Satisfaction vs. year ago same | 0.7663 | 0.7752 | –0.7969 | ns |
| Satisfaction vs. year ago higher | 0.0688 | 0.0485 | 3.4011 | *** |
| Value for money vs. year ago lower | 0.5184 | 0.5758 | –4.3280 | *** |
| Value for money vs. year ago same | 0.2153 | 0.2133 | 0.1834 | ns |
| Value for money vs. year ago higher | 0.2663 | 0.2109 | 4.9810 | *** |
| Pack appeal vs. year ago lower | 0.4110 | 0.4083 | 0.1906 | ns |
| Pack appeal vs. year ago same | 0.5029 | 0.5303 | –1.9161 | * |
| Pack appeal vs. year ago higher | 0.0861 | 0.0614 | 3.4652 | *** |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

87. The myriad of differences between those who participated in the follow-up survey and those that did not create sample selection biases as the follow-up group is not a random group of the original survey participants. These issues are not addressed in any way by

the Durkin et al. (2015) study, or the Brennan et al. (2015) study based on the cohort data.

88. In conclusion, the cohort component of the NTPPTS data has fundamental flaws and is not representative of the underlying survey group. The Durkin et al. (2015) and Brennan et al. (2015) studies ignore the sampling issues. However, even setting aside the sample selection issues, the data provide no evidence of efficiency of the 2012 Packaging Changes.

89. I note that these published studies on the NTPPTS data are included in the Cochrane Review,[52] which relies on these studies on their face without doing any critical review of data analysis or any analysis of the original data on which the studies were based. However, my examination of the outputs of each of the CITTS and NTPPTS datasets indicates that the articles are disturbing from the standpoint of academic integrity and are highly misleading. As such the conclusions drawn from the studies as presented in the Cochrane Review are unjustified.

[52] McNeill, A., Gravely, S., Hitchman, S.C., Bauld, L., Hammond, D., and Hartmann-Boyce, J., "Tobacco Packaging Design for Reducing Tobacco Use," Cochrane Database of Systematic Reviews 2017, Issue 4, Art. No.: CD011244.

## VII. REVIEW OF THE AUSTRALIAN GOVERNMENT'S AUSTRALIAN POST IMPLEMENTATION REVIEW REPORT

90. The Australian government's Post-Implementation Review Tobacco Plain Packaging 2016 reached a favorable conclusion regarding the impact of Plain Packaging in Australia, stating that: "[i]n light of the evidence, the PIR concludes that tobacco plain packaging is achieving its aim of improving public health outcomes into the future." However, this conclusion is contradicted by my analysis presented in this report.[53]

91. The PIR's only statistical evidence consistent with the 2012 Packaging Changes having a positive effect on smoking behaviors is based on the highly flawed report by Dr. Chipty. The PIR did not draw on any econometric analysis of other data, including the CITTS and the NTPPTS data which also provide some information that can be used to evaluate the association of the 2012 Packaging Changes with actual smoking behavior. Although these datasets utilize different samples and provide different perspectives on smoking behaviors, they provide a consistent theme that there is no evidence suggesting that the 2012 Packaging Changes are associated with a decrease in smoking. This failure to examine these other available datasets produced excessive reliance on a single statistical study of one dataset undertaken by Dr. Chipty. While the PIR also cites the existence of downward trends in smoking behavior from other datasets, it reports no statistical analysis linking these trends to the 2012 Packaging Changes.

92. In addition, the PIR merely relies on published papers regarding the impact of Plain Packaging without undertaking any critique or review of those papers. Based on my

[53] I note that the PIR is also criticized in the paper by Sinclair Davidson and Ashton de Silva, "Stubbing out the Evidence of Tobacco Plain Packaging Efficacy: An Analysis of the Australian National Tobacco Plain Packaging Survey," May 17, 2016, SSRN id=2780938.

review of the papers and the underlying NTPPTS and CITTS datasets, I conclude that the published papers on these datasets cannot be relied upon.

93. Accordingly, there is no sound basis for the PIR's conclusion set out above. The PIR's reference to "all this evidence" is especially inappropriate because the cited studies did not report all the evidence from the NTPPTS and CITTS datasets, but only the selected results that provide the most favorable perspective on the performance of plain packs. In addition, as noted above, my extended analysis of the RMSS data and the CITTS data, which is the most extensive data analysis undertaken to date (and includes 15 months of additional data to the analysis undertaken by Dr Chipty), confirms that there is no support for the conclusion that Plain Packaging has been effective. The 2012 Packaging Changes have a zero statistical association with smoking prevalence rates, which further demonstrates that the conclusion reached in the PIR is unjustified.

## VIII. CONCLUSION

94. The availability of post-implementation data from Australia, including survey data commissioned by the Australian Government to assess the impact of the 2012 Packaging Changes and prevalence data relied on by the Australian Government, makes it possible to assess whether the 2012 Packaging Changes policy in Australia has had the effects that advocates of Plain Packaging claim.

95. My analysis of 4 years of post-implementation RMSS data as well as 3 ½ years of post-implementation CITTS data and the Australian Government commissioned NTPPTS data indicates that the 2012 Packaging Changes in Australia are not associated with a reduction in smoking or smoking consumption. My analysis of the RMSS data, which includes 15 additional months of data in the post-2012 Packaging Changes period than was considered in Dr. Chipty's report, found that the estimated effect of the 2012 Packaging Changes in Australia on smoking prevalence rates cannot be distinguished statistically from zero. An evaluation of the CITTS and NTPPTS data relating to actual cigarette consumption behavior in Australia also indicates that the 2012 Packaging Changes are not associated with a decrease in smoking behaviors amongst current smokers.

96. There is also evidence consistent with either a mixed or an unfavorable effect of the 2012 Packaging Changes on a number of intermediary metrics even setting aside issues pertaining to the efficacy of these intermediate variables in predicting actual smoking behaviors. Indeed the overriding implication of the findings from my analysis is that the 2012 Packaging Changes in Australia are associated with an increase degree of rejection

of the graphic warnings message. There is also some evidence of mixed effects, including some negative changes in risk beliefs and efforts to stop smoking.

97. The favorable conclusions reached in other analyses of the RMSS data are unfounded. The article by Diethelm and Farley (2015) had no original RMSS data but attempted to impute monthly average values based on visual inspection of a figure from a working paper by Kaul and Wolf. As a result, the statistical analysis included no demographic or regional variables whatsoever, but only a 'bare-bones' group of four variables including a linear trend. Cigarette prices and a potential nonlinear trend were completely ignored. The report by Dr. Chipty likewise ignored these two sets of influences. While Dr. Chipty's study did include a more extensive variable list than did Diethelm and Farley (2015), and also utilized the actual RMSS data, the omission of the key factors driving the temporal trend—cigarette prices and the nonlinear aspect of the trend—results in a flawed analysis that cannot be relied on. I demonstrated the absence of a statistically significant effect for the 2012 Packaging Changes variable using the time period used by Dr. Chipty as well as a longer time period and a larger RMSS sample. These differences with Dr. Chipty's report are not differences of opinion but are matters of basic statistics (i.e., a statistical test indicating a nonlinear trend) and fundamental economics (i.e., the key role of prices in affecting consumer demand of all products).

98. The Australian Government Post-Implementation Review Tobacco Plain Packaging 2016 report provided an inadequate and incorrect assessment of the effect of the 2012 Packaging Changes on smoking. The PIR's only statistical evidence of an effect of the 2012 Packaging Changes on actual smoking behaviors is based on the flawed report by Dr. Chipty.

99. Moreover, unlike the presentations of the evidence provided in the PIR and in the recently published Cochrane Review, which relies on the published papers, I also undertake a full analysis of the underlying Australian NTPPTS data and the New South Wales CITTS data. My analysis shows that the published articles analyzing these data are disturbing from the standpoint of academic integrity and are highly misleading. Rather than provide an unbiased assessment of the survey results, the studies present selected findings that purport to demonstrate the efficacy of the 2012 Packaging Changes policy, but after more thorough assessment do not. Unbiased assessments of the post-implementation data require that one not select isolated components of questions but instead consider the implications of the full set of responses. The published articles on these data do not do this and cannot be relied on as being accurate or a complete assessment of the data.

100. My review of the Roy Morgan Research, CITTS, and NTPPTS data before and after the imposition of the 2012 Packaging Changes in Australia, which I understand is the most comprehensive analysis of these Australian datasets to date, compels the conclusion that the 2012 Packaging Changes have not been effective in reducing smoking. In addition, even with respect to the non-behavioral measures, which have no validated link to actual smoking behaviors, there is no consistent evidence that the 2012 Packaging Changes are achieving its stated aims. Particularly with respect to the credibility of cigarette warnings, the 2012 Packaging Changes appear to be having a counterproductive effect.

W. Kip Viscusi

2 January 2018

## APPENDIX A

## RMSS Data

1. This section of the appendix provides details of my statistical analysis. Table A1 of regression results analyzes the determinants of the probability that any particular respondent in the RMSS data is a smoker. A respondent is defined as a smoker if they smoke factory-made cigarettes, roll-your-own cigarettes, pipes, or cigars. To examine whether a nonlinear relationship between smoking prevalence rates and time preceded the 2012 Packaging Changes, the first two equations consider only the pre-2012 Packaging Changes period. Column 1 includes a linear time trend as well as a series of demographic and policy variables, and column 2 adds a time squared variable to test for the nonlinearity of the time trend. While the linear time trend variable is statistically significant in the first equation, the addition of the quadratic time trend variable in the second equation is statistically significant whereas the linear trend no longer is statistically significant. Note that the evidence of a nonlinear temporal trend in smoking prevalence rates for the second column is for the pre-2012 Packaging Changes period. Thus, even before the advent of the Packaging Changes policy in 2012, there is evidence of a nonlinear trend.[54] The overall relationship is nonlinear in the pre-2012 Packaging Changes era, controlling for excise taxes and a detailed set of sample characteristic variables.

[54] I note that this is the same conclusion reached by Diethelm P, McKee M. "Tobacco industry-funded research on standardised packaging: there are none so blind as those who will not see!", Tob Control 2015;24:e113–e115 in respect of a sample of the RMSS data for 14-17 year olds.

Appendix Table A1
RMSS Data Regressions Predicting Smoking Behavior

| | Smoker (pre-policy) | Smoker (pre-policy) | Smoker | Smoker |
|---|---|---|---|---|
| 2012 Packaging Changes, full (Dec 1, 2012) | | | –0.0061*** | –0.0030 |
| | | | (0.0021) | (0.0026) |
| Graphic warning labels, 2006 | 0.0004 | 0.0007 | 0.0003 | 0.0004 |
| | (0.0021) | (0.0021) | (0.0020) | (0.0020) |
| Tax policy, 2010 (25%) | –0.0108*** | –0.0059** | –0.0105*** | –0.0069*** |
| | (0.0019) | (0.0027) | (0.0018) | (0.0025) |
| Tax policy, 2013 (12.5%) | | | –0.0052** | –0.0033 |
| | | | (0.0026) | (0.0028) |
| Tax policy, 2014 (12.5%) | | | –0.0009 | 0.0011 |
| | | | (0.0026) | (0.0028) |
| Tax policy, 2015 (12.5%) | | | –0.0023 | 0.0003 |
| | | | (0.0024) | (0.0027) |
| Tax policy, 2016 (12.5%) | | | –0.0073** | –0.0055 |
| | | | (0.0035) | (0.0036) |
| Time trend, months | –8.5E-5*** | 4.8E-5 | –9.5E-5*** | 7.8E-6 |
| | (3.2E-5) | (6.2E-5) | (3.1E-5) | (5.9E-5) |
| Time trend, months (squared) | | –1.2E-6** | | –9.0E-7** |
| | | (4.8E-7) | | (4.4E-7) |
| Female | –0.0396*** | –0.0396*** | –0.0396*** | –0.0396*** |
| | (0.0011) | (0.0011) | (0.0009) | (0.0009) |
| Marital status, single | 0.0353*** | 0.0353*** | 0.0401*** | 0.0401*** |
| | (0.0016) | (0.0016) | (0.0013) | (0.0013) |
| Marital status, divorced | 0.1000*** | 0.1000*** | 0.0985*** | 0.0985*** |
| | (0.0020) | (0.0020) | (0.0017) | (0.0017) |
| Marital status, widowed | 0.0474*** | 0.0474*** | 0.0495*** | 0.0495*** |
| | (0.0022) | (0.0022) | (0.0019) | (0.0019) |
| Marital status, separated | 0.1278*** | 0.1278*** | 0.1278*** | 0.1278*** |
| | (0.0027) | (0.0027) | (0.0023) | (0.0023) |
| Student | –0.0748*** | –0.0744*** | –0.0783*** | –0.0781*** |
| | (0.0043) | (0.0043) | (0.0035) | (0.0035) |
| Years of education | –0.0204*** | –0.0204*** | –0.0199*** | –0.0199*** |
| | (0.0002) | (0.0002) | (0.0001) | (0.0001) |
| Age | 0.0085*** | 0.0085*** | 0.0092*** | 0.0092*** |
| | (0.0002) | (0.0002) | (0.0002) | (0.0002) |
| Age (squared) | –1.4E-4*** | –1.4E-4*** | –1.4E-4*** | –1.4E-4*** |
| | (1.8E-6) | (1.8E-6) | (1.5E-6) | (1.5E-6) |
| Non-adults (14-17) | –0.2233*** | –0.2234*** | –0.2010*** | –0.2011*** |
| | (0.0030) | (0.0030) | (0.0027) | (0.0027) |
| Employed full time | –0.0264*** | –0.0264*** | –0.0268*** | –0.0268*** |

| | | | | |
|---|---|---|---|---|
| | (0.0015) | (0.0015) | (0.0012) | (0.0012) |
| Retired | –0.1022*** | –0.1023*** | –0.0966*** | –0.0966*** |
| | (0.0048) | (0.0048) | (0.0040) | (0.0040) |
| Income | –0.0005*** | –0.0005*** | –0.0005*** | –0.0005*** |
| | (3.8E-5) | (3.8E-5) | (3.1E-5) | (3.1E-5) |
| Income (squared) | 1.2E-6*** | 1.3E-6*** | 1.2E-6*** | 1.3E-6*** |
| | (1.7E-7) | (1.7E-7) | (1.3E-7) | (1.3E-7) |
| Income, multiple household members | –0.0176*** | –0.0176*** | –0.0188*** | –0.0188*** |
| | (0.0012) | (0.0012) | (0.0011) | (0.0011) |
| Bread winner | 0.0099*** | 0.0100*** | 0.0084*** | 0.0084*** |
| | (0.0013) | (0.0013) | (0.0011) | (0.0011) |
| Household size | –0.0010** | –0.0010** | –0.0009** | –0.0009** |
| | (0.0005) | (0.0005) | (0.0004) | (0.0004) |
| Home owner | –0.1150*** | –0.1150*** | –0.1115*** | –0.1115*** |
| | (0.0012) | (0.0012) | (0.0010) | (0.0010) |
| Victoria | 0.0142*** | 0.0143*** | 0.0131*** | 0.0131*** |
| | (0.0013) | (0.0013) | (0.0011) | (0.0011) |
| Queensland | 0.0067*** | 0.0067*** | 0.0057*** | 0.0057*** |
| | (0.0014) | (0.0014) | (0.0012) | (0.0012) |
| South Australia | 0.0096*** | 0.0097*** | 0.0082*** | 0.0082*** |
| | (0.0020) | (0.0020) | (0.0016) | (0.0016) |
| Western Australia | 0.0064*** | 0.0065*** | 0.0055*** | 0.0056*** |
| | (0.0018) | (0.0018) | (0.0015) | (0.0015) |
| Tasmania | 0.0262*** | 0.0262*** | 0.0243*** | 0.0243*** |
| | (0.0023) | (0.0023) | (0.0020) | (0.0020) |
| Darwin-Alice Springs | 0.0364*** | 0.0364*** | 0.0348*** | 0.0348*** |
| | (0.0048) | (0.0048) | (0.0042) | (0.0042) |
| Lives in capital city | –0.0251*** | –0.0251*** | –0.0259*** | –0.0260*** |
| | (0.0010) | (0.0010) | (0.0009) | (0.0009) |
| Constant | 0.5635*** | 0.5609*** | 0.5254*** | 0.5234*** |
| | (0.0054) | (0.0055) | (0.0046) | (0.0047) |
| R-squared | 0.1133 | 0.1133 | 0.1139 | 0.1139 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

2. The failure to consider the nonlinearity of the underlying relationship leads to Dr. Chipty's spurious claim that the post-2012 Packaging Changes departure of smoking prevalence rates from the previous linear trend reflects the impact of the 2012 Packaging Changes on smoking prevalence rates. Neither Dr. Chipty nor Diethelm and Farley (2015) included a nonlinear time trend variable in their analyses.

3. The final two equations in Table A1 are for the entire sample period. Column 3 included a linear time trend variable, and column 4 also includes a squared time trend variable to test for the potential nonlinearity of the results. In the first full sample period equation, which is patterned generally after that of Dr. Chipty, the 2012 Packaging Changes indicator variable has a statistically significant negative sign. However, addition of the quadratic time trend variable in the final equation eliminates the statistical significance of the 2012 Packaging Changes variable.

4. The Table A2 regressions utilize the full sample as did columns 3 and 4 in Table A1, but includes a set of variables to focus on the role of cigarette prices, setting aside the potential influence of a quadratic time trend. Thus, I revert to including only the time trend variable without the square of that variable (following the approach in column 3 of Table A1), but instead of the excise tax indicator variables I include alternative measures of prices. Column 1 replaces the excise taxes indicator variables used by Dr. Chipty with a continuous measure of excise tax levels. Column 2 replaces excise taxes with an overall price index for the economy. Column 3 substitutes the price index for Craven 20 cigarettes for that price variable. Because smoking prevalence rates and cigarette prices may be mutually dependent, column 4 uses an instrumental variables version of Craven 20 prices in which these price levels are predicted by excise tax rates and the overall consumer price index. The 2012 Packaging Changes variable remains negative and significant in the first equation in which the excise tax level variable replaces the excise tax indicator variable. However, the 2012 Packaging Changes variable loses its significance once any measure of overall prices is included.

Appendix Table A2
RMSS Data Regressions with Linear Trend, Including Tax, CPI, or Pack Cost[55]

| | Smoker | Smoker | Smoker | Smoker (IV) |
|---|---|---|---|---|
| 2012 Packaging Changes, full (Dec 1, 2012) | –0.0058*** | –0.0029 | –0.0032 | –0.0029 |
| | (0.0018) | (0.0021) | (0.0021) | (0.0021) |
| Graphic warning labels, 2006 | 0.0020 | 0.0013 | 0.0022 | 0.0020 |
| | (0.0020) | (0.0020) | (0.0019) | (0.0019) |
| Cigarette tax, per cigarette | –0.0658*** | | | |
| | (0.0127) | | | |
| Consumer price index (2012=100) | | -0.0004*** | | |
| | | (0.0001) | | |
| Cost per pack (Craven 20, real $) | | | –0.0016*** | –0.0017*** |
| (IV estimates using tax, CPI) | | | (0.0003) | (0.0003) |
| Time trend, months | –1.13E-4*** | –5.5E-5 | –9.0E-5** | –8.3E-5** |
| | (3.2E-5) | (4.1E-5) | (3.5E-5) | (3.5E-5) |
| Constant | 0.5401*** | 0.5443*** | 0.5389*** | 0.5393*** |
| | (0.0050) | (0.0053) | (0.0049) | (0.0049) |
| R-squared | 0.1139 | 0.1139 | 0.1139 | 0.1139 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01. Other variables include all those in Table A1.

5. The first price measure is the overall CPI for all products, not just cigarettes. The Australian CPI variable alone eliminates the significance of the 2012 Packaging Changes variable, indicating that the purported 2012 Packaging Changes effect simply tracks other economic trends. The pertinent cigarette price variables are the Craven 20 price per pack in inflation-adjusted terms in the third column and an instrumental variables ("IV") version of the Craven price per pack variable in the fourth column. The instrumental variables technique is a statistical procedure to account for any possible mutual dependence of smoking rates and cigarette prices. The instrumental variables estimator

[55] These regressions also include the demographic and geographic variables in Table A1. These variables have coefficients and significance levels that are stable across these regressions.

uses the economy-wide CPI and excise tax rates, which are exogenous, to predict the level of cigarette prices.[56]

6. Table A3 of regression results with the RMSS data adds the quadratic time variable to this set of equations. Otherwise the columns in Table A3 directly parallel those in Table A2 in terms of the set of variables included in the analysis.

Appendix Table A3
RMSS Data Regressions with Quadratic Trend, Including Tax, CPI, or Pack Cost[57]

| | Smoker | Smoker | Smoker | Smoker (IV) |
|---|---|---|---|---|
| 2012 Packaging Changes, full (Dec. 1, 2012) | –0.0019 | –0.0013 | –0.0015 | –0.0015 |
| | (0.0023) | (0.0022) | (0.0022) | (0.0022) |
| Graphic warning labels, 2006 | 0.0018 | 0.0015 | 0.0019 | 0.0018 |
| | (0.0020) | (0.0020) | (0.0019) | (0.0019) |
| Cigarette tax, per cigarette | –0.0135 | | | |
| | (0.0231) | | | |
| Consumer price index (2012=100) | | –0.0001 | | |
| | | (0.0001) | | |
| Cost per pack (Craven 20, real $) | | | –0.0003 | –0.0006 |
| (IV estimates using tax, CPI) | | | (0.0006) | (0.0007) |
| Time trend, months | 3.1E-6 | 1.5E-5 | 5.5E-6 | –3.2E-6 |
| | (5.3E-5) | (4.8E-5) | (5.2E-5) | (5.3E-5) |
| Time trend, squared | –0.0118*** | –0.0111*** | –0.0117** | –0.0099* |
| | (4.4E-7) | (4.2E-7) | (4.8E-7) | (5.1E-7) |
| Constant | 0.5268*** | 0.5290*** | 0.5265*** | 0.5288*** |
| | (0.0070) | (0.0079) | (0.0071) | (0.0074) |
| R-squared | 0.1139 | 0.1139 | 0.1139 | 0.1139 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01. Other demographic and geographic variables include all those in Table A1.

7. The 2012 Packaging Changes variable loses its statistical significance in every instance. Because of the correlation of the time squared variable with the nonlinear trajectory of

[56] Instrumental variables estimates using only excise taxes as instruments and not the overall CPI likewise do not indicate significant effects of the 2012 Packaging Changes.

[57] These regressions also include the demographic and geographic variables seen in Table A1. These variables have coefficients and significance levels that are stable across these regressions.

cigarette prices, the price variables also drop out of significance given the dominant role of the nonlinear temporal trend. This lack of a significant influence on prices is not because prices are unimportant. Rather, as was illustrated with the Craven 20 price trajectory, prices have been rising in a nonlinear fashion and this determinant of smoking prevalence rates is being captured by the nonlinear trend variable.

8. Finally, Table A4 presents representative regressions including a linear and quadratic time trend variable for different specifications of the advent of the 2012 Packaging Changes. Column 1 introduces the 2012 Packaging Changes starting on December 1 but using the full sample, column 2 introduces the 2012 Packaging Changes starting on October 1 and also using the full sample, while column 3 introduces the 2012 Packaging Changes starting on December 1 but excluding the data from October and November, 2012, as does Dr. Chipty. In every instance there is no evidence of a statistically significant effect of the 2012 Packaging Changes.

Appendix Table A4
RMSS Data: Regressions Predicting Smoking Prevalence by Policy Date

| | Full (Dec. 1) | Partial (Oct. 1) | Full Excluding Oct.–Nov. |
|---|---|---|---|
| 2012 Packaging Changes | –0.0030 | –0.0023 | –0.0030 |
| | (0.0026) | (0.0025) | (0.0027) |
| Graphic warning labels, 2006 | 0.0004 | 0.0005 | 0.0004 |
| | (0.0020) | (0.0020) | (0.0020) |
| Tax policy, 2010 (25%) | –0.0069*** | –0.0067*** | –0.0069*** |
| | (0.0025) | (0.0025) | (0.0025) |
| Tax policy, 2013 (12.5%) | –0.0033 | –0.0036 | –0.0033 |
| | (0.0028) | (0.0027) | (0.0028) |
| Tax policy, 2014 (12.5%) | 0.0011 | 0.0012 | 0.0012 |
| | (0.0028) | (0.0028) | (0.0028) |
| Tax policy, 2015 (12.5%) | 0.0003 | 0.0004 | 0.0003 |
| | (0.0027) | (0.0027) | (0.0027) |
| Tax policy, 2016 (12.5%) | –0.0055 | –0.0054 | –0.0055 |
| | (0.0036) | (0.0036) | (0.0036) |

| | | | |
|---|---|---|---|
| Time trend, months | 7.8E-6 | 1.2E-5 | 8.8E-6 |
| | (5.9E-5) | (5.9E-5) | (5.9E-5) |
| Time trend, months (squared) | –9.0E-7** | –9.5E-7** | –9.1E-7** |
| | (4.4E-7) | (4.4E-7) | (4.5E-7) |
| Female | –0.0396*** | –0.0396*** | –0.0396*** |
| | (0.0009) | (0.0009) | (0.0009) |
| Marital status, single | 0.0401*** | 0.0401*** | 0.0399*** |
| | (0.0013) | (0.0013) | (0.0013) |
| Marital status, divorced | 0.0985*** | 0.0985*** | 0.0982*** |
| | (0.0017) | (0.0017) | (0.0017) |
| Marital status, widowed | 0.0495*** | 0.0495*** | 0.0493*** |
| | (0.0019) | (0.0019) | (0.0019) |
| Marital status, separated | 0.1278*** | 0.1278*** | 0.1281*** |
| | (0.0023) | (0.0023) | (0.0023) |
| Student | –0.0781*** | –0.0781*** | –0.0780*** |
| | (0.0035) | (0.0035) | (0.0035) |
| Years of education | –0.0199*** | –0.0199*** | –0.0198*** |
| | (0.0001) | (0.0001) | (0.0001) |
| Age | 0.0092*** | 0.0092*** | 0.0092*** |
| | (0.0002) | (0.0002) | (0.0002) |
| Age (squared) | –1.4E-4*** | –1.4E-4*** | –1.4E-4*** |
| | (1.5E-6) | (1.5E-6) | (1.5E-6) |
| Non-adults (14-17) | –0.2011*** | –0.2011*** | –0.2016*** |
| | (0.0027) | (0.0027) | (0.0027) |
| Employed full time | –0.0268*** | –0.0268*** | –0.0267*** |
| | (0.0012) | (0.0012) | (0.0013) |
| Retired | –0.0966*** | –0.0966*** | –0.0963*** |
| | (0.0040) | (0.0040) | (0.0041) |
| Income | –0.0005*** | –0.0005*** | –0.0005*** |
| | (3.1E-5) | (3.1E-5) | (3.1E-5) |
| Income (squared) | 1.3E-6*** | 1.3E-6*** | 1.3E-6*** |
| | (1.3E-7) | (1.3E-7) | (1.3E-7) |
| Income, multiple household members | –0.0188*** | –0.0188*** | –0.0188*** |
| | (0.0011) | (0.0011) | (0.0011) |
| Bread winner | 0.0084*** | 0.0084*** | 0.0085*** |
| | (0.0011) | (0.0011) | (0.0011) |
| Household size | –0.0009** | –0.0009** | –0.0009** |
| | (0.0004) | (0.0004) | (0.0004) |
| Home owner | –0.1115*** | –0.1115*** | –0.1114*** |
| | (0.0010) | (0.0010) | (0.0010) |
| Victoria | 0.0131*** | 0.0131*** | 0.0132*** |
| | (0.0011) | (0.0011) | (0.0011) |
| Queensland | 0.0057*** | 0.0057*** | 0.0059*** |
| | (0.0012) | (0.0012) | (0.0012) |
| South Australia | 0.0082*** | 0.0082*** | 0.0084*** |
| | (0.0016) | (0.0016) | (0.0017) |

| | | | |
|---|---|---|---|
| Western Australia | 0.0056*** | 0.0056*** | 0.0057*** |
| | (0.0015) | (0.0015) | (0.0015) |
| Tasmania | 0.0243*** | 0.0243*** | 0.0242*** |
| | (0.0020) | (0.0020) | (0.0020) |
| Darwin-Alice Springs | 0.0348*** | 0.0348*** | 0.0350*** |
| | (0.0042) | (0.0042) | (0.0042) |
| Lives in capital city | –0.0260*** | –0.0260*** | –0.0260*** |
| | (0.0009) | (0.0009) | (0.0009) |
| Constant | 0.5234*** | 0.5233*** | 0.5243*** |
| | (0.0047) | (0.0047) | (0.0048) |
| R-squared | 0.1139 | 0. 1139 | 0. 1139 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

# APPENDIX B

## CITTS Data

Appendix Table B1
CITTS Data: Regressions Predicting Cigarettes Smoked Per Day by Policy Date

| | Full (Dec. 1) | Partial (Oct. 1) | Full Exclude Partial |
|---|---|---|---|
| 2012 Packaging Changes | 0.8904*** | 0.6038* | 0.8346** |
| | (0.3438) | (0.3330) | (0.3571) |
| Year trend | 0.3940* | 0.3651* | 0.3985* |
| | (0.2112) | (0.2143) | (0.2152) |
| Year trend, squared | -0.0561** | -0.0474** | -0.0551** |
| | (0.0238) | (0.0233) | (0.0238) |
| Mobile phone survey participation | -0.8646*** | -0.7866*** | -0.8782*** |
| | (0.2540) | (0.2506) | (0.2538) |
| Female | -1.7319*** | -1.7372*** | -1.7148*** |
| | (0.1639) | (0.1639) | (0.1656) |
| Age | 0.5766*** | 0.5767*** | 0.5665*** |
| | (0.0296) | (0.0296) | (0.0299) |
| Age, squared | -0.0048*** | -0.0048*** | -0.0047*** |
| | (0.0003) | (0.0003) | (0.0003) |
| Income, low | -0.1570 | -0.1467 | -0.0706 |
| | (0.2070) | (0.2070) | (0.2095) |
| Income, high | -0.1510 | -0.0836 | -0.0682 |
| | (0.4268) | (0.4254) | (0.4269) |
| Education, low | 2.3043*** | 2.3117*** | 2.3398*** |
| | (0.3267) | (0.3267) | (0.3301) |
| Education, high | -1.5282*** | -1.5278*** | -1.5522*** |
| | (0.1722) | (0.1722) | (0.1739) |
| Number of children | 0.0583 | 0.0606 | 0.0435 |
| | (0.0789) | (0.0789) | (0.0796) |
| English primary language | 1.6657*** | 1.6644*** | 1.6716*** |
| | (0.2247) | (0.2248) | (0.2267) |
| Original peoples | 1.9389*** | 1.9354*** | 1.8136*** |
| | (0.4183) | (0.4184) | (0.4246) |
| Constant | -3.6559*** | -3.6635*** | -3.4774*** |
| | (0.8228) | (0.8262) | (0.8317) |
| R-squared | 0.07 | 0.07 | 0.07 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

Appendix Table B2
CITTS Data: Regressions Predicting Cigarettes Smoked Per Day by Policy Date, Quitters Excluded

| | Full (Dec. 1) | Partial (Oct. 1) | Full Exclude Partial |
|---|---|---|---|
| 2012 Packaging Changes | 1.4234*** | 1.0850*** | 1.4021*** |
| | (0.3544) | (0.3430) | (0.3674) |
| Year trend | 0.5636*** | 0.5040** | 0.5520** |
| | (0.2168) | (0.2199) | (0.2206) |
| Year trend, squared | -0.0787*** | -0.0659*** | -0.0767*** |
| | (0.0244) | (0.0240) | (0.0245) |
| Mobile phone survey participation | -1.2610*** | -1.1551*** | -1.2598*** |
| | (0.2631) | (0.2596) | (0.2625) |
| Female | -1.9620*** | -1.9691*** | -1.9341*** |
| | (0.1691) | (0.1692) | (0.1707) |
| Age | 0.5960*** | 0.5961*** | 0.5852*** |
| | (0.0307) | (0.0307) | (0.0309) |
| Age, squared | -0.0050*** | -0.0049*** | -0.0048*** |
| | (0.0003) | (0.0003) | (0.0003) |
| Income, low | -0.0541 | -0.0388 | 0.0241 |
| | (0.2126) | (0.2126) | (0.2151) |
| Income, high | -0.0398 | 0.0496 | 0.0358 |
| | (0.4426) | (0.4412) | (0.4422) |
| Education, low | 2.6286*** | 2.6376*** | 2.6625*** |
| | (0.3334) | (0.3334) | (0.3364) |
| Education, high | -1.5553*** | -1.5565*** | -1.5678*** |
| | (0.1775) | (0.1775) | (0.1791) |
| Number of children | 0.1514* | 0.1535* | 0.1515* |
| | (0.0812) | (0.0813) | (0.0819) |
| English primary language | 2.2907*** | 2.2877*** | 2.2985*** |
| | (0.2309) | (0.2309) | (0.2326) |
| Original peoples | 1.4122*** | 1.4069*** | 1.2227*** |
| | (0.4218) | (0.4219) | (0.4272) |
| Constant | -3.0505*** | -3.0155*** | -2.8705*** |
| | (0.8551) | (0.8589) | (0.8634) |
| R-squared | 0.09 | 0.09 | 0.09 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

## APPENDIX C

## NTPPTS Data[58]

Appendix Table C1
NTPPTS Data: Regressions Predicting Cigarettes Smoked Per Day by Policy Date

| | Full (Dec. 1) | Partial (Oct. 1) | Full Exclude Partial |
|---|---|---|---|
| 2012 Packaging Changes | 0.1198 | 0.3733* | 0.3380 |
| | (0.2029) | (0.2206) | (0.2231) |
| Age | 0.4916*** | 0.4915*** | 0.4965*** |
| | (0.0453) | (0.0453) | (0.0471) |
| Age, squared | –0.0036*** | –0.0036*** | –0.0037*** |
| | (0.0005) | (0.0005) | (0.0006) |
| Female | –2.6352*** | –2.6431*** | –2.6330*** |
| | (0.1941) | (0.1942) | (0.2019) |
| Years of education | –0.5142*** | –0.5135*** | –0.5583*** |
| | (0.0384) | (0.0384) | (0.0401) |
| Income, high (> $100k) | 0.3168 | 0.3119 | 0.2199 |
| | (0.2589) | (0.2589) | (0.2696) |
| Income, low (< $30k) | 1.1297*** | 1.1286*** | 1.0538*** |
| | (0.2712) | (0.2712) | (0.2813) |
| Original peoples | 1.6490*** | 1.6553*** | 1.5516*** |
| | (0.5042) | (0.5041) | (0.5246) |
| English primary language | 3.4684*** | 3.4641*** | 3.4061*** |
| | (0.3817) | (0.3816) | (0.3971) |
| Phone: land line in home | 0.0552 | 0.0608 | 0.1234 |
| | (0.2374) | (0.2373) | (0.2463) |
| Phone: mobile line in home | –0.5414 | –0.5441 | –0.1341 |
| | (0.3812) | (0.3811) | (0.3951) |
| Hours of television per day | 0.1944*** | 0.1956*** | 0.1910*** |
| | (0.0436) | (0.0436) | (0.0452) |
| Victoria | –0.0918 | –0.0955 | –0.1094 |
| | (0.2538) | (0.2538) | (0.2639) |
| Queensland | 1.2380*** | 1.2375*** | 1.1982*** |
| | (0.2720) | (0.2720) | (0.2831) |
| South Australia | 0.3751 | 0.3709 | 0.1701 |
| | (0.3886) | (0.3885) | (0.4012) |
| Western Australia | 1.4274*** | 1.4254*** | 1.4012*** |
| | (0.3449) | (0.3448) | (0.3590) |
| Tasmania | 0.6510 | 0.6541 | 0.7958 |
| | (0.6520) | (0.6519) | (0.6756) |
| Northern Territory | 0.8806 | 0.8728 | 1.0230 |

[58] Regressions also include variables identifying whether data for demographic variables are missing. Missing data coded as zero.

| | | | |
|---|---|---|---|
| | (0.8681) | (0.8680) | (0.9040) |
| Capital city | -0.8438*** | -0.8410*** | -0.8660*** |
| | (0.2119) | (0.2119) | (0.2209) |
| Constant | 4.8122*** | 4.6228*** | 4.8703*** |
| | (1.1703) | (1.1747) | (1.2211) |
| R-squared | 0.15 | 0.15 | 0.15 |

*Notes*: Significance levels: *0.10, **0.05, ***0.01.

## APPENDIX D

## EDUCATIONAL BACKGROUND AND PROFESSIONAL EXPERIENCE

1. 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. I have previously held tenured full professor positions at Harvard Law School, Duke University, and Northwestern University. I hold a Bachelor's degree in Economics, two master's degrees, and a Ph.D. in economics, all from Harvard University. I graduated summa cum laude, Phi Beta Kappa, and won the awards at Harvard University for the best undergraduate thesis in economics and the best doctoral dissertation in economics.

2. My research focuses on the economics of risk and uncertainty, with particular emphasis on risks to health and safety. I have published more than 350 articles and 20 books dealing primarily with health and safety risks. Most of these articles and books have been peer reviewed. I have been ranked among the top 25 economists in the world based on citations in economics journals and have been ranked as the leading contributor to the health economics literature by *Health Economics* and the leading contributor to the risk and insurance literature by the *Journal of Risk and Insurance*. My research has won numerous article of the year and book of the year awards from organizations such as the Royal Economic Society and the American Risk and Insurance Association. I am the founding Editor of the *Journal of Risk and Uncertainty*, which is the leading international journal in its field and which I continue to edit.

3. My research currently focuses on how consumers make decisions involving products such as cigarettes and drinking water that may pose precisely understood risks and more uncertain risks. Much of my research has analyzed hazard warnings and how they affect consumer behavior. I worked extensively with the U.S. Environmental Protection Agency ("EPA") on a continuous basis from 1983 to 2012, serving in several different roles. Much of my work for EPA has focused on the development of guidelines 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 with Wesley Magat: *Learning about Risk: Consumer and Worker Responses to Hazard Information* (Cambridge: Harvard University Press, 1987), and *Informational Approaches to Regulation* (Cambridge: MIT Press, 1992). I have also written many articles and two peer-reviewed books devoted to consumer decisions pertaining to smoking, *Smoking: Making the Risky Decision* (Oxford University Press, 1992) and *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (University of Chicago Press, 2002). None of this research has been funded by the tobacco industry or law firms representing the industry.

4. In addition to my extensive work for EPA, I have consulted for several other governmental and private entities on a variety of issues. I have taught courses about risk, uncertainty, risk analysis, and hazard warnings to hundreds of U.S. 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. 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.

5. 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, Bristol-Meyers Squibb, Anheuser-Busch, Black & Decker, R.J. Reynolds, and Medline Industries. During this period, I also directed studies for the U.S. Environmental Protection Agency on the design and policy role of hazard warnings for chemicals and pesticides. I testified on behalf of the Province of Québec in the Loto Québec class action, Jean Brochu v. Loto Québec, regarding warnings for video lottery terminals. I also have testified in Québec on behalf of JTI-Macdonald Corp. and Rothmans, Benson & Hedges Inc. in the Blais and Létourneau cigarette class actions. I have submitted several expert reports on behalf of British American Tobacco group companies in relation to proposed tobacco regulation, including the introduction of graphic health warning requirements and legal challenges to such regulation. I have also testified on tobacco-related issues and have submitted expert reports in various U.S. proceedings on behalf of cigarette companies. I have also served as an expert witness on other matters, such as economic damages in wrongful death and personal injury cases and hazardous waste site remediation efforts. My discussion below draws on my professional expertise and knowledge of the literature on risk and warnings.

6. I have extensive professional experience evaluating regulatory impact analysis and the economic methodology used in benefit-cost analysis. From 1979-1980, I was the Deputy Director of the President's Council on Wage and Price Stability, which was responsible

for White House oversight of all new federal regulations during that period as well as executive branch review of all regulatory impact analyses. I served as the President of the Society for Benefit-Cost Analysis in 2015.

7. A full copy of my Curriculum Vitae is available at http://www.vanderbilt.edu/econ/faculty/cv/ViscusiCV.pdf