Comments on


From: Cancer Council Victoria, Melbourne, 3 June 2016

1. **Summary**

This is a working paper that has not been scientifically peer-reviewed. It misunderstands or misrepresents

- the purpose, scope and role of the National Tobacco Plain Packaging Survey in the Government’s overall evaluation of the Tobacco Plain Packaging Act 2012
- the approach taken in the three major published papers assessing the impact of the legislation
- the scope of the British Medical Journal’s Tobacco Control supplement comprising papers on the initial impact of the legislation in Australia and
- the extent of Professor Wakefield’s involvement in the policy formulation.

The whole premise of the critique is that evaluation should be open and transparent and that analysis should be replicable. It gives an impression that data has been suppressed and that numerous errors and misrepresentations have been detected. However in fact the researchers were provided the data promptly after requesting it and were able to replicate almost all of the findings. The researchers dispute the validity of the alternative analysis performed by Davidson and de Silva.

The Davidson and de Silva paper also contains numerous errors of fact.

Finally it grossly oversimplifies the sophisticated and nuanced description outlined in the Australian Government’s Productivity Commission on evidence-based policy and fails to assess the evaluation against all of the principles set out.

2. **Critique not an independent, academic review**

Davidson and De Silva’s critique has been published on the SSRN website rather than in an academic journal where it would have been subject to peer review prior to publication.

Professor Davidson does not have a neutral academic interest in this topic. He took a strong stance against plain packaging legislation, and his views were extensively canvassed by *The Australian* newspaper in June 2014. The Institute of Public Affairs with which he is a senior research fellow has been a highly vocal opponent of plain packaging legislation since it was first mooted in 2010.

The IPA describes itself as a free-market think tank.
“For 60 years the Institute of Public Affairs has been the most effective advocate for small, efficient government, low regulation, low taxes and individual liberty in Australia. The Institute of Public Affairs is the only organisation in Australia actively opposing:

• bad climate change policies,
• the Nanny State,
• high taxes and over-regulation.”

http://www.ipa.org.au/about/donations

The IPA has received funding from tobacco companies in Australia.¹

3. Critique misrepresents role of the National Tobacco Plain Packaging Tracking Survey in Government’s overall evaluation

Davidson and de Silva’s paper either misunderstands or misrepresents the purpose and scope of the National Tobacco Plain Packaging Tracking Survey (NTPPTS).

The overall Objects of the *Tobacco Plain Packaging Act 2011* are

1. to improve public health by:
   (1) (a) to improve public health by:
       (i) discouraging people from taking up smoking, or using tobacco products;
       (ii) encouraging people to give up smoking, and to stop using tobacco products
       (iii) discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing; and
       (iv) reducing people’s exposure to smoke from tobacco products.”
   (b) to give effect to certain obligations that Australia has as a party to the Convention on Tobacco Control”  

2. It is the intention of the Parliament to contribute to (emphasis added) achieving the objects in subsection 1 by regulating the retail packaging and appearance of tobacco products in order to

   (a) reduce the appeal of tobacco products to consumers
   (b) increase the effectiveness of health warnings on retail packaging of tobacco products; and
   (c) reduce the ability of retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.”

(Section 3, Sub-section 2)

However the NTPPTS focused not on these overall Objects but rather on the specific objectives as set out in the next clause of the Act.


The NTPPS was quite explicitly not designed to assess quitting success or change in smoking prevalence but rather focussed on the immediate impact of the legislation on perceptions of the pack, effects of health warnings and understanding of product harmfulness. The Australian Government already had two large surveys of adults that provide reliable information on smoking prevalence—the Australian Institute of Health and Welfare’s three-yearly National Drug Strategy Household Survey and the Australian Bureau of Statistics’ National Health Survey. It also funds a very large three-yearly survey of smoking among secondary school students. All of these surveys show substantial declines in the prevalence of smoking in Australia—from 2010 to 2013 in the National Drug Strategy Household Survey, from 2011-12 to 2014-15 in the ABS National Health Survey and from 2011 to 2014 in the Australian Secondary School Survey of Smoking Alcohol and Drugs (ASSAD).

The Government’s Post-Implementation Review (PIR) of the tobacco plain packaging measure was more broadly focussed than the NTPPTS. It included a consideration not just of findings from the NTPPTS on the initial impact of the legislation on adult smokers, but also the findings from other Australian research, and from the international experimental literature. The PIR (but not the NTPPTS) also considered evidence in relation to the prevalence of smoking.

Plain packaging is just one of numerous strategies in place to discourage smoking in Australia. It is not possible to attribute change in prevalence to any one factor using a single before-and-after comparison from three-yearly surveys. However, the PIR was also able to consider data from a commercial research company that provided monthly data. The Roy Morgan Research Company’s single source survey interviewed more than 4000 people every month. The PIR took into account the results of a very careful and detailed analysis of data from that survey from January 2001 to September 2015—see Figure 1 reproduced from the Chipty report below.


Chipty estimates that, on average, prevalence of smoking was 2.2 percentage points lower in the 34 months after plain packaging was introduced than in the 34 months before—see Table 1.

**Chipty Table 1: Average Smoking Prevalence, Before and After the Packaging Changes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Full Period Jan 01-Sept 15</th>
<th>Before: Dec 09-Sept 12</th>
<th>After: Dec 12-Sept 15</th>
<th>Percentage Point Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>20.6 %</td>
<td>19.4 %</td>
<td>17.2 %</td>
<td>-2.2***</td>
</tr>
</tbody>
</table>

*Note: Average calculated using the sample weights provided by RMSS. Asterisks ***, **, and * indicate that the difference between the before and after periods is statistically significant at the 1, 5, and 10 percent level, respectively.

*Source: RMSS Data (January 2001 – September 2015)*.

Contrary to the statement by Davidson and de Silva (page 15), this analysis did control for several major tax increases that occurred in Australia prior to the implementation of the tobacco plain packaging policy and during one and two years afterwards—see ‘YES’ indications in Table 3 from the Chipty report reproduced below. It also controlled for numerous demographic factors and overall trends in smoking over time.
Chipty Table 3: Summary Estimation Results Using Individual-Level RMSS Data, January 2001 to September 2015

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td>2012 Packaging Changes</td>
<td>-0.0237**</td>
<td>0.0215**</td>
<td>-0.0232**</td>
<td>-0.0239**</td>
</tr>
<tr>
<td></td>
<td>(0.017)</td>
<td>(0.029)</td>
<td>(0.016)</td>
<td>(0.011)</td>
</tr>
<tr>
<td>Excise Tax 2010</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
</tr>
<tr>
<td>Excise Tax 2013</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
</tr>
<tr>
<td>Excise Tax 2014</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
<td>YES*</td>
</tr>
<tr>
<td>GHW 2006</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Time Trend</td>
<td>YES*</td>
<td>YES*</td>
<td>YES**</td>
<td>YES*</td>
</tr>
<tr>
<td>Female</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
</tr>
<tr>
<td>Married</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
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<tr>
<td>Age Groups</td>
<td>YES***</td>
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<td>YES***</td>
<td>YES***</td>
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<td>Education Groups</td>
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<td>Work Status</td>
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</tr>
<tr>
<td>Income Groups</td>
<td>YES***</td>
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<tr>
<td>State/Territory Indicators</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
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<tr>
<td>Constant</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
<td>YES***</td>
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<tr>
<td>Observations</td>
<td>786,518</td>
<td>794,750</td>
<td>794,750</td>
<td>794,750</td>
</tr>
</tbody>
</table>

Notes: P-values are reported in parentheses. Asterisks ***, **, and * indicate statistical significance at the 1, 5, and 10 percent level, respectively. “YES” indicates that the variable or group of variables is included in the regression model.

Source: RMSS Data (January 2001 - September 2015).

While undoubtedly some of the fall in the prevalence of smoking in Australia can be attributed to the 12.5% increases in taxes in December 2013 and September 2014, the Government’s analysis shows that about a quarter of the reduction could be attributed to the plain packaging policy (refer Table 4 in the Chipty report also reproduced below).
### Chippy Table 4: Predicted Effects of the 2012 Packaging Changes on Smoking Prevalence, December 2012 to September 2015

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td></td>
</tr>
<tr>
<td>Smoking Prevalence With Packaging Changes</td>
<td>17.21%</td>
<td>17.21%</td>
<td>17.21%</td>
<td>17.21%</td>
</tr>
<tr>
<td>Smoking Prevalence Without Packaging Changes</td>
<td>17.77%</td>
<td>17.71%</td>
<td>17.75%</td>
<td>17.77%</td>
</tr>
<tr>
<td>Change</td>
<td>-0.55</td>
<td>-0.50</td>
<td>-0.54</td>
<td>-0.56</td>
</tr>
<tr>
<td>P-value</td>
<td>0.02</td>
<td>0.03</td>
<td>0.02</td>
<td>0.01</td>
</tr>
<tr>
<td>95% Confidence Interval</td>
<td>[-1.01; -0.095]</td>
<td>[-0.954; -0.050]</td>
<td>[-0.984; -0.099]</td>
<td>[-0.992; -0.126]</td>
</tr>
</tbody>
</table>

*Note:* Due to rounding, calculations based on displayed precision may not replicate the numbers presented.

*Source:* Table 3.

The Australian Government’s Post-Implementation Review concluded that there is a growing body of evidence that plain packaging of tobacco products is contributing to the achievement of the Objects set out in the *Tobacco Plain Packaging Act 2011*. The same conclusion was recently reached by the UK High Court as part of its 380+ page ruling on standardised packaging regulations in the United Kingdom.⁵

### 4. Critique misunderstands the approach taken in the three major published papers assessing the impact of the legislation

The aims of the NTPPTS were clearly stated in each of the papers including the introductory paper to the *Tobacco Control Supplement* and in the Technical Report which is provided as an online open access supplement to the *Wakefield 2015* paper.⁶ This states:

“The primary aim of the evaluation of tobacco plain packaging among the adult population described in this report was not to assess change in smoking prevalence which is influenced by a variety of demographic, marketing and policy factors over time, but rather:

a. to document the timing and rate at which the intervention was ‘delivered’ to the Australian population


⁶ See [http://tobaccocontrol.bmj.com/content/24/Suppl_2/ii17/suppl/DC1](http://tobaccocontrol.bmj.com/content/24/Suppl_2/ii17/suppl/DC1)
b. to determine the extent to which the three specific objectives of plain packaging were achieved; and

c. to investigate any downstream influences of these proximal outcomes (used to assess the specific objectives) on quitting cognitions and behaviours.

The NTPPTS had two components:

i. an ongoing survey of smokers and recent quitters and

ii. a follow-up survey (one month later) of those smokers and ex-smokers who participated in the survey a month earlier.

The survey is not a survey of smoking prevalence.

The baseline survey did not interview non-smokers, so it is not possible to determine smoking prevalence from the survey—as noted above, prevalence could be determined from the well-established long-running very large population surveys.

Rather it is a tracking survey, with a nested series of follow-up studies one-month later.

The baseline tracking survey was designed with the much more modest aim of tracking over time what people thought about their cigarette packs, the health warnings and the harmfulness of tobacco. These results are reported on in full in the Wakefield paper and it is noted that the Davidson ‘replication’ produced virtually identical results.

While changes in the perceived attractiveness of the packaging and the perception of health warnings would be affected by little other than the policy itself, (and hence could simply be tracked over time with minor adjustments for population demographics and policy factors such as exposure to health-related advertising) beliefs about smoking and attitude and intentions about quitting are affected by a multitude of factors related to industry marketing, government regulation of such marketing and individual characteristics of the smoker.

Smoking tobacco is a highly addictive behaviour, and only a small proportion of smokers try to quit in any particular month, and a smaller-still percentage actually succeed. Davidson and de Silva assert that the Tracking Survey should have examined quitting success but it quite simply was not statistically powered to do so.

The participants in the baseline survey were randomly selected each month from the general population of smokers and recent quitters. Over time, the remaining smokers in the Australian population would be by definition those who had not quit in the preceding months and years. Each month there was a lot of variability in beliefs about smoking, quitting history and current quitting

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7 It is also not a simple cohort study (which would have interviewed a large number of smokers prior to implementation and then looked at the proportion who quit by a later point in time). A different group of people were interviewed every month but were re-interviewed only one month later and not again, so it was also not possible to assess the proportion of respondents who quit over the following months and year.

attentions. While the composition of the smokers in the baseline study was affected by the changing nature of the smoking population over time and was also subject to too much variability to detect small changes in intentions and behaviours, the nested series of monthly follow-up surveys provided the opportunity examine one-month changes in quitting related thoughts and behaviour. The methodological advantage of the cohort design of these follow-up surveys allowed the researchers to detect any possible elevation post-policy implementation in thoughts about quitting, intentions to quit and one-month quit attempts, using smokers as their own control group.

As explained in the Technical Report, the three main papers from the tracking survey used different parts of the survey dataset (not selectively as implied by Davidson and de Silva) but purposefully, by design, in order to achieve the objectives of the survey. The Wakefield paper focussed on the immediate changes in the perceptions among adults about packs and health warnings (as per Aim b of the survey), and the Brennan and Durkin papers focussed on the follow-up survey as a way of exploring the influence of proximal outcomes on quitting cognitions and behaviours (Aim c of the Survey).

The alternative analysis by Davidson and de Silva inappropriately uses the cross-sectional baseline data to examine changes in quitting attitudes and behaviours pre to post-policy implementation. This completely misses the point of the cohort element of the study exploited in the Brennan and Durkin papers. As is well understood in public health research—indeed as explained in the Productivity Commission report which Davidson and de Silva cite—a cohort study is a methodologically superior design for examination of more downstream outcome variables and for establishing causation.

5. Critique misunderstands the aims of the British Medical Journal’s Tobacco Control Supplement reporting on initial impact of the legislation

Davidson and de Silva’s critique either misunderstands or misrepresents the Supplement dedicated to plain packaging in the BMJ’s Tobacco Control journal. The editorial and the introductory paper at the beginning of the Supplement quite clearly state that the purpose is to report on studies conducted to that point relevant both to the specific objectives of the legislation, and the findings so far relevant to the unintended consequences on the retail sector and tobacco prices that were predicted by the industry. The publication makes it quite clear that its purpose is not to evaluate the broad Objects of the legislation but rather the specific objectives.

“The studies in this volume examine the impact of Australia’s tobacco plain packaging legislation and the simultaneously introduced large graphic health warnings, not on smoking prevalence which is affected by a variety of demographic, marketing and policy factors over time, but rather on the perceived appeal of
tobacco packaging, the effectiveness of health warnings and consumer misperceptions of harm.”

Only the Tracking Survey, the cigar study and adolescent surveys were government-funded contracts. The Personal Pack Display Observational Study and Tobacco Retail Outlet Monitoring Study were primarily funded by nongovernment organisations.

Davidson and de Silva are critical that findings from the survey were not reported in a single document. Reporting on findings in a peer-reviewed journal had the disadvantage of limiting the authors to the strict limits imposed by this as all other journals on the number of words and the numbers of tables and figures that could be included in each article. However journal publication provided the advantages of external scientific reviews by people judged to be most expert internationally in this domain of evaluation. The opportunity for deeper more rigorous academic evaluation of the policy was judged to be a highly desirable.

6. **Critique grossly overstates Professor Wakefield’s role in policy formulation**

This critique grossly overstates Professor Wakefield’s role in the policy formulation process and errs in assuming the proposed evaluation study was not subject to expert scientific review. Professor Wakefield was one among ten members of an expert working group that oversaw the development of a background technical paper articulating world best practice in tobacco control. She was not on the National Preventive Health Taskforce which considered the contents of this background technical paper and she had no role in formulating the Taskforce’s Discussion paper. She played no role in organising consultation on the Discussion paper, had no role in its consideration by Government and no role in the drafting of, or consultation on, the legislation.

Professor Wakefield was approached to undertake a survey of smokers to be conducted over that time and agreed. Professor Wakefield is one of the most experienced people in the world in evaluating tobacco control policies, having managed evaluation of the Quit campaigns in both South Australia and Victoria, and having played a key role in the evaluation of the National Tobacco Campaign that began in 1997. Her exceptional expertise in this work is recognised through her membership of the working groups producing reports for the US National Cancer Institute Monograph on tobacco marketing, the US Surgeon General, and as an Australian NHMRC Principal Research Fellow, as a Fellow of the Academy for Social Sciences in Australia and as a past member of the tobacco products scientific advisory committee of the Food and Drug Administration, as well as through dozens of other awards, roles and committee memberships.

The design of the National Tobacco Plain Packaging Tracking survey was carefully considered and endorsed by the Government’s Expert Advisory Committee which included several international

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9 Scollo M, Bayly M, Wakefield M. Plain packaging: a logical progression for tobacco control in one of the world’s ‘darkest markets’. *Tobacco Control* 2015;24(Suppl 2):ii3-ii8.

10 There was also a practical limit on the number of articles that could be accommodated in the supplement.

experts in this kind of research. Naturally Professor Wakefield was a member of this committee as she is among those leading international experts.

Professor Wakefield’s participation in expert groups was fully disclosed in all the published papers.

The NTPPTS papers were of course considered in the Government’s Post-Implementation Review, however Professor Wakefield and her co-authors on the three papers did not otherwise contribute to or participate in the PIR process.

7. Critique gives an unfounded impression of suppression of data and errors in analysis

The premise of the paper is that evaluation should be open and transparent and that analysis should be replicable. The title and the overall tenor of the paper give a vague, ominous impression of lack of independence, of suppression of data and of errors and misrepresentations. However in fact the authors admit that the researchers’ affiliations, involvement and funding sources were fully disclosed (para 3, page 3). It is true that data from school children have not been made publicly available. This was not possible due to the undertakings made to educational authorities, schools, parents and students prior to collection of this information. The Cancer Council Victoria stands by its decision to refuse to provide data from surveys of school children to lawyers representing British American Tobacco.

Davidson and de Silva admit that they were provided the data from the National Tobacco Plain Packaging Survey within a month of requesting it (top p6). They also indicate that they were able to replicate almost all12 of the findings (page 6, paras 1 to 4).

“We are comfortable and satisfied that we are able to replicate Wakefield et al’s tables 2, 3 and 4.”

“We are comfortable and satisfied that we are able to replicate Durkin et al’s table 2.”

“We are comfortable and satisfied that we are able to replicate Brennan’s et al (stet) tables 2 and 3.”

8. Critique includes alternative analysis that researchers regard as inappropriate

Davidson and de Silva’s computations of weighted Pseudo-R2 figures for regressions were not significant. However it should be noted that these are an inappropriate application and interpretation of this statistic. Pseudo-R2 calculations do not—as Davidson and De Silva claim—provide a measure of the amount of variance explained by the model. Neither are Pseudo-R2 figures an accepted measure of model fit.

12 Davidson & de Silva’s figure for pack appeal must be in error. They use an n of 8255. As stated in the paper only 7175 cigarette smokers were interviewed. They likely included cases from beyond November 2013 by which time the questions relating to ‘compared with 12 months ago’ were no longer relevant.
Although Pseudo R-squared values can be valid and useful for evaluating multiple models predicting the same outcome on the same dataset (e.g., to assess the effect of adding an additional covariate to the model), they should not be interpreted independently or compared across datasets. That is, a Pseudo R-squared only has meaning in comparison to another Pseudo R-squared calculated from a model predicting the same outcome, using the same data, and using the same procedure in the same statistical software.

The Davidson & De Silva paper has not been peer-reviewed: it remains to be seen whether other economists or public health researchers regard these as an appropriate form of analysis for this data.

9. Critique contains numerous errors of fact

The critique contains numerous errors of fact.

At the bottom of page 4, and again on page 9 it is stated in relation to the Brennan et al paper ‘what is especially problematic... is the non-inclusion of the attempted to quit in last month variable’. However, the Brennan paper did test quitting attempts. The results of the Brennan analysis are reported across three tables (2, 3 and 4). The results on quit attempts are not reported in Table 2, but they are reported two pages further down in Table 4.

It is stated in the second para on page 11 that the Wakefield and Brennan papers were published without revision. This is incorrect: the Wakefield and Brennan papers were revised after reviewers’ comments prior to final publication.

The paper states that Victorian FOI laws were modified to prevent adolescent data from being publicly released. This is incorrect. Evidence provided at an appeal of the Cancer Council’s decision not to provide data from its research on drug use by Victorian school children is currently being considered by the Victorian Civil and Administrative Appeals Tribunal.

10. Critique fails to grapple with the fully articulated concept of evidence outlined in the Productivity Commission document.

Davidson and de Silva have based their analysis on three criteria apparently drawn from a Productivity Commission document on evidence-based policy. On inspection it is evident that the Productivity Commission report sets out a framework that is much more thoughtful, nuanced and sophisticated than the three simplistic criteria articulated by Davidson and de Silva. The Government’s approach to evaluation of the plain packaging policy can be judged against that wider framework.