PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products
AUTHORS	Hatchard, Jenny; Fooks, Gary; Evans-Reeves, Karen; Ulucanlar, Selda; Gilmore, Anna

VERSION 1 - REVIEW

REVIEWER	Smith, Katherine University of Edinburgh, School of Social and Political Science
REVIEW RETURNED	31-Aug-2013

GENERAL COMMENTS	This paper presents an assessment of the overall quality of evidence that the tobacco industry submitted opposing plain cigarette packaging in the UK and compares it with the kind of evidence submitted in support of plain packaging. The overall conclusion is that the quality of evidence the industry submitted was generally low. Another point of the paper is the conflict between the dictates of "Better Regulation" (encouraging the industry that is being regulated to comment on the regulations) and those of FCTC Article 5.3 (requiring that the setting of tobacco control policies is free from commercial and other vested interests of the tobacco industry). While the concept of "Better Regulation" may be familiar and compelling to UK audiences, it may be less so to other audiences. Because the principles illuminated by this paper apply well beyond the UK, the principles and origins of "Better Regulation" should be better explained to make the relevance to other audiences clear. A Google search revealed that it was established in 2008 in Britain to reduce "administrative costs" aka to chisel away at regulatory initiatives. This article could usefully show how a trade group uses neutral sounding language like "evidence based standards" and a reverence for procedure to undermine public health regulations. This would also make it relevant, in a certain way, to the article you showed me earlier about the trade negotiation standards. The two paragraphs currently on page 4 of the document seem to me rather thin in explaining how the framework itself (and not just the standards computed into it) is a part of a political-economic system that seems particularly porous to industry influence—not just the tobacco industry's influence. This overarching focus would be more interesting than another entry on the laundry-list of tobacco industry moves. The Methods would benefit from a more focused discussion of the "coding framework for classifying evidence" used the criteria of "relevance" (measured only by what the topic is, but not by its strength) and "quality" (measured in terms of independence and peer-review status). It would be useful and important to add the

	criterion of the strength, value, or cogency of the evidence. What I really want to know is, does this evidence make sense? Should this evidence convince the policymaker that the proposed policy is good or bad? It is not clear to me why “evidence was interpreted narrowly as formal written research sources”, thereby excluding “opinion, political statements, press coverage,” etc. Aren’t these pieces of the political culture responsible for the existence of the EBP? The authors do not appear to have critically appraised the methodology of the studies submitted as evidence? Doesn’t this go against all we’ve learned about the “funding effect” of industry-sponsored studies? I know that they looked at the independence of the study—though I’m not sure how hard they looked into this given that their analysis couldn’t allow them to scrutinize all of the documents submitted. But the relevant biases in the think tank or scholar who produced a study might not be in their formal connection to the tobacco industry; rather, it could be the predisposition of a neo-classical economist or a wonk at the heritage foundation that the tobacco industry knows will reliably produce studies on behalf of more trade and less regulation whether or not they are funded by tobacco. How do the authors characterize those studies? Knowledge production is political. This is kind of the overarching point of this analysis, in a way. Given that, how can they “code” for independence? Likewise, the authors should also consider where the “peer reviewed” papers the industry does cite are published. As Garne et al (Environmental tobacco smoke research published in the journal Indoor and Built Environment and associations with the tobacco industry. Lancet 2005: 365 (9461): 804-809) point out, the companies have established their own journals as publication outlets and there are several industry-dominated journals, such as Food and Chemical Toxicology (Wertz et al, The Toxic Effects of Cigarette Additives. Philip Morris' Project Mix Reconsidered: An Analysis of Documents Released through Litigation, PLoS Medicine 2011; 8(12): e1001145. doi:10.1371/journal.pmed.1001145). Other journals of concern include Regulatory Toxicology and Inhalation Toxicology. The Discussion includes the important conclusion, “These findings raise concerns about the impact of BR on tobacco control policy…how BR…and IAs imposes costs on government challenges at the earliest stage of policy development. Just as TTCs habitually launch legal challenvges in post-decision phase of policymaking, so too can they use resource advantage to exploit BR processes by commissioning research and submitting responses in predecision.” Can the authors say anything about how TTC’s blizzard of facts/paper snags the regulatory process. The EBP and BR framework is where the interesting question lies. Could the authors lay out their analysis in a way that makes clear HOW the bad studies of the tobacco industry creates friction in this new regulatory system? Specific comments: Page Line Comment 2 48 Policy-makers’ needs apostrophe at end

	3 17 What are the “two sources”? TTC submissions and systematic review? Not completely clear. 4 5 The authors need to briefly define “standardized packaging,” GHWL, and Plain packaging so that this paper will make sense to the broader audience it deserves. 4 13 Is “public consultation” in UK the same as “Notice and Comment” in the US? Does BMJ assume all readers are from UK and know this? Again, a brief explanation would help here. 4 44 Should quote language of FCTC Art. 5.3 or include relevant portions from the FCTC Art. 5.3 Guidelines. This document is basically the underlying justification for the paper, so should it should be presented in more detail. 5 7 Second abbreviation should be SP, not SR. (Shows problem with abbreviations!) 5 11-15 Awkward and unclear. 5 15 Why cite secondary source from 2008 to characterize industry’s position on SP? Why not use their own language from the thousands of pages they submitted (refs 20-23)? 5 16 Why not have as one of the criteria for assessing the evidence, “Does this make sense?” These are all process measures, and no outcome or content measures. 6 3-5 Unclear. 7 54-56 To me, this is the most important point – what did the “evidence” say, or not say? 8 27-35 I found this discussion and the accompanying figures 1a and 1b rather confusing. 1a shows that about three pieces of TTC evidence are “independent of the tobacco industry”, so I interpreted that to mean it was OK. But then the text says that “none were published in a peer-reviewed journal.” At first I thought that was contradictory, until I turned the page to see figure 1b and the peer-reviewed journal count. Is there a cleaner way to put this information in a figure? In this case, a few words (not even a thousand) were worth more than a picture. 8 31-32 The fact that the industry’s documentation included information about tobacco packaging and other issues does not necessarily mean that it’s not relevant to the issue of SP. I imagine some of the principles of “Better Regulation” call for comparing alternatives to proposed policy, so it would make sense for the industry to discuss current packaging as the status quo or alternative policy, assuming the government must ask for their input to begin with. 9 24 What does “parallel/quality” indicators mean? 10 3-5 This point is good and more compelling. 10 19-20 Again, would be helpful to have text of FCTC Article 5.3.

	12 45 Needs period after initial “A” and before title of paper.

REVIEWER	David J Hill, PhD, Professorial Fellow, University of Melbourne, Australia No competing interests
REVIEW RETURNED	03-Sep-2013

THE STUDY	There are neither 'participants' nor 'patients' in this study. Documents are the source material.
RESULTS & CONCLUSIONS	This type of research not covered by CONSORT considerations, and there were no human research subjects.
GENERAL COMMENTS	This is a well-conceived, timely, well-written and important paper. It goes beyond 'exposing' the self-interest and manipulation of evidence by transnational tobacco companies and offers an analytic approach governments could use in organizing and assessing the quality of evidence submitted when new policies are being considered. While the context is the particular regulatory environment of the UK, applicability of some of the principles discussed is international and will be relevant and useful in other countries where tobacco control policies are being contested. The way the authors have presented and linked text, tables and figures is exemplary. The deliberative style and measured conclusions add conviction to this work. Two small details could be considered; 1. Reference 39 seems to be insufficient/incomplete. 2. At least in the PDF viewed for this review, Figure 2 seemed lack some of the labels/legends it needs to be clearly understood.

REVIEWER	Olivia Maynard PhD student School of Experimental Psychology University of Bristol United Kingdom
REVIEW RETURNED	24-Sep-2013

GENERAL COMMENTS	This is an important and timely paper, given the recent move by the UK government to postpone a decision on standardised packaging, citing a lack of evidence as the primary explanation. I suggest a couple of small changes to further improve an already excellent manuscript. It is not clear in the Abstract what the first p value is referring to – is this a comparison between the percentage of evidence which was published in peer-reviewed journals? If so, the authors should make this clear. The authors should describe in more detail how the evidence in the systematic review was categorised. Was the systematic review evidence categorised as per the transnational tobacco companies' (TTCs) main arguments, as is stated in the text? If so, this seems counterintuitive as the systematic review evidence does not support any of these arguments. For clarity in the Results section, the sentence beginning “Of the 143 documents, TTC promoted 131 as supporting their arguments....” should be moved to after the first sentence of the Results (before the

	breakdown of how the evidence was categorised).

VERSION 1 – AUTHOR RESPONSE

Stanton Glantz
In the introduction (pp.4-5) more information regarding the global reach of Better Regulation has been included. For example, reference to similar systems across the EU, and in the US, Canada and Australia. We have also emphasised the point that Better Regulation is business-oriented generally, and thus does not only benefit the tobacco industry.

The issue of the narrow interpretation of evidence as 'formal written research sources' is explained in the text (p. 6 Methods: Defining evidence). In order to compare the TTCs' evidence with evidence included in the Systematic Review, it was necessary to restrict the analysis to similar research. Clarifying comments have been added to the outline of criteria for assessing evidence in the methods sections (p. 6, methods: criteria for assessing evidence).

On the subject of types of peer-reviewed journals being cited by TTCs, the journals are predominantly mainstream health and psychology journals, such as the American Journal of Public Health, Preventive Medicine, Addictive Behaviours and Health Psychology. Thus, it does not appear to be the case that the tobacco industry has sought to cite evidence which has been published in journals which they have established. While this is now indicated in the text for clarity (p.8, Results: Overview of evidence cited by TTCs in their submissions), further investigation into all the journals would be required to ascertain this in detail and is beyond the scope of this paper.
With regard to the conclusions drawn, more explanation has been included in the discussion section of how the TTCs' evidence and its lack of transparency presents challenges to policymakers which Better Regulation is not currently addressing (p.13 Discussion: para beginning 'Taken Collectively…'). Two suggestions were made which are beyond the remit of this paper. First, that the strength, value or cogency of the evidence itself should be assessed. Second, that the political production of knowledge should be considered. These aspects, while certainly of interest, have not been added to the analysis as the purpose of the research was to consider the initial challenges posed to policymakers by the volume of evidence cited in consultation submissions. A key priority in this research was to restrict the assessment criteria to objective facts which could be checked and recorded in a policy environment. In other work, the Tobacco Control Research Group is investigating the way in which the tobacco companies have interpreted the evidence they cite to oppose standardised packaging of their products. This work will go some way to addressing the nature of the evidence. (It is referred to on p. 5 in the final paragraph of the Introduction)

All the specific comments regarding the text have been addressed in the manuscript.
Specific comments:

Page Line Comment

2 48 Policy-makers' needs apostrophe at end
An apostrophe has been added. (Article summary)

3 17 What are the "two sources"? TTC submissions and systematic review? Not completely clear.
The term 'two sources' has been replaced with 'TTC and Systematic Review' evidence (Abstract: Methods)

4 5 The authors need to briefly define "standardized packaging," GHWL, and Plain packaging so that this paper will make sense to the broader audience it deserves.
A new paragraph has been added to the start of the introduction (p.4) to define these key concepts:

“Standardised packaging of tobacco products entails the prohibition of logos, brand imagery, symbols, other images, colours and promotional text from tobacco products and tobacco product packaging. Despite the common use of the term ‘plain packaging’ in media coverage of this issue, graphic and textual health warning labels would still feature prominently on packs and key anti-counterfeiting marks would be retained.”

4 13 Is “public consultation” in UK the same as “Notice and Comment” in the US? Does BMJ assume all readers are from UK and know this? Again, a brief explanation would help here.
Reference has been made in the introduction to the public consultation systems such as ‘notice and comment’ in place in other jurisdictions in order to make the context of the paper more accessible to readers (p. 4)
“Public consultations effectively frontload problem-resolution in the policy process by offering affected businesses and other interested parties an early opportunity to comment on policy ideas and proposals, and to submit evidence supporting their views (13, 14). Examples of consultation systems elsewhere include ‘notice and comment’ in the US (15) and the European Commission’s ‘Your voice in Europe’ (16). Evidence gathered from consultations can then be taken into account in developing impact assessments, which entail quantitative evidence-based assessments of the potential effects of proposed regulations and consideration of alternative policy options (17). Evidence plays a key role in the policy process, and, in practice, Better Regulation underpins a form of evidence-based policy making which is deliberately open to stakeholder, and particularly business, influence (18, 19).”

4 44 Should quote language of FCTC Art. 5.3 or include relevant portions from the FCTC Art. 5.3 Guidelines. This document is basically the underlying justification for the paper, so should it should be presented in more detail.
Article 5.3 text has been inserted: (p. 5 Introduction, para beginning ‘New tobacco control policies…’)

5 7 Second abbreviation should be SP, not SR. (Shows problem with abbreviations!)
Acronyms have been reduced to a minimum throughout the paper.

5 11-15 Awkward and unclear.
This section has been rephrased (p.5 Introduction, para beginning ‘A Systematic Review of the evidence…’):
“They cited extensive evidence to support their arguments, claimed that key evidence on smoking behaviour had not been considered in the Systematic Review, and pointed to the absence of real-world evidence as problematic: the UK consultation preceded implementation of standardised packaging in Australia in December 2012.”

5 15 Why cite secondary source from 2008 to characterize industry’s position on SP? Why not use their own language from the thousands of pages they submitted (refs 20-23)?
The TTC submissions have been referenced here as suggested. (p.5 Introduction, para beginning ‘A Systematic Review of the evidence…’)

5 16 Why not have as one of the criteria for assessing the evidence, “Does this make sense?” These are all process measures, and no outcome or content measures.
This suggestion has been identified as being beyond the remit of this paper – see earlier comments regarding the purpose of the research as being to inform evidence management processes by policymakers.

6 3-5 Unclear.
This sentence has been rephrased (p. 6 Methods, Criteria for assessing evidence):
“It was beyond the scope of this study to critically appraise the methodology used in evidence cited by TTCs. However where required, analysis of study design, data and methods (38-40) could be used by

policymakers on an ad hoc basis to review key pieces of evidence in more detail."

7 54-56 To me, this is the most important point – what did the "evidence" say, or not say?
An additional paragraph has been added to address this point (p. 8, Results: Overview of evidence cited by TTCs in their submissions'):
"Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the SR papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence."

8 27-35 I found this discussion and the accompanying figures 1a and 1b rather confusing. 1a shows that about three pieces of TTC evidence are "independent of the tobacco industry", so I interpreted that to mean it was OK. But then the text says that "none were published in a peer-reviewed journal." At first I thought that was contradictory, until I turned the page to see figure 1b and the peer-reviewed journal count. Is there a cleaner way to put this information in a figure? In this case, a few words (not even a thousand) were worth more than a picture.
The figures have been replaced with a data table and an alternative figure has been inserted to illustrate the difference between the Systematic Review and transnational tobacco corporation (TTC) evidence (pp. 9-10).

8 31-32 The fact that the industry's documentation included information about tobacco packaging and other issues does not necessarily mean that it's not relevant to the issue of SP. I imagine some of the principles of "Better Regulation" call for comparing alternatives to proposed policy, so it would make sense for the industry to discuss current packaging as the status quo or alternative policy, assuming the government must ask for their input to begin with.
This issue is addressed in the introduction (p.4, 6th paragraph of intro) and in the discussion (p. 12, Discussion, paragraph 3):
"Second, Better Regulation's requirement that policymakers consider alternative policy options, with its underlying intention of preventing unnecessary regulation, imposes additional upfront costs on governments. In the case of standardised packaging, this requirement encouraged extensive citation of evidence beyond the focus of the policy proposal. This may partly explain why nearly two thirds of the evidence the TTCs cited to claim that standardised packaging 'won't work' addressed non-packaging drivers of youth and adult smoking: studies which do not consider standardised packaging in their methodology or analysis. A second possible explanation is that the level of independence and peer-review of this parallel evidence is significantly higher than that of the evidence they cite on tobacco packaging and its inclusion may therefore have been intended to add legitimacy to TTC arguments. "

9 24 What does "parallel/quality" indicators mean?
These terms are defined in the last paragraph of the methods (p. 8), and they are described in the results in both the text (p.11) and the a new Table 5 (replacing Figure 2).

10 3-5 This point is good and more compelling.
No response required.

10 19-20 Again, would be helpful to have text of FCTC Article 5.3.
The text has been included as suggested (p. 13, Discussion para beginning 'Taken collectively…')

12 45 Needs period after initial "A" and before title of paper.

The references have been reviewed.

David Hill

1. Reference 39 seems to be insufficient/incomplete.
The references have been reviewed – Number 39 is now number 46 and includes more detail.

2. At least in the PDF viewed for this review, Figure 2 seemed lack some of the labels/legends it needs to be clearly understood.
Figure 2 has been replaced with Table 5, which includes clearer labelling for the reader.

Olivia Maynard

1. It is not clear in the Abstract what the first p value is referring to – is this a comparison between the percentage of evidence which was published in peer-reviewed journals? If so, the authors should make this clear.
The following sentence has been added to the results section of the abstract to clarify the meaning of the p-value:
"The difference in quality of the Systematic Review and TTC evidence on standardised packaging was found to be statistically significant ($p<0.0001$)."

2. The authors should describe in more detail how the evidence in the systematic review was categorised. Was the systematic review evidence categorised as per the transnational tobacco companies' (TTCs) main arguments, as is stated in the text? If so, this seems counterintuitive as the systematic review evidence does not support any of these arguments.
The Systematic Review evidence was not coded for argument made to oppose standardised packaging. The following sentence has been included to clarify this issue (p. 6, Methods, Evidence from the Systematic Review):
"Details of the papers cited in the Systematic Review were recorded in Excel and obtained for further analysis of their relevance and quality."

3. For clarity in the Results section, the sentence beginning "Of the 143 documents, TTC promoted 131 as supporting their arguments...." should be moved to after the first sentence of the Results (before the breakdown of how the evidence was categorised).
This change has been made has suggested (p. 8, Results, Overview of evidence cited by TTCs in their submissions).