



31 Purchase Street, Ste. 3-4
Rye, New York 10580
914 • 967 • 9421
info@keeganandco.com
www.keeganandco.com

**Analysis of Consumer Survey Evidence Relevant to the
European Commission's Proposal to Increase the Size of Health
Warnings on Tobacco Packaging**

Submitted by:

Dr. Warren J. Keegan

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**Keegan & Company LLC
31 Purchase Street, Suite 3-4
Rye, New York 10580
(914) 967-9421**

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Exhibits

Exhibit 1—Resume of Dr. Keegan

Exhibit 2—Publications of Dr. Keegan

Exhibit 3—Other materials (including review of additional studies cited in Hammond (2011))

Introduction

Moodie et al. (2009)

Gallopel-Morvan et al. (2011)

Rey Pino et al. (2010)

Studies cited in Wardle et al. (2010) and Hammond (2011)

Fathelrahman et al. (2009)

Hammond et al. (2003)

Lyle (Centre for Behavioural Research) (1992)

Linthwaite (1985)

Exhibit 4—Research Types

Introduction

(A) Focus Groups

(B) Opinion / Attitudinal

(C) Self-Reported Behavioral

(D) Observed Behavioral

(E) Experimental

(F) Longitudinal

(G) Market Response

Introduction

1. My name is Dr. Warren J. Keegan. I am Distinguished Professor Emeritus and Visiting Professor of Marketing and International Business at the Lubin School of Business, Pace University, New York, USA. I am also a founder of Keegan & Company LLC, a consultancy firm specializing in consumer research, international business, marketing, and economics. My full curriculum vitae and my current listing of publications are attached as Exhibits 1 and 2, respectively, to this report.
2. On December 19, 2012, the European Commission published its Proposal to Revise the Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (the “Possible Revision”).¹ I understand that the European Commission has also prepared an Impact Assessment accompanying the Possible Revision dated December 19, 2012 (the “Impact Assessment”) which sets out the evidence base considered by the European Commission.
3. I have prepared this report for Japan Tobacco International, in which I review publicly available consumer survey studies and papers cited by the European Commission as relevant to Article 9 (1) (c) of Possible Revision which would require increasing the size of the health warnings on tobacco products (the “Proposal”).²
4. Among the measures recommended included in the Possible Revision are proposals in respect of the current labeling requirements for tobacco products. In particular, the Proposal seeks to require that all tobacco products are labeled with health warnings which would cover 75

¹ The Possible Revision is available at http://ec.europa.eu/health/tobacco/docs/com_2012_788_en.pdf.

² See the Possible Revision at p. 32.

percent of the front and back of the packaging. Section 2.1.2 and Section 5.3 of the Impact Assessment sets out evidence considered by the European Commission in respect of the Proposal. I note that this section includes studies cited as being relevant to other recommendations made by the European Commission in the Possible Revision in respect of the packaging and labeling of tobacco products. In this regard, I note that the remit of my report extends only to evidence put forward by the European Commission in respect of the Proposal.

5. I have been asked to prepare the current report in regard to the Proposal. Specifically, I have been asked to determine whether there is any credible and methodologically sound evidence (which I will refer to in this report as “reliable evidence”) suggesting that increasing the size of health warnings on cigarette packs is likely to result in changes in smoking behavior.
6. I have previously considered the consumer surveys cited in earlier stages in the preparation of the Possible Revision. I am author of the report “Analysis of Consumer Survey Evidence Relevant to DG SANCO’s Proposal to Increase the Size of Health Warnings on Tobacco Packaging,” dated November 24, 2010 (the “2010 Report”), in which I reviewed the consumer survey evidence relevant to the size of health warnings on tobacco packaging which were previously cited by the European Commission’s Directorate General for Health and Consumer Affairs Consultation on the Possible Revision of the Tobacco Products Directive (the “Consultation”) and the report by RAND Europe accompanying the Consultation (the “RAND Report”).³ In my 2010 Report, I concluded that no study in the Consultation or the RAND Report provided reliable evidence as to the potential behavioral impact of increasing the size of health warning labels. A number of the same consumer survey studies which were cited in the Consultation, and which I discussed in my 2010 Report, are now cited in support of the Proposal. My assessment and opinions regarding these studies are unchanged and are incorporated into this report by reference below.
7. I describe in detail at paragraphs 21 through 64 the evaluation criteria that I apply to consumer survey evidence that I have been asked to consider. In reviewing each study, I seek to apply an objective methodology to determine the extent to which, if at all, the study’s

³ The 2010 Report is available at www.jti.com/how-we-do-business/key-regulatory-submissions.

methodological design and execution and its authors' interpretation of the results meet with a reasonable degree of scientific rigor so as to be deemed reliable evidence. In preparing the current report, I have utilized the same evaluation criteria as those employed in my 2010 Report.⁴

8. Therefore, in undertaking my 2010 Report and my current report, I have examined each study on the topic of increasing the size of health warnings cited by the European Commission in its development of the Proposal. In so doing, I have concluded that no single study constitutes reliable evidence in respect of the potential impact of larger health warnings on consumers' smoking behavior.

⁴ See my 2010 Report at para. 24 through 67.

Executive Summary of Findings

Studies with the Potential to Inform the Debate

9. Some of the studies cited in the Possible Revision and the Impact Assessment in support of the Proposal have the potential to inform the debate regarding possible impacts of increasing the size of the health warnings on cigarette packs. Such studies include those that collect or examine primary data and have a behavioral element—i.e. an attempt to measure potential way(s) in which an increase in the size of health warnings could impact consumers' smoking behavior.
10. To determine whether such studies actually provide any reliable evidence on this topic, it is necessary to conduct a full analysis of each study's design, execution, results, and conclusions. In so doing, one must assess to what extent each study measures the variable it sets out to measure, whether data collection is undertaken objectively, whether the data used are relevant to what the author is trying to assess, whether results are prepared and interpreted objectively, the degree to which the study is statistically rigorous, and whether the authors' conclusions are supported by the data. As with my 2010 Report, I have undertaken this task in preparing this report.
11. The studies I reviewed as defined above at paragraph 9 are listed below (additional study reviews appear at Exhibit 3, see paragraphs 15 through 18 below). My findings, in brief, for each of those studies are as follows:
 - Hammond, D. (2011). "Health warning messages on tobacco products: a review." *Tobacco Control*, Vol. 20, p. 327-333 ("Hammond (2011)") Hammond (2011) is a summary review article and does not present any primary consumer research evidence on the topic of larger health warnings. I therefore do not consider the Hammond (2011) article to be reliable evidence in respect of the potential impact of larger health warnings on consumers' smoking behavior. Additionally, I have reviewed all of the underlying evidence relied upon in Hammond (2011) and provide analysis of relevant studies herein.
 - Sambrook Research International (2009). "A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages." Newport: Sambrook Research

International (“Sambrook (2009)”). The Sambrook (2009) report is a secondary source that presents no original consumer survey research. I therefore do not consider the Sambrook (2009) report to be reliable evidence with respect to the potential impact of larger health warnings on smoking behaviors. I have previously reviewed all of the relevant underlying primary research cited in the Sambrook (2009) report in my 2010 Report.

- Créatec (2008). “Effects of Modified Packaging Through Increasing the Size of Warnings On Cigarette Packs. Quantitative Study of Canadian Youth Smokers And Vulnerable Non-Smokers.” Report submitted to Health Canada (“Créatec (2008)”). I have previously reviewed the Créatec (2008) study at paragraphs 250 through 262 of my 2010 Report and found that in addition to suffering from a number of methodological limitations, this study is attitudinal in nature and therefore irrelevant to a discussion of the potential behavioral impact of larger health warnings.
- Shanahan, P. and Elliott, D. (2008). “Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging.” For the Australian Government, Department of Health and Aging, p. 1-230 (“Elliott & Shanahan (2008)”). I have previously reviewed the Elliot & Shanahan (2008) study at paragraphs 145 through 177 of my 2010 Report and found that this study suffers from material methodological design issues which preclude it from providing reliable data on the issue of larger health warnings.
- Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers” and “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth.” Prepared for Health Canada (collectively “Environics (2008)”). I have previously reviewed the Environics (2008) study at paragraphs 178 through 198 of my 2010 Report and found that the study employs consistently poor question design and a variety of other methodological limitations. Accordingly, I do not consider the Environics (2008) study to be reliable evidence in respect of larger health warnings.
- Vardavas et al. (2009). “Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels.” *European Journal of Public Health*. Vol. 19, No. 2. p.

212-217 (“Vardavas et al. (2009)”). This study employs a flawed methodological design, uses an inappropriate sample, and presents unsupported conclusions, among other limitations. Therefore, I do not consider the Vardavas et al. (2009) study to be reliable evidence in respect of larger health warnings.

- White et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1562-1571 (“White et al. (2008)”). This study fails to control for the impact of a significant event—a mass media campaign—which took place between the two phases of data collection. As such, this study does not provide reliable evidence as to the potential impact of larger health warnings.
- Borland et al. (2009). “Impact of graphic and text warnings on cigarette packs: findings from four countries over five years.” *Tobacco Control*. Vol. 18, p. 358-364 (“Borland et al. (2009)”). This study is hampered by a number of limitations, including reliance on unavailable data, unreliable inter-country comparisons, failure to control for confounding variables, and inconclusive results, among others. As such, I do not consider Borland et al. (2009) to constitute reliable evidence in respect of larger health warnings.
- Thrasher et al. (2011). “Estimating the impact of pictorial health warnings and “plain” cigarette packaging: Evidence from experimental auctions among adult smokers in the United States.” *Health Policy*, Vol. 102, No. 1 (“Thrasher et al. (2011)”). This study reveals its purpose to respondents through its design, potentially biasing its results. It also fails to test all possible conditions within its experimental design. Consequently, this study does not provide reliable evidence in respect of larger health warnings.
- Wardle et al. (2010). “Evaluating the impact of picture health warnings on cigarette packets.” London: Public Health Research Consortium (“Wardle et al. (2010)”). This study does not directly test for the potential impact of larger health warnings on consumers’ smoking behaviors. Its only comment on the issue of larger health warnings comes in the form of an unsupported conclusion. I therefore do not consider the Wardle et al (2010) study to provide any reliable evidence with respect to the potential impact of larger health warnings.

12. In addition, I note that a number of additional consumer survey studies are cited in support of statements made in Hammond (2011) and Wardle et al. (2010). Rather than accepting these statements on their face, and in order to ensure a thorough analysis of all the evidence underlying the Proposal, I have also reviewed the studies cited in Hammond (2011) and Wardle et al. (2010) relevant to larger health warnings. Indeed, one of my purposes in compiling this report has been to evaluate this underlying data in the context of the crucial question of whether there is any reliable *primary* evidence supporting the idea that increasing the size of tobacco health warnings has the potential to lead to behavioral change among consumers.
13. My findings, in brief, for each of these such studies cited in Hammond (2011) and Wardle et al. (2010) is as follows:
- Hammond et al. (2007). “Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study.” *American Journal of Preventive Medicine*, Vol. 32, No. 3 (“Hammond et al. (2007)”). I have previously reviewed the Hammond (2007) study at paragraphs 132 through 144 of my 2010 Report and found that this study suffers from a number of limitations including a focus on attitudinal questions only, reliance on unavailable data, unreliable inter-country comparisons, and a flawed sampling method, among others. I therefore do not consider this study to be reliable evidence in respect of larger health warnings.
 - Fathelrahman et al. (2009). “Smokers’ responses toward cigarette pack warning labels in predicting quit intention, stage of change, and self-efficacy.” *Nicotine & Tobacco Research*, Vol. 11, No. 3 (“Fathelrahman et al. (2009)”). This study used leading questions and relied upon unfounded assumptions to reach its conclusions. As such, the study’s conclusions are unsupported and therefore Fathelrahman et al. (2009) does not constitute reliable evidence in respect of larger health warnings.
 - Hammond et al. (2003). “Impact of the graphic Canadian warning labels on adult smoking behaviour.” *Tobacco Control*. Vol. 12 (“Hammond et al. (2003)”). This study yielded inconclusive results which led to speculative and unreliable conclusions. I do not consider this study reliable evidence with respect to the potential impact of larger health warnings.

- International Tobacco Control (ITC) (2009). “FCTC Article 11 – Tobacco Warning Labels: Evidence and Recommendations from the ITC Project” (“The ITC Project/ITC Summary Document (2009)”). I have previously reviewed the ITC Project (2009) study at paragraphs 77 through 114 of my 2010 Report and found that the ITC Project data has significant limitations including the unavailability of underlying data, inconsistency of results, inappropriate sampling, leading questions, and unreliable inter-country comparisons, among others. For these reasons, I do not consider this study reliable evidence in respect of larger health warnings.
- Hammond et al. (2006). “Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey.” *Tobacco Control*. Vol. 15, Suppl III (“Hammond et al. (2006)”). I have previously reviewed the Hammond (2006) study at paragraphs 116 through 131 of my 2010 Report and found that the study suffers from significant limitations including reliance on unavailable data, uncontrolled cultural differences between studied countries, and failure to control for differences in warning size across countries, among others. I therefore do not consider the Hammond et al. (2006) study reliable evidence in respect of larger health warnings.
- BRC Marketing & Social Research (2004). “Smoking Health Warnings Study – Optimising Smoking Health Warnings Stage 2 – Text, Graphics, Size and Colour Testing.” BRC Marketing and Social Research for the Ministry of Health, New Zealand (“BRC Marketing & Social Research (2004)”). I have previously reviewed the BRC Marketing & Social Research (2004) study at paragraphs 274 through 277 of my 2010 Report and found that this study presents the findings of focus group research. As focus group research is not statistically meaningful and cannot be generalized to broader populations outside of the study group, I do not consider this study reliable evidence in respect of larger health warnings.
- Lyle (Centre for Behavioural Research) (1992). “Health Warnings And Contents Labelling On Tobacco Products: An Evaluation.” Centre for Behavioural Research (“Lyle (Centre for Behavioural Research) (1992)”). This is a summary article which presents no original research on the topic of larger health warnings. The article reviews primary research which dates back to the 1980s. Because this article is a secondary

source and it reviews evidence which is too outdated as to be relevant to the current debate about larger health warnings, I do not consider this study to be reliable evidence.

- Linthwaite (1985). “Health Warnings.” Health Education Journal (“Linthwaite (1985)”). This study was published in 1985, when for example, tobacco advertising in magazines was still permitted in the UK. As such, this study is not relevant to the current policy debate. Combined with the fact that this study reports on the findings of focus group research, I do not consider Linthwaite (1985) to be reliable evidence in respect of larger health warnings.
- Rootman et al. (1995). “A Study on Youth Smoking, Key Figures and Findings. A Joint Research Project by: University of Toronto, University of Illinois at Chicago, York University, Ontario Tobacco Research Unit, Addiction Research Foundation.” (“Rootman et al. (1995)”) I have previously reviewed the Rootman et al. (1995) study at p. 18 of my 2008 Report⁵ and found that this study relies on a flawed design which does not accurately reflect what would occur in the marketplace. It is also attitudinal in nature and therefore does not provide information regarding the potential behavioral impact of larger health warnings. I therefore do not consider Rootman et al. (1995) reliable evidence in respect of larger health warnings.

14. A brief review of the studies listed above which are relied on in Hammond (2011) and Wardle et al. (2010), but which are not directly cited in the Possible Revision or the Impact Assessment, is presented in Exhibit 4 of this report. In summary, none of these studies provides reliable evidence as to the potential behavioral impact of the size of health warning labels on cigarette packs.

Studies with No Potential to Inform the Debate

15. The Impact Assessment also cites studies that do not have the potential to inform regarding the potential behavioral impacts of increasing the size of health warnings.

⁵ Keegan, W.J. *Analysis of Consumer Survey Evidence Relevant to the UK Department of Health Consultation on the Future of Tobacco Control*, September 2, 2008. Available at www.jti.com/how-we-do-business/key-regulatory-submissions.

16. Such studies include focus group research, which is exploratory in nature, carries no statistical weight and the results of which cannot be generalized to broader populations outside the study sample. Also included in this category are studies that only present attitudinal /opinion data. Because attitudinal data is not a reliable indicator of potential behavioral change associated with a policy shift, such studies do not inform the current debate regarding larger health warnings.
17. This category also includes studies that do not present or analyze any original data (e.g., policy papers) and those studies that do not contain any data relevant to the topic of interest (i.e., the potential impact of increasing the size of health warnings on consumers' smoking behavior).
18. I have reviewed the studies cited in the Possible Revision and the Impact Assessment which fall into this category. A brief review of such studies is presented in Exhibit 3 to this report. Irrespective of their inherent inability to inform the current debate, these reviews show that none of these studies provides reliable evidence that larger health warnings would have any impact on smoking behavior.

Conclusion

19. As shown above, and consistent with the findings of my 2010 Report, I have found that none of the studies I have reviewed herein provides reliable evidence as to the potential behavioral impact on consumers of increasing the size of health warnings on cigarettes.
20. In the remainder of this report I set out my specific analyses of those studies which are cited in the Possible Revision and Impact Assessment.

Consumer Research Overview

21. To contextualize my findings, I have summarized below the approach I have followed in determining the relative reliability of the studies cited in light of the methodology underpinning them.
22. Consumer research can be categorized into several different groupings based on the study design employed by the researcher. These groupings are reflective of the study's intended purpose and author's research approach, and assist the reader in assessing the potential validity and reliability of a particular piece of research.

23. I have set forth in Exhibit 4 a review of the characteristics, limitations, and relative reliability of different types of consumer research. The types of research discussed in Exhibit 4 are (a) focus group, (b) opinion or attitudinal, (c) self-reported behavioral, (d) observed behavioral, (e) experimental, (f) longitudinal, and (g) market response studies.

Consumer Research Limitations

24. When evaluating the types of research discussed above, it is important to be aware of limitations that can impact the reliability of the results. Such limitations can result from variations in study design and execution—i.e., methodology—and/or from the authors’ analysis and interpretation of the data collected in the study. Whereas a well designed and executed study can avoid and/or correct for such limitations, their effect in the case of a less well designed or executed piece of research may be to call into question the reliability of the research results, or even render those results unusable. I describe these issues in further detail below.

International Standards of Survey Research

25. To determine the reliability and weight, if any, that can be assigned to a study, it is important to determine whether the authors adhered to commonly accepted principles of survey research. Such principles consist of best practices of study design and execution upheld by research practitioners to ensure the highest level of confidence in survey research and advance the credibility of the discipline of social science research.

26. In order to promote research of acceptable integrity and reliability, international research organizations have developed standards of practice which researchers follow.⁶ These standards are developed by professional associations and codified as best practices which can be used to evaluate the design and execution of specific research projects.

27. A variety of professional organizations have compiled standards for researchers engaging in survey research. Such organizations include the Market Research Society (MRS),⁷ the

⁶ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 371-372.

⁷ Market Research Society, *MRS Code of Conduct* (2005). <http://www.mrs.org.uk/standards/downloads/code2005.pdf>.

American Association for Public Opinion Research (AAPOR),⁸ the World Association for Public Opinion Research (WAPOR),⁹ the Council of American Research Organizations (CASRO),¹⁰ the International Statistical Institute (ISI),¹¹ the Market Research and Intelligence Association (MRIA),¹² and the European Society for Opinion and Marketing Research (ESOMAR).¹³

28. The standards upheld by these organizations set guidelines for all aspects of the research process, including study design, selection and treatment of subjects, data collection procedures, data integrity, statistical analysis, and data interpretation and presentation. Consistent across these standards are the principles of forthrightness in the design and execution of research as well as clarity in the presentation and interpretation of data.
29. For example, MRS sets out standards of sound questionnaire design, stating that researchers should ensure that:
- Questions are fit for [the] purpose [being researched];
 - The design and content of questionnaires are appropriate for the audience being researched;
 - Respondents are able to answer the questions in a way that reflects the view they want to express;

⁸ American Association for Public Opinion Research, *AAPOR Code of Professional Ethics & Practices* (2005). <http://www.aapor.org/aaporcodeofethics>.

⁹ World Association for Public Opinion Research, *WAPOR Code of Professional Ethics and Practices*, <http://www.unl.edu/WAPOR/ethics.html>.

¹⁰ Council of American Research Organizations, *Code of Ethics and Standards for Survey Research*, (2008). <http://www.casro.org/pdfs/CodeVertical-FINAL.pdf>.

¹¹ International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>.

¹² Market Research and Intelligence Association, *Code of Conduct for Members* (2007). <http://www.mria-arim.ca/STANDARDS/CODE2007.asp>.

¹³ European Society for Opinion and Marketing Research, *ICC/ESOMAR International Code on Market and Social Research*. http://194.38.169.84/uploads/pdf/professional-standards/ICCESOMAR_Code_English_.pdf.

- Respondents are not led toward a particular answer;
- Answers are capable of being interpreted in an unambiguous way.¹⁴

30. The ISI warns against data misuse and misrepresentation in its *Declaration on Professional Ethics*:

The statistician should consider the likely consequences of collecting and disseminating various types of data and should guard against predictable misinterpretations or misuse...[He/she] should also not engage or collude in selecting methods designed to produce misleading results, or in misrepresenting statistical findings by commission or omission.¹⁵

31. The AAPOR *Code of Professional Ethics & Practices* mirrors this, stating that researchers should:

Exercise due care in developing research designs and survey instruments, and in collecting, processing, and analyzing data, taking all reasonable steps to assure the reliability and validity of results.¹⁶

32. In addition, the AAPOR code specifies that “good professional practice” obliges the researcher to provide complete information about his/her research design, including the exact wording of the questions asked, description of the sampling frame, sample sizes, eligibility criteria, and a discussion of the precision of the findings. Furthermore, the ICC/ESOMAR *International Code on Market and Social Research* states that “researchers shall ensure that market research projects are designed, carried out, reported and documented accurately, transparently and objectively,”¹⁷ and that “researchers shall always be prepared to make

¹⁴ Market Research Society, *MRS Code of Conduct* (2005). <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, paragraph B.14.

¹⁵ International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>.

¹⁶ American Association for Public Opinion Research. *AAPOR Code of Professional Ethics & Practice* (2005). www.aapor.org/AAPOR_Code.htm.

¹⁷ http://www.iccwbo.org/uploadedFiles/ICC/policy/marketing/Statements/ICESOMAR_Code_English.pdf, p. 4.

available the technical information necessary to assess the validity of any published findings.”¹⁸ Similarly, the UK-based Market Research Society states in its *Code of Conduct* that researchers “must comply with reasonable requests to make available to anyone the technical information necessary to assess the validity of any published findings from a research project.”¹⁹ The International Statistical Institute’s *Declaration on Professional Ethics* states that researchers “should provide adequate information to colleagues to permit their methods, procedures, techniques and findings to be assessed.”²⁰

33. By following these and the other standards prescribed in its code, the AAPOR states that researchers can “support sound and ethical practice in the conduct of public opinion research and in the use of such research for policy- and decision-making in the public and private sectors.”²¹
34. These international standards of survey research serve as best practice guidelines to ensure sound research. To the extent that a study deviates from these standards, the results should be treated with increased caution.
35. In addition to the above, I have reviewed the chapter of the U.S. Federal Judicial Center’s Reference Manual on Scientific Evidence, second edition (the “FJC Manual”) that deals with consumer survey research.²² The Federal Judicial Center is the education and research agency for the U.S. Federal Courts, and the FJC Manual was prepared in order to respond to a recommendation of the U.S. Federal Courts Study Committee that the Federal Judicial Center

¹⁸ http://www.iccwbo.org/uploadedFiles/ICC/policy/marketing/Statements/ICCESOMAR_Code_English.pdf, p. 6.

¹⁹ <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, p. 16.

²⁰ <http://isi.cbs.nl/ethics.htm>.

²¹ American Association for Public Opinion Research. *AAPOR Code of Professional Ethics & Practice* (2005). www.aapor.org/AAPOR_Code.htm.

²² The FJC Manual is available at <http://www.fjc.gov/pdf/nsf/lookup/sciman00.pdf>.

prepare a manual to assist judges in managing cases involving complex scientific and technical evidence.²³

36. The chapter of the FJC Manual that deals with consumer research (Chapter 6: “Reference Guide on Survey Research”) was authored by Dr. Shari Seidman Diamond,²⁴ who wrote that it is intended to assist U.S. federal judges “in identifying, narrowing, and addressing issues bearing on the adequacy of surveys whether as offered as evidence or proposed as a method for developing information.”²⁵ Dr. Diamond’s chapter of the FJC Manual provides sound guidance to assessing the overall validity and reliability of survey evidence which is of relevance to my assessment of consumer survey research relevant to this report. Specifically, I have considered the following principles stated by Dr. Diamond in conducting my review:

- (a) an appropriate universe or population should be identified when designing a survey;²⁶
- (b) questions in the survey should be clear, precise and unbiased, and filter questions should be included to reduce guessing;²⁷
- (c) in order to test a causal proposition, the survey should include an appropriate control group or question;²⁸
- (d) the survey report should include complete and detailed information on all relevant characteristics;²⁹ and

²³ FJC Manual, page v.

²⁴ Dr. Shari Seidman Diamond, J.D., Ph.D, is Professor of Law and Psychology, Northwestern University, Evanston, Illinois, and Senior Research Fellow, American Bar Foundation, Chicago, Illinois. The second edition of FJC Manual is available from: [http://www.fjc.gov/public/pdf_nsf/lookup/sciman00.pdf/\\$file/sciman00.pdf](http://www.fjc.gov/public/pdf_nsf/lookup/sciman00.pdf/$file/sciman00.pdf).

²⁵ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 231.

²⁶ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 239.

²⁷ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 248-249.

²⁸ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 256.

²⁹ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 270.

(e) interviewers should be appropriately selected and trained.³⁰

37. I acknowledge that Dr. Diamond's chapter in the FJC Manual has been prepared for the purposes of the assessment of consumer survey evidence in the context of the American legal system, specifically, to determine whether survey evidence presented in U.S. Federal Courts is of sufficient reliability as to clear the hurdles required to be considered legal evidence. I further note that academic researchers are not bound by the FJC Manual because it addresses survey evidence in the legal context. However, the principles presented by Dr. Diamond are firmly rooted in the scientific discipline of consumer survey research, and are therefore informative in the assessment of any consumer research study.

Methodological Limitations

38. The methodological rigor of a study must be confirmed prior to considering the results. It is the responsibility of the researcher to identify and address any methodological issues that arise in the design and execution of a study. For example, the researcher must ensure that a proper sampling technique is applied such that the study's sample is representative of the population of interest. The researcher conducting the study should be afforded a reasonable degree of deference as to the particular design decisions made, as reasonable variations in study design do not necessarily negate the results and, indeed, no study is perfect.

39. This is not to say, however, that methodological weaknesses do not affect the quality of results attained in a study. Often, methodological limitations are considered as a factor when evaluating the weight of the evidence proffered by the researcher. In more egregious cases, as noted already, the methodology is so severely flawed that the results cannot be relied upon for any purpose.

Study Age

40. A consumer research study can only be considered relevant insofar as it is reflective of the market conditions and regulatory environment to which it is to be applied.³¹ This is determined, in part, by when the research was executed.

³⁰ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 264.

41. Consumer research generally has a limited lifespan in that one is provided a snapshot of the social, market, and regulatory environments as they existed at the time of data collection. To the extent that these factors change over time, a study may become less applicable. For this reason, it is advisable that regulators primarily focus on evidence from research that was conducted under conditions that reflect the current social and policy environment and that older studies be weighted accordingly.

Question Design

42. A question should not cue or influence a respondent's response, i.e., "beg the answer." Questions should not make assumptions about a respondent's knowledge or experiences. Questions should also be clear, and the researcher should confirm that the respondent has understood the question before asking the respondent to offer an answer. When appropriate, respondents should be given the opportunity to give a "don't know" or "no opinion" answer so as not to force them into making a choice that does not reflect their true opinion. Ensuring proper question design is a requirement that is reflected across internationally accepted research standards.³²
43. A commonly encountered flaw in survey-based research is biased survey question design. Rather than objectively measuring a variable of interest, the presentation of leading questions yields a biased result. Examples of factors that contribute to leading questions include unclear wording, the suggestion of an unrealistic hypothetical, and the assumption of facts, among others.³³
44. An example of a leading question would be "Has the higher cost of coffee caused you to consume less coffee?" The wording of this question not only suggests that the respondents'

³¹ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 63.

³² See, for example, Market Research Society, *MRS Code of Conduct* (2005). <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, paragraph B.14; American Association for Public Opinion Research, *AAPOR Code of Professional Ethics & Practices* (2005). <http://www.aapor.org/aaporcodeofethics>, paragraph 1A.

³³ Rea & Parker (2005). *Designing & Conducting Survey Research: A Comprehensive Guide, 3rd Edition*. San Francisco: John Wiley & Sons, Inc., p. 52-60.

coffee consumption has changed, but it also draws the respondent's attention to the price. A more sound way to explore this issue would be to ask, "Have your coffee consumption habits changed in the past six months?" and, if yes, "How have they changed?" and "Why?" Posed in this way, the researcher does not introduce information to the respondent, but rather objectively gauges the respondent's unbiased opinion on the topic at hand.

45. Leading questions, when exacerbated by the context, can result in invalid and unreliable findings that cannot be used to draw any conclusions about the sample population or to make predictions about the wider population in general. For example, asking a respondent, "How much did you enjoy the film 'Gone With The Wind?'" is expressly leading in that it (a) suggests that the respondent has seen the film; and (b) that he/she enjoyed it to some degree. It is utterly lacking in neutrality and therefore would be expected to yield results that are less than a true measure of the phenomenon.
46. Conversely, other leading questions do not affect the results in a meaningful way. A question that asks "You are a girl, right?" is explicitly leading in that it is strongly suggestive that the respondent is a female. However, the likelihood that this leading question would impact the data collected is minimal because it is unlikely that a male respondent would misrepresent his gender simply because of the leading nature of this question.
47. In the worst cases, findings based on leading questions are invalid and unreliable and cannot be used to draw any conclusions about the sample population or to make predictions about the wider population in general.
48. Another type of flawed question is misguided or off-point questions which do not measure the variable of interest, but instead, due to their poor design, measure something else. Conclusions drawn from such questions must also be analyzed with caution.

Researcher Objectivity

49. The power of a researcher to influence results is great. Therefore, professionalism and objectivity must be paramount. A researcher, whatever his or her views or opinions on a topic, must ensure that the study design is impartial and not designed to yield any particular

result.³⁴ To the extent that an author's personal views or beliefs influence the study design, the study's reliability and validity suffers. Indeed, there may be some cases where the introduction of bias is so great that the study cannot be used at all.

Interviewer/Respondent Bias

50. To the extent that it may bias the results, neither respondents nor persons responsible for the data collection (i.e. the interviewers) should be informed as to the sponsor or purpose of the study.^{35,36} This “double-blinding” of the study serves two purposes. First, it ensures that respondents do not try to give “correct” answers or answers they believe the researcher wants to hear.³⁷ For example, if respondents are informed that a study is sponsored by the national department of health, they might be inclined—whether intentionally or unintentionally—to answer questions in a way that reflects that they have a healthier lifestyle than they actually do. This data would be biased and would not be a valid representation of the sample's actual habits.
51. Additionally, the double-blind format ensures that the interviewers do not influence the results given by respondents. For example, if an interviewer knows the purpose of a study, he or she may—again, intentionally or unintentionally—read the questions in such a way as to emphasize or downplay certain answer options, or otherwise change their voice inflection in such a way as to influence the answer offered by the respondent. Again, this influence results in biased results that are not truly representative of the sample.

³⁴ International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>, paragraph 1.3; American Association for Public Opinion Research, *AAPOR Code of Professional Ethics & Practices* (2005). <http://www.aapor.org/aaporcodeofethics>, section IA.

³⁵ World Association for Public Opinion Research, *WAPOR Code of Professional Ethics and Practices*, <http://www.unl.edu/WAPOR/ethics.html>, paragraph II.A.10.

³⁶ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 124.

³⁷ Bradburn, Sudman & Wansink (2001). *Asking Questions: The Definitive Guide to Questionnaire Design*. San Francisco: Jossey-Bass, p. 11.


52. Study designs that in any way inform the interviewer or the respondent of the sponsor or purpose of the study should be considered less reliable than studies in which this is not an issue, and should be weighted accordingly.

Recall Reliability

53. As is explained in more detail in paragraphs 21 through 23 above and in Exhibit 4, different study designs should be accorded varying levels of weight. Recall reliability is also an important methodological consideration. Observing what people do is a better predictor of behavior than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report they have done.³⁸ In consumer research, the gold standard is to get as close as one can to observing behavior. For example, in shopping behavior, the greatest insights into what people do when shopping has come from hidden cameras in retail environments, not from what people say they have done or will do.

54. The gradient of recall reliability, from most reliable to least reliable, is generally as follows:

Table 1. Recall Reliability by Data Collection Method and Research Type.

Reliability	Data Collection Method	Research Type
	Direct observation	Observed Behavioral
	Recall of own recent behavior ("exit interview")	Observed Behavioral
	Recall of non-recent own past behavior	Self-Reported Behavioral
	Prediction of future own behavior	Opinion / Attitudinal
	Least reliable	Prediction of others' future behavior

55. The table above demonstrates that depending on the study design employed, variations in recall reliability can occur.

³⁸ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. The Dryden Press, Orlando, FL, p 209; Synovate, "Measuring Buying Intention: How Valid is the Estimate?" <http://www.synovate.com/insights/research-on-research/read-23.html>.

Age of Respondents

56. Conducting research among youth presents particular issues that must be accounted for to ensure the reliability of the data collected.³⁹ Young respondents are more likely to feel pressured during an interview situation; such pressure can result in answers that are inaccurate.⁴⁰
57. It is the researcher's responsibility when interviewing minors to design studies that are capable of yielding reliable and valid results. One can ask a child a factual question—for example, "What is your age?"—and be confident, within a degree of reason, that the recollection of the respondent is accurate and therefore reliable and valid.
58. It is much more difficult to ask a minor a difficult policy question and have an acceptable degree of confidence that the information collected will have any resemblance to the effect that would be observed if the policy were actually enacted. For example, asking a minor "Will young people buy fewer bus passes if fares are increased?" is unlikely to generate reliable data. Other than potentially being a consumer of public transportation services, a minor presumably has no specific qualifications to enable him or her to predict the impact of a fare increase.
59. Additionally, respondent fatigue is an important factor in any survey of moderate to excessive length; the importance of this factor is compounded in studies conducted among youth due to reduced capacity of young respondents to afford the directed attention required to respond with accurate responses.⁴¹

Cross-Cultural Applicability

60. Cultures can have unique characteristics that must be accounted for when designing a study, and specifically, a questionnaire. Cultural differences exist both between countries and,

³⁹ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. The Dryden Press, Orlando, FL, p. 387-390.

⁴⁰ Weber, Miracle & Skehan (1994). "Interviewing Early Adolescents: Some Methodological Considerations." *Human Organization*, Vol. 53, No. 1, p. 42-47.

⁴¹ Weber, Miracle & Skehan (1994). "Interviewing Early Adolescents: Some Methodological Considerations." *Human Organization*, Vol. 53, No. 1, p. 42-47.

indeed, in many cases, within different geographic regions of one country. For example, in countries where there is more than one native language, or when making country-to-country comparisons, the researcher must ensure that the questionnaire cues the same cognitive response across all respondents. To the extent that this is not accounted for, the data can reflect unique cultural characteristics that are not directly comparable.

Analytical Limitations

61. In addition to assessing the methodological characteristics of a study, it is also necessary to determine whether analytical limitations affect the study's reliability. Some potential analytical limitations are discussed below.
62. According to internationally accepted research standards, authors should refrain from projecting results from a sample onto the wider population unless the sample is representative of a larger population or market and proper adjustments (e.g., weighting) have been made.⁴² Similarly, one should use extreme caution in projecting the results of a study conducted in one market to the population of another where the prevailing cultural and/or marketplace characteristics differ significantly from the characteristics of the original study. Even within markets, wide variations may occur as a result of difference in age, social group, or lifestyle, for example between urban and rural populations.
63. Furthermore, it is sometimes the case that an investigator, in the effort to support a hypothesis, will suggest a correlation or even a causal relationship by highlighting results that statistical analysis has deemed not significant. This is a misleading practice, as it is widely recognized in the research community that statistical significance is a necessary pre-requisite in determining that a causal relationship is an observed result and not caused by chance or error or other factors.⁴³

⁴² The use of unsupported results is cautioned against by internationally accepted research standards, See International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>, paragraphs 1.3, 3.1.

⁴³ Thompson, Bruce (1994). "The Concept of Statistical Significance Testing." *Practical Assessment, Research & Evaluation*, Vol. 4, No. 5.

64. Researchers must be careful to only draw those conclusions that are supported by the data; conclusions that stray beyond this are speculative.⁴⁴ In interpreting study results, authors sometimes make “leaps” between the data yielded by the study and the conclusion the author puts forth in a discussion section. Such discussions must be recognized as speculative and not always directly supported by the study’s data.

Review of Specific Studies

65. As discussed above at paragraphs 9 through 11, I have reviewed each of the studies cited in the Possible Revision and the Impact Assessment against the standards discussed above. In so doing, it became apparent that certain studies, due to their methodological design, have the potential to provide information regarding the behavioral impact of an increase to the size of health warnings on cigarette packs, while others do not have this potential.

66. I have comprehensively reviewed each study that has the potential to impact the discussion on potential behavioral effects of an increase to the size of health warnings against the evaluation criteria adopted in my 2010 Report. I set out below my findings in respect of each of the following studies:

- Vardavas et al. (2009). “Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels.” *European Journal of Public Health*. Vol. 19, No. 2. p. 212-217 (“Vardavas et al. (2009)”).
- White et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1562-1571 (“White et al. (2008)”).
- Borland et al. (2009). “Impact of graphic and text warnings on cigarette packs: findings from four countries over five years.” *Tobacco Control*. Vol. 18, p. 358-364 (“Borland et al. (2009)”).

⁴⁴ International standards urge researchers not to draw unsupported conclusions. See American Association for Public Opinion Research, *AAPOR Code of Professional Ethics & Practices* (2005). <http://www.aapor.org/aaporcodeofethics>, paragraph I.A.2, I.A.3.

- Thrasher et al. (2011). “Estimating the impact of pictorial health warnings and “plain” cigarette packaging: Evidence from experimental auctions among adult smokers in the United States.” *Health Policy*, Vol. 102, No. 1 (“Thrasher et al. (2011)”).
- Wardle et al. (2010). “Evaluating the impact of picture health warnings on cigarette packets.” London: Public Health Research Consortium (“Wardle et al. (2010)”).
- Hammond, D. (2011). “Health warning messages on tobacco products: a review.” *Tobacco Control*, Vol. 20, p. 327-333 (“Hammond (2011)”).

67. Certain of the studies listed above at paragraph 11 have been previously reviewed in my 2010 Report. I confirm that my views on these studies remain the same. To avoid repetition, I have not sought to set out in this report my views on these studies.

Vardavas (2009)

Introduction

68. This study sought to gauge the reactions of Greek adolescents to proposed European Union pictorial health warnings as compared to the current text health warnings in place in Greece at the time of the study. Specifically, the authors sought to evaluate the potential of the pictorial messages as a source of information and as a means of preventing smoking initiation.

69. The authors interviewed 574 students ranging from 12 to 18 years of age in Crete, Greece. Respondents were shown seven sets of side-by-side warnings—one text only and one pictorial and text—in random order. In each pairing, respondents were asked to select the warning that was more likely to prevent them from smoking. Respondents were then asked a series of attitudinal questions regarding the information presented in and the strength of the message conveyed by the warning they selected.

Inappropriate Design

70. The results of this study do not give a valid estimation of the actual impact of the pictorial warnings tested because the authors utilized an inappropriate survey design. Respondents were presented with side-by-side stimuli and were asked “Which warning is more likely to prevent you from smoking?” This experiment design does not yield meaningful results.

71. The question that was asked of respondents is a prime example of a leading question. By asking respondents “Which warning is more likely to prevent you from smoking,” the researchers suggest, without foundation, that the warnings are inherently capable of affecting respondents’ behaviors—i.e., preventing respondents from smoking. This is an untested, and therefore faulty assumption which leads respondents into making a selection and does not give the respondent the opportunity to opt-out of the question (e.g., with a “neither” or “no opinion” answer option).
72. Additionally, by presenting respondents with the side-by-side choice of a text warning versus a pictorial warning, this question simply gauges the respondent’s preference for one stimulus relative to the other. This design does not give any indication of the magnitude of effectiveness, if any, of the chosen health message in an actual marketplace scenario. Respondents are faced with a choice and they are instructed to make a selection between the two options. This is an exercise that is unrelated to the behavioral impact of the warning messages. Therefore, the data produced by this question are not relevant to a discussion of the impact of pictorial health warnings.
73. A more appropriate design would have separated the respondents into two cells, whereby one group of respondents were shown the text warnings and another group were shown the pictorial warnings, and then asked questions related to the behavioral impact, if any, of the warnings they just viewed. A comparison of these two groups could have yielded a meaningful analysis of the relative potential effectiveness of the text versus pictorial warnings.

Inappropriate Sample

74. This study surveyed both smokers and non-smokers; however, the questionnaire is more applicable to smokers alone. Asking “Which warning is more likely to prevent you from smoking?” is likely irrelevant to non-smokers. Because smoking is not an activity in which they engage, non-smokers do not encounter cigarette packages with the same frequency as smokers. When they do, one would not expect them to exhibit a high level of cognitive processing with respect to the health warning message because they do not smoke. Thus, it is possible that neither warning design shown in the questionnaire is in any way relevant to non-smokers.

75. Furthermore, the study design does not give the respondent the option to answer “neither.” Rather, it forces all respondents, including non-smokers, to assign some level of impact to one of the two warning label formats. This is a faulty design considering that non-smokers do not purchase cigarettes and likely are not impacted by cigarette pack warnings. Therefore, non-smokers should have been excluded from this study.

Unsupported Conclusion

76. Respondents were also asked a question regarding the effectiveness of the warning that they selected (text-only or picture and text). They were asked, “How effective would this warning be in preventing you from smoking?” and asked to rate their response on a five point Likert scale.⁴⁵ The authors do not present the full data for this question, and make a reporting error on the results that are discussed. They state:

Up to 84 percent of interviewed adolescents (non-smokers only) reported that graphic warning labels would be much more effective...in preventing them from initiating smoking *in comparison to existing EU text only warning labels*.⁴⁶
(Emphasis added.)

77. This is a misleading interpretation of the data. The question does not ask the respondent about the warning’s effectiveness relative to the warning that they did not select (as suggested by the text above), but only in absolute terms. Hence, for the authors to be accurate here, this should be stated: “Up to 84 percent of interviewed adolescents (non-smokers only) reported that graphic warning labels would be effective in preventing them from initiating smoking.” This point is moot however: in light of the considerable limitations of this study described herein, this is not a reliable conclusion that can be drawn from this study.

78. Because the authors do not provide data for the text-only warnings, it is impossible to know how respondents rated text-only messages in terms of their ability, if any, to prevent them

⁴⁵ Vardavas et al. (2009). “Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels.” *European Journal of Public Health*. Vol. 19, No. 2, p. 214.

⁴⁶ Vardavas et al. (2009). “Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels.” *European Journal of Public Health*. Vol. 19, No. 2, p. 214.

from initiating smoking. The results from this question are without a point of comparison and are therefore uninformative.

Departure from Marketplace Reality

79. This study is also limited by the authors' treatment of the experimental condition. The study design requires the respondent to make a choice between two pack designs: text-only or picture and text. Because cigarette warning labels comply with the prevailing policy in a particular jurisdiction, such a choice would never occur in the marketplace. The comparison presented to respondents in this study is inherently artificial. Because a respondent would never be faced with such a choice outside of the experimental condition, this design does not yield reliable results that are applicable to any marketplace reality. Again, as discussed above, the use of two different cells could have prevented this limitation.

Regional Limitations

80. The projectability of this study is limited by the fact that the sample consists of respondents from Crete, Greece. It is unknown whether the opinions and/or behavioral intentions of Greek high school students mirror those of the Greek public more broadly, or of any other population in Europe. For this reason, the study results should be viewed with this limitation in mind.

Ethical Consideration

81. The authors report that they informed the respondents that "their levels of cotinine (the main metabolite of nicotine) would be derived from saliva samples for verification of their smoking status."⁴⁷ It appears that the authors did not actually follow through with this test. However, threatening such a tactic rests on dubious ethical ground.

82. Informing the respondent that they will be medically tested to ensure that they are not lying is a scare tactic. It communicates a lack of trust on the part of the researcher and asserts the authoritarian nature of the relationship at hand—i.e., that the adult researchers are in control.

⁴⁷ Vardavas et al. (2009). "Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels." *European Journal of Public Health*. Vol. 19, No. 2. p. 214.

Indeed, it is unlikely that such a tactic would have been employed if the subjects had been adults, as adults would not tolerate this.

83. The authors' use of this tactic creates an adversarial interviewing environment. This is undesirable in that the researcher's ultimate goal is to elicit accurate, honest answers from his or her respondents. Because it is unknown how, in this case, the authors' threat of confirming respondent's smoking status may have influenced respondents' answers to any or all of the interview questions, the integrity of the study data is further called into question.

Conclusions

84. This study contains a variety of methodological limitations, including a flawed study design, inappropriate sample, unsupported conclusions, and ethical limitations that call into question the reliability of the findings. Accordingly, this study cannot be considered reliable evidence in support of any proposal to institute larger health warnings.

White (2008)

85. This study attempts to measure the impact of newly introduced graphic health warnings in Australia by evaluating the findings of two cross-sectional school-based surveys of 12 through 17 year olds. The first survey data (N=2,432) was collected in 2005 (baseline) and the second survey data (N=2,050) was collected in September 2006 (follow-up).
86. In March 2006, between the baseline and follow-up studies, Australia introduced larger health warning messages on cigarette packs. This study found that participants had thought about quitting and forgoing cigarettes more frequently after the introduction of larger graphic health warnings, and that intention to smoke was lower among those who had thought about the warning labels.
87. There are a number of weaknesses in this study that materially impact the reliability of the findings.
88. This study does not sufficiently isolate the changes to the size and the introduction of pictorial health warning messages. In addition to the health warnings being introduced in the time between the two data collection points, "a mass media campaign promoting the health

warnings”⁴⁸ was also conducted. There was also a change in the content and the rotation of the warnings. As the authors note, this limited their ability “to determine the sole effect of the warning labels on adolescents’ smoking behaviours.”⁴⁹

89. So, while the authors’ claim that students paid attention to, thought, and talked about the warnings at increased levels from the baseline to the follow-up measurements, they do not attempt to assess whether that increase is due to other factors (e.g., the contemporaneous media campaign or the change in warning content) or is a result of the introduction of larger pictorial health warnings.
90. One of the variables measured to assess the effectiveness of the new warnings is how frequently the warning labels were read. The study found that there was no increase between the baseline and follow-up measurements in how frequently the warning labels were read by these students.⁵⁰
91. So, while the authors conclude that “it is possible that the introduction of graphic warnings labels may lead to a reduction in adolescent smoking,”⁵¹ the data supporting this is clouded, at best, by the mass media campaign that also ran in the time between these studies.
92. The authors also claim to have found a correlation between the students’ attitudes toward cigarette packs (positive or negative) and smoking intentions (increased or decreased). Whereas the authors attempt to assign a direction to this correlation, suggesting the favorable influence of the warnings has impacted smoking intentions, the true direction of this relationship is unknown. For example, those with decreased smoking intentions may rate

⁴⁸ White, Victoria et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1570

⁴⁹ White, Victoria et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1570

⁵⁰ White, Victoria et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1568, Table 3.

⁵¹ White, Victoria et al. (2008). “Do graphic health warning labels have an impact on adolescents’ smoking-related beliefs and behaviours?” *Addiction*. Vol. 103, p. 1569

packs lower because they have less involvement with the product than those with increased smoking intentions.

93. In summary, the authors' failure to control for the influence of the mass media campaign conducted between the baseline and follow-up surveys compared in this study nullifies their findings regarding the impact of larger health warnings. Therefore this study does not provide meaningful support for the introduction of larger health warnings.

Borland et al. (2009)

Introduction

94. The authors in this study use ITC Project Four Country Survey annual data from 2002 through 2006. Four measurements were evaluated over this period: salience of health warning label, cognitive response to health warning label, forgoing cigarettes as a result of the health warning label, and health warning label avoidance.
95. Australia introduced new graphic health warnings before the 2006 wave of data collection. The UK introduced larger text warnings before the 2003 wave of data collection. Canada introduced new graphic health warnings in 2000, about two and a half years prior to the first wave of data collection in 2002. The warning labels in the U.S. had not changed over the data collection period evaluated.
96. It should be noted that this study makes complex statistical claims upon which I do not comment. This study is based on ITC data, which is not publicly available and to which I did not have access (see discussion below). A full statistical examination of the data is impeded without such access. Additionally, even if the ITC data were available to me, robust statistical modeling is more appropriately analyzed by an expert working within the field of statistics. For these reasons, my opinions regarding the statistical claims in this study are limited in scope.

ITC Unavailability of Data

97. The ITC Project data—upon which this study relies—is made available only to approved researchers, and the ITC has specifically stated that it will not share data with the tobacco

industry or any affiliated party.⁵² This policy stands in contrast with recommended data transparency practices as recommended by international consumer survey research organizations and prevents me from completing a full independent analysis of the data reported in this study.

Cross-country comparisons

98. Using intra-country and cross-country comparisons, the authors sought to establish that the warning labels impacted the measurements of interest. These comparisons, however, show contradictory results.
99. Cross-country comparisons of absolute (not relative) findings may be problematic due to the constellation of social, political, economic and other confounding variables that exist between people from different nations. For example, the authors report a cognitive score for Australian respondents of approximately 1.7 in 2005. The UK score for this period is approximately 1.9. However, despite the numeric difference, one cannot say that the UK score is “higher” with any degree of reliability. When asked to rate the extent to which the warnings made the respondent think about the health risk of smoking, for example, there are many variables, other than the health warning, that may cause a UK respondent to respond differently than an Australian respondent. Therefore a direct comparison between the absolute variable scores between countries is not meaningful due to the influence of confounding variables that has not been accounted for.
100. An example of the unique country environments that exist can be found by looking at tobacco related activity in Australia during this 2005 period discussed above. Indeed, this study has not accounted for the many variables that may have influenced respondents over this period. It is my understanding that such variables include:
- Tobacco and Other Smoking Products Amendment Act 2004 with certain public smoking bans becoming effective 1 January 2005;
 - Public Health Amendment Act 2004 with certain further public smoking bans becoming effective 1 January 2005;

⁵² <http://www.itcproject.org/datarequ>

- A new AUS\$300,000 ‘Quit Victoria’ anti-smoking campaign was launched by The Victoria State Government in January;
- Butt Free City campaign is launched in Sydney in March;
- Tobacco Product Regulation (Further Restrictions) Amendment Act with certain further public smoking bans becoming effective in October;
- Australian Consumer and Competition Commission (ACCC) implemented descriptor bans in November; and
- A national media campaign launched to coincide with descriptor bans.

101. Therefore, comparing an Australian score to a UK score ignores the many influences that make these two cohorts unique and does not sufficiently isolate any particular variable.

102. The lack of data collection until two years after the Canadian implementation of an increased warning label makes impact comparisons with that country also unreliable. For Australia and the UK, impact comparisons are conducted with data collected less than a year after the introduction of the new warning. In Canada, not only is there no data from before the introduction of their increased warning label, but the first wave of data was not collected until two and half years after that introduction. The extended difference in time that has lapsed between the event and the measurement of that event results in data sets that are not compatible and therefore cannot be compared.

103. It is also worth noting that the warning labels in each country are unique to that country in regard to content, size and placement. The stimuli to which the respondents are exposed are not the same; therefore comparisons of their responses to these stimuli are problematic. The stimuli themselves are a confounding variable between countries.

Intra-country comparisons

104. Intra-country comparisons in the UK and Australia⁵³ after the introduction of an increased health warning are also problematic in that the magnitude of any increase is limited and other variables have not been accounted for as potential factors driving an increase.
105. In the UK, only two of the four variables measured showed statistically higher measurements, while one, actually forgoing cigarettes as a result of the new health warning, was not statistically different after the introduction.⁵⁴
106. In Australia, while some level of increase was shown for all four variables, this increase cannot be attributed with confidence to the warning labels. As the authors concede, “Australia may have also been partly influenced by exposure to tobacco control mass media campaigns using identical imagery to that of some of the new warnings.”⁵⁵ This environment, which was not controlled for in this study, severely weakens the reliability of the data as it relates to warning labels alone.

Conclusion

107. Both the cross-country comparisons and intra-country analyses presented in this study lack the reliability to support the author’s conclusions. Specifically, this study suffers from the following limitations:
- This study relies on ITC data which is unavailable to me and therefore impedes a full review of the findings reported by the authors;

⁵³ No measurement exists in this data set prior to the Canadian increased warning introduction. The U.S. warning did not change over this period.

⁵⁴ Borland et al. (2009). “Impact of graphic and text warnings on cigarette packs: findings from four countries over five years.” *Tobacco Control*. Vol. 18, p. 361, Table 1. The other variable, cognitive response, was not measured prior to the introduction.

⁵⁵ Borland et al. (2009). “Impact of graphic and text warnings on cigarette packs: findings from four countries over five years.” *Tobacco Control*. Vol. 18, p. 362.

- The cross-country comparisons presented in this study are inherently unreliable due to confounding variables which have not been controlled for;
- Differences in the elapsed time between a warning change and data collection across countries further reduces the reliability of the cross-country comparisons presented in this study; and
- Within-country analyses presented in this study do not provide credible evidence as to the impact of larger health warnings, as results were inconclusive and confounding variables were not controlled for.

108. Therefore this study does not provide credible evidence in support of the introduction of larger health warnings.

Thrasher et al. (2011)

109. This study used a bidding experiment to examine the price elasticity of demand for four cigarette packages each bearing a different health warning label format. In-person interviewing took place across four U.S. grocery store locations between May and September 2009; 402 smokers participated in the study.⁵⁶

110. I am aware that this study has been reviewed in full by Professor Timothy M. Devinney in his report titled “*Analysis of Consumer Research Evidence on the Impact of Plain Packaging for Tobacco Products (Updated to 2012)*” (the “Devinney Report”).⁵⁷ Principal among Professor Devinney’s conclusions about this study are 1) that the study lacks a fully balanced orthogonal design in that it fails to test all possible conditions within its experimental design; and 2) that the methodological design of the study reveals the purpose of the study to participants, thereby creating the potential for bias in the results.

111. I have read and considered the Thrasher et al. study in full and I concur with Professor Devinney’s conclusions with regard to the methodological limitations of this study. Insofar as Professor Devinney has already undertaken a full written review of this study, it is

⁵⁶ Thrasher et al., p. 2.

⁵⁷ Available at www.jti.com/files/9813/4149/4426/Prof_Devinney.pdf; See para. 4.43 through 4.48.

unnecessary for me to replicate that effort as part of my current assignment. Accordingly, I adopt in full Professor Devinney's analysis with regard to the Thrasher et al. study⁵⁸ for the purpose of this report.

112. Based on the considerable methodological limitations outlined in Professor Devinney's review of the Thrasher et al. study, I do not consider the evidence presented in this study to be reliable evidence with regard to the potential impact of larger health warnings.

Wardle et al. (2010)

Introduction

113. This is a comprehensive study which was conducted in the UK in 2010 to "assess the impact and effectiveness of the new picture health warnings on cigarette packets among the English population."⁵⁹ Pictorial health warnings were first introduced in the UK on October 1, 2008.

114. Cross sectional data was collected from independent samples in two waves: one in August through September 2008 (prior to the introduction of the pictorial health warnings) and the other in May through July 2009 (following full implementation of the pictorial health warnings). Smokers and non-smokers aged 13 and older participated in the study.

115. Wave 1 of the study included 2,227 respondents and Wave 2 included 2,279 respondents.⁶⁰ Respondents completed a telephone interview which was designed to gauge their perceptions of the risks of smoking, smoking-related behavior, and attitudes regarding health warnings and other smoking related topics.⁶¹

116. The Wardle et al. (2010) study was not designed to generate predictive results with regard to changes in smoking prevalence from pre- to post-implementation of pictorial health warnings: "This study was not designed to detect statistically significant changes in smoking

⁵⁸ Devinney Report, June 29, 2012, at para. 4.43 through 4.48.

⁵⁹ Wardle et al. (2010), p. 5.

⁶⁰ Wardle et al. (2010), p. 12.

⁶¹ Wardle et al. (2010), p. 5.

prevalence; a much larger sample is needed to achieve this.”⁶² Rather, the Wardle et al. (2010) study seeks to provide information on a range of self-reported measures related to participants’ knowledge, understanding, and opinions about smoking and its risks as well as participants’ smoking and quitting behaviors.

117. It is important to note that the implementation of pictorial health warnings in October 2008 in the UK was not accompanied by an increase in the size of the health warning on the cigarette pack. Indeed, both prior to and following the implementation of the pictorial warnings in 2008, health warnings on cigarette packs in the UK covered 30 percent of the front and 40 percent of the back of the package.⁶³ The Wardle et al. (2010) study therefore does not directly test for any potential change in the size of health warnings, but instead examined the impact of a change in warning content (i.e., from text-only warnings to pictorial warnings). Therefore, the study does not present any primary evidence in respect of the size of the health warning and its impact, if any, on actual smoking behavior.

Untested opinions

118. Wardle et al.’s findings showed that there was minimal (often not statistically significant) impact on the variables of interest (e.g., knowledge, awareness, behavior, etc.) from pre- to post-implementation of pictorial health warnings in the UK. This range of findings was all that the Wardle et al. (2010) study was designed to yield and indeed, the authors did not collect any data outside of this scope of study.

119. Nevertheless, the authors propose an untested and unsupported conclusion regarding the size of health warning messages after presenting their own findings:

Research evidence has consistently demonstrated that the size and placement of the warning is critical to impact upon smokers. In particular, size and placement of the warning on the front of the packet is paramount, with recommendations being that larger is better than smaller and that messages should be placed on the front of cigarette packets for maximum impact (Hammond 2007; Borland et al, 2009; Créatec 2008). Evidence from this study among young people lends

⁶² Wardle et al. (2010), p. 7.

⁶³ See for example, Wardle et al. (2010), p. 71.

some support to this view. The impact of the picture health warnings upon young people was negligible. It is notable that even after the picture health warnings were introduced, the most recognised health warning message by young people continued to be the front of packet message 'Smoking Kills'. This suggests that youth in particular may be most susceptible to the placement of the warning. Further work is needed to investigate this issue fully, but this preliminary evidence suggest that if warning messages are to be effective in communicating the health risks of smoking to youth, they should be positioned in the most visible place on cigarette packets; the front.⁶⁴

120. The excerpt above is an example of an unfounded leap that is made by the authors to proffer a decidedly advocatory position. The Wardle et al. (2010) study does not test for the impact of size in any way; yet despite this, the authors imply that, in the absence of a strong impact resulting from the implementation of pictorial warnings, size must be an important factor in creating awareness and behavioral change in consumers with regard to smoking. In fact, this study presents no empirical evidence to support this position. Accordingly, Wardle et al.'s comments regarding the size of the health warning amount to nothing more than untested opinions put forward by the authors.

121. As shown in the quotation above, Wardle et al. (2010) cite several studies in support of their opinions regarding larger health warnings. These studies include the following:

- Borland et al. (2009).
- Créatec (2008).
- Hammond et al. (2007). "Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study." *American Journal of Preventive Medicine*, Vol. 32, No. 3 ("Hammond et al. (2007)").

122. I have addressed the Borland et al. (2009) study at paragraphs 94 to 108 above. In addition, I have previously reviewed Créatec (2008) and Hammond (2007) study at paragraphs 250 through 262 of my 2010 Report and paragraphs 132 through 144 of my 2010

⁶⁴ Wardle et al. (2010), p. 71.

Report respectively, and found that neither is reliable evidence as to the potential impact of larger health warnings on smoking behavior.

123. Based on the limitations outlined above, I do not consider the Wardle et al. study reliable evidence regarding the potential impact of larger health warnings.

Hammond (2011)

Introduction

124. This study is a review article wherein the author summarizes the findings of a range of articles presenting evidence on the impact of health warning messages on cigarette packages. Hammond selected from studies that were available by December 2010.⁶⁵ The total sample of 94 articles was comprised of 72 quantitative studies, 16 qualitative studies, 5 multi-component studies (quantitative and qualitative), and one review article.⁶⁶ The studies were conducted across a wide range of countries.⁶⁷
125. Hammond's study is cited in the Impact Assessment to support statements suggesting that larger health warnings may be more effective than text-only warnings at increasing cessation among current smokers⁶⁸ and may increase smokers' and non-smokers' awareness of warnings, knowledge of health risks, depth of processing and quitting behaviors.⁶⁹ However, citing the Hammond article in this regard is problematic in that it contains no original survey research.
126. On reviewing Hammond (2011), it is simply a summary document which presents the findings of other studies rather than presenting its own original consumer survey research. In this regard, the Hammond article is a secondary source on the topic of larger health warnings. Secondary sources are problematic as sources because it is impossible for the reader to

⁶⁵ Hammond (2011), p. 3.

⁶⁶ Hammond (2011), p. 3.

⁶⁷ Hammond (2011), p. 3.

⁶⁸ Impact Assessment at FN 142.

⁶⁹ Impact Assessment at FN 143.

objectively assess the underlying research upon which conclusions are drawn without conducting his or her own extensive research.⁷⁰ For example, in this case, Hammond required that a study's "key measures appear[ed] to be valid"⁷¹ and its "main outcomes [were] defined and measurable"⁷² for that study to be included in his review. However, no additional details about the extent to which the included articles were subjected to objective scientific scrutiny were provided. The reader is therefore asked to accept the author's characterization of the studies as scientifically valid.

127. Thus, although Hammond draws his own conclusions based on his review of the set of selected articles, these conclusions must be regarded with caution, and Hammond's article cannot, in and of itself, be considered reliable evidence in the current debate regarding larger health warnings.

128. Indeed, rather than relying on Hammond's secondary review, a more rigorous approach is to directly examine the relevant underlying primary research studies upon which Hammond's conclusions are based. I have undertaken this task as part of my current analysis with regard to larger health warnings. A review of Hammond's article shows that he cites the following studies in support of his opinions regarding larger health warnings:

- Créatec (2008). I have previously reviewed the Créatec (2008) study at paragraphs 250 through 262 of my 2010 Report.
- Environics (2008). I have previously reviewed the Environics (2008) study at paragraphs 178 through 198 of my 2010 Report

⁷⁰ I have previously addressed the problems associated with relying on secondary resources. See for example, Keegan, W.J. "Third Report concerning Consumer Survey materials relevant to the Display Ban Requirement in England." November 28, 2011, at para. 27-28; Keegan, W.J. "Analysis of Consumer Survey Evidence Relevant to the Display Ban Requirement in England," April 28, 2010, para. Ex.5.65; See also Churchill & Iacobucci (2005). *Marketing Research: Methodological Foundations*, 9th Ed., Thomson South-Western Publishing, p. 169-170, 172.

⁷¹ Hammond (2011), p. 3.

⁷² Hammond (2011), p. 3.

- Elliott & Shanahan (2008). I have previously reviewed the Elliot & Shanahan (2008) study at paragraphs 145 through 177 of my 2010 Report
- White et al. (2008). I have reviewed the White et al. (2008) study at paragraphs 85 to 93 above.
- Borland et al. (2009). I have reviewed the Borland et al. (2009) study at paragraphs 94 to 108 above.
- Fathelrahman et al. (2009). “Smokers’ responses toward cigarette pack warning labels in predicting quit intention, stage of change, and self-efficacy.” *Nicotine & Tobacco Research*, Vol. 11, No. 3 (“Fathelrahman et al. (2009)”).
- Hammond et al. (2003). “Impact of the graphic Canadian warning labels on adult smoking behaviour.” *Tobacco Control*. Vol. 12 (“Hammond et al. (2003)”).
- International Tobacco Control (ITC) (2009). “FCTC Article 11 – Tobacco Warning Labels: Evidence and Recommendations from the ITC Project” (“The ITC Project/ITC Summary Document (2009)”). I have previously reviewed the ITC Project (2009) study at paragraphs 77 through 114 of my 2010 Report.
- Hammond et al. (2006). “Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey.” *Tobacco Control*. Vol. 15, Suppl III (“Hammond et al. (2006)”). I have previously reviewed the Hammond (2006) study at paragraphs 116 through 131 of my 2010 Report.
- BRC Marketing & Social Research (2004). “Smoking Health Warnings Study – Optimising Smoking Health Warnings Stage 2 – Text, Graphics, Size and Colour Testing.” BRC Marketing and Social Research for the Ministry of Health, New Zealand (“BRC Marketing & Social Research (2004)”). I have previously reviewed the BRC Marketing & Social Research (2004) study at paragraphs 274 through 277 of my 2010 Report.

- Lyle (Centre for Behavioural Research) (1992). “Health Warnings And Contents Labelling On Tobacco Products: An Evaluation.” Centre for Behavioural Research (“Lyle (Centre for Behavioural Research) (1992)”).
- Linthwaite (1985). “Health Warnings.” *Health Education Journal* (“Linthwaite (1985)”).
- Rootman et al. (1995). “A Study on Youth Smoking, Key Figures and Findings. A Joint Research Project by: University of Toronto, University of Illinois at Chicago, York University, Ontario Tobacco Research Unit, Addiction Research Foundation.” (“Rootman et al. (1995)”). I have previously reviewed the Rootman et al. (1995) study at p. 18 of my 2008 Report.

129. Several of these studies are cited directly in the Impact Assessment and are discussed above.⁷³ For those not directly cited in the Impact Assessment, and which I have not previously reviewed in my 2010 Report, I have reviewed each additional study cited by Hammond in support of larger health warnings in Exhibit 4 to this report. As shown in these reviews, each of the studies cited by Hammond in support of his arguments in favor of increasing the size of health warnings suffer from significant flaws which render them inherently unreliable.

130. For these reasons, I do not consider the Hammond (2011) study to be reliable evidence regarding the potential impact of larger health warnings.

Conclusion

131. I have undertaken a comprehensive review of all studies referenced in the Possible Revision and Impact Assessment related to the Proposal to increase the size of the health warnings on tobacco products.

132. Among these studies, some had the potential to inform the current debate regarding larger health warnings on cigarette packaging. I conducted a full review of each of these studies in

⁷³ The Environics (2008), Créatec (2008), and Elliot & Shanahan (2008), White et al. (2008) and Borland et al. (2008) studies are directly cited in the Impact Assessment and discussed above.

accordance with the evaluation criteria which I have established herein and in my prior Reports.

133. For those studies that did not have the potential to inform the current debate on larger health warnings, I conducted an analysis of each study to explain its shortcomings and/or lack of applicability to the current debate.

134. Finally, several of the studies cited in the Possible Revision and Impact Assessment referenced relevant underlying research studies which themselves merited examination in respect of the current debate regarding the Proposal. Although not specifically cited by the European Commission, I examined each of these studies in accordance with my evaluation criteria.

135. Upon completing my comprehensive analysis, I have found that no study provides reliable evidence in support of the Proposal to increase the size of the health warnings on tobacco products.

I reserve the right to supplement and revise this report and the opinions expressed herein based on new information provided to me.



Dr. Warren J. Keegan

May 24, 2013

Date

Exhibit 1—Resume of Dr. Keegan

Dr. Warren J. Keegan

Fellow, Academy of International Business

Education

- Doctor of Business Administration, Harvard University (1967)
- Master of Business Administration, Harvard University (1961)
- MS, Economics, Kansas State University (1959)
- BS, Economics, Kansas State University (1958)

Academic Appointments—Full Time, Current and Former

- Distinguished Professor Emeritus, Visiting Professor of Marketing and International Business, Pace University, Lubin School of Business.
- MarkPlus Global Institute, Singapore, Chairman. Responsible for professional post graduate education program of the Institute.
- New York University, Graduate School of Business Administration, Visiting Professor of Marketing. Taught in MBA, PhD and Undergraduate programs.
- The George Washington University, School of Government and Business Administration, Professor of Business Administration. Taught in MBA, Doctoral, and Executive programs.
- Baruch College, City University of New York, Associate Professor of Marketing; Professor. Taught in MBA and PhD programs.
- Columbia University, Graduate School of Business, Assistant Professor; Associate Professor. Taught in MBA, PhD and Executive programs.
- Harvard Business School, Research Associate, Multinational Enterprise Research Project. Project Director: Professor Raymond Vernon.
- University College, Dar es Salaam, Tanzania, Lecturer in Public Administration.
- Sloan School of Management, MIT, Research Assistant.
- IMD, formerly IMEDE, (Institute pour l'Etude des Methode de Direction de l'Enterprise), Lausanne, Switzerland. Research Associate. Assisted Professor David S. R. Leighton in teaching in IMEDE Executive Program and on consulting

assignments. Wrote 14 cases, published in D.S.R. Leighton, International Marketing, McGraw Hill.

Other Academic Appointments—Visiting, Current and Former

- Cranfield University School of Management (UK), Visiting University Professor
- CEIBS (China European International Business School), Shanghai, Professor of Marketing and International Business.
- ESSEC, Cergy-Pontoise, France. Visiting Professor of Marketing and International Business.
- The Wharton School of the University of Pennsylvania, Visiting Professor, Aresty Institute of Executive Education.
- Columbia Business School, Adjunct Professor of International Business, Executive Degree Program for Managers.
- Stockholm School of Economics, Visiting Professor.
- Emmanuel College, Cambridge (UK), Visiting Professor, International Marketing Program.
- University of Hawaii, Advanced Management Program, Professor.
- INSEAD, Fontainebleau, France, Visiting Professor of Marketing, Director European Marketing Program.

Business Experience

Keegan & Company LLC (current)

Litigation consulting and expert testimony in state and federal courts and before administrative agencies.

Warren Keegan Associates, Inc. (current)

Consultant to senior management in the areas of strategic management, global business and marketing strategy. Confidential strategic advisor to CEOs. Author of trade and academic texts on strategic management, marketing, and international business.

MarkPlus Global Institute, Singapore, Chairman

Responsible for professional post graduate education program of the Institute.

Douglas A. Edwards, Inc., Chairman

Leadership responsibility for formulating and implementing business strategy that positioned firm as a unique provider of corporate real estate services in the New York market.

Arthur D. Little

Staff consultant and faculty member of ADL Institute.

Boston Consulting Group

Client assignments in corporate strategy development and implementation. Worked closely with founding partners Bruce Henderson, Jim Abegglen, Si Tillis and Art Contas.

Government of Tanzania, MIT Fellow in Africa

Assistant Secretary, Ministry of Development Planning and Executive Secretary, Economic Development Commission. Member of team which prepared a national Five Year Economic and Social Development Plan.

General Motors Corporation

Marketing Staff, Pontiac Motor Division. Reported to national sales manager.

Professional Association & Editorial Activities**Academy of International Business**

Fellow of the Academy (a lifetime appointment), former officer, active Board Member, and National Program Chairman. Chairman of the Membership Committee of the AIB Fellows.

American Marketing Association

Former Officer, active in national program planning.

Editorial Advisory Board

Board Member, Cranfield School of Management and Financial Times Management Monograph Series.

General Advisory Board

Board Member, *International Business and Investing in Russia*, The Haworth Press.

Marketing Science Institute

Former Co-chairman of research workshops on Global Product Management.

Editorial Advisory and Review Boards (former and current)

- Journal of International Marketing
- Journal of Marketing
- Journal of Segmentation in Marketing
- Journal of International Business Studies
- The Global Economic Quarterly
- Columbia Journal of World Business

- Journal of Business
- Journal of Asia-Pacific Business
- Journal of Marketing Practice
- Applied Marketing Science
- Detroit Journal of Multinational Business
- International Journal of Medical Marketing
- The Academy of Marketing Science Journal

Selected Publications

Keegan, Warren J. and Mark C. Green. *Global Marketing, Sixth Edition*. Englewood Cliffs, NJ.: Pearson Prentice Hall, 2011.

Keegan, Warren J. and Mark Green, *Global Marketing, Fourth Edition*, Chinese Simplified Translation, China Renmin University Press, Hong Kong, Pearson Education Asia Ltd, 2005.

Keegan, Warren J. *Global Marketing Management, Seventh Edition*, Portuguese Translation, Prentice Hall, 2005.

Offensive Marketing: An Action Guide to Gaining the Offensive in Business, First Edition, with Hugh Davidson. Elsevier, Butterworth Heinemann, 256 pages, 2004.

The New Landscape of Global Marketing: Winners and Losers in the 21st Century. Special World Marketing Association Edition, Singapore Nanyang Business Review, Vol. 2 No. 1 January–June 2003.

Global Marketing Management, Seventh Edition, Prentice Hall, Inc., part of Prentice-Hall series in marketing, Philip Kotler, Editor, 2002.

Global Income and Population 2002 Edition: 2002 and Projections to 2010 and 2020, Center for Global Business Strategy, Lubin School of Business, Pace University, New York, New York, 2002.

Marketing Plans That Work: Targeting Growth and Profitability, Second Edition, with McDonald, M. H. B, Butterworth-Heinemann, 2002.

Global Marketing Management: A European Perspective, with Bodo Schlegelmilch, Harlow, England: Pearson Education, 2001.

Princípios de Marketing Global, with Mark C. Green, São Paulo, Brasil: Editora Saraiva, 1999.

Fundamentos de Mercadotecnia Internacional, with Mark C. Green (Primera edición ed.) Naucalpan de Juárez, Edo. de México: Prentice-Hall Hispanoamericana, S.A., 1998.

Principles of Global Marketing, with Mark C. Green, Upper Saddle River, New Jersey: Prentice Hall, Inc., 1997.

Global Marketing Management, Canadian Edition, with F.H. Rolf Seringhaus, Scarborough, Ontario: Prentice-Hall Canada Inc., 1996.

Marketing, Canadian Edition, with Sandra E. Moriarty, Thomas R. Duncan and Stanley J. Paliwoda, Scarborough, Ontario: Prentice-Hall Canada Inc., 1995.

Marketing, Second Edition, with Sandra Moriarty and Tom Duncan, Prentice Hall, Inc. 1995

The Global Observer, A Weekly Column in “International Business” a core content feature of The Prodigy On- Line Interactive Service, April 13, 1993 to June 30, 1994.

Marketing Sans Frontières, with Jean-Marc De Leersnyder, Paris: InterEditions, 1994.

Advertising Worldwide, with Marieke de Mooij, Prentice Hall, Ltd, 1991.

Judgments, Choices and Decisions: Effective Management Through Self-Knowledge, New York, John Wiley & Sons, 1984.

Keegan Type Indicator and Guide to Type, Warren Keegan Associates Press, 1983.

Case Studies in the Management of Economic Development, Oxford University Press. 1968.

Numerous articles in the Harvard Business Review, Journal of Marketing, Administrative Science Quarterly, Journal of International Business Studies, Columbia Journal of World Business, Executive, Long Range Planning, Planning Review, International Marketing Review, and other magazines and journals.

Directorships and Advisory Boards (Current and Former)

Independent Commissioner: PT Indofood Sukses Makmur (Jakarta), Director: The S. M. Stoller Corporation; The Cooper Companies, Inc.; Inter-Ad, Incorporated; American Thermal Corporation, Inc.

Member, International Advisory Board of École des Hautes Études Commerciales (HEC), Montreal and the Talaga Bestari Learning Center, Jakarta, Indonesia. Board of Governors, World Trade Council of Westchester, Director, Wainwright House, Rye, NY, Director, Harvard Club of Westchester, Director, Rye Historical Society, Co-chair, Advisory Finance Committee, City of Rye, NY.

Honors & Awards

- Distinguished Professor, Lubin School of Business, Pace University. This Presidential appointment is based on the recommendation of the graduate faculty and Dean of the

Lubin School of Business and approved by the University Provost. The appointment is based on global academic reputation in strategic marketing and international business and exemplary performance and outstanding contributions to the University and School.

- Fellow of the Academy of International Business. One of 50 scholars in the world recognized for outstanding contributions and significant development of knowledge in the field of international business.
- Individual Eminent Person (IEP). Appointed by Asian Global Business Leaders Society (Other awardees include: Noel Tichy, Rosabeth Moss Kanter and Gary Wendt). Inducted February 2000.
- International Marketing Author of American Marketing Association Dictionary of Marketing Terms, First and Second Editions, American Marketing Association.
- Honorary member, Indonesian Marketing Association and Asian Marketing Federation.
- “Multinational Product Planning: Strategic Alternatives” (cited as one of the 150 books and articles that have had the most impact on the marketing discipline) in Larry M. Robinson and Roy D. Adler, Marketing Megaworks, New York: Praeger Publisher, 1987, pp. 86-87.
- First Prize in Pace University’s Annual Contest for Best Faculty Publication for *Judgments, Choices, and Decisions*, John Wiley & Sons.

Office

Keegan & Company LLC
31 Purchase Street, Ste. 3-4
Rye, NY 10580
914-967-9421
wkeegan@keeganandco.com

Exhibit 2—Publications of Dr. Keegan

Publications of Dr. Warren J. Keegan

2013

Keegan, Warren J. *Global Marketing Management, Eighth Edition*, Pearson Prentice Hall, 2013.

2012

Keegan, Warren J. and Mark C. Green. *Global Marketing, Seventh Edition*, Pearson Prentice Hall, 2012.

2011

Keegan, Warren J., and Naval K. Bhargava. *Global Marketing Management, Seventh Edition*, Indian Edition, Pearson Education, 2011.

Keegan, Warren J. and Mark C. Green. *Global Marketing, Sixth Edition*, Korean Translation, Sigma Press, Inc., 2011.

Keegan, Warren J. and Mark C. Green. *Global Marketing, Sixth Edition*, International Edition, Pearson Education , 2011.

2010

Keegan, Warren J. and Mark C. Green. *Global Marketing, Fifth Edition*, Traditional Chinese translation, Prentice Hall International (Taiwan), 2010.

Keegan, Warren J. and Mark C. Green. *Global Marketing, Fourth Edition*, Simplified Chinese translation, China Renmin University Press, Hong Kong, Pearson Education Asia Ltd, 2010.

2009

Keegan, Warren J. and Mark C. Green. *Global Marketing, Sixth Edition*, Englewood Cliffs, NJ.: Pearson Prentice Hall, 2009.

2008

Keegan, Warren J. and Mark C. Green. *Global Marketing, Fifth Edition*, Englewood Cliffs, NJ.: Pearson Prentice Hall, 2008.

2007

Keegan, Warren J. (1995) 'Global Product Management: Strategic Alternatives' in Stanley J. Paliwoda and John K. Ryans, Jr., *The International Library of Critical Writings on Business and Management: International Marketing*, Edward Elgar Publishing Ltd., Cheltenham, UK, 2007.

2006

Keegan, Warren J. (contributor), "The Marketing Plan", Chapter Eight in *Marketing Management: International Perspectives*. M.S. Raju and Dominique Xardel, Editors, Chennai, India: Vijay Nicole Imprints, 2006.

2005

Keegan, Warren J. and Mark Green, *Global Marketing, Fourth Edition*, Chinese Simplified Translation, China Renmin University Press, Hong Kong, Pearson Education Asia Ltd, 2005.

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Keegan, W. J. and M. C. Green. *Global Marketing*, Fourth Edition, Upper Saddle River, NJ: Prentice Hall, Inc., 2004.

2003

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Keegan, W.J., Keegan International Development Indicator (KIDI), Version 6.0., Warren Keegan Associates, Inc.

Keegan, W. J. and M. C. Green. *Global Marketing*, Third Edition. Upper Saddle River, NJ: Prentice Hall, Inc.

2002

Keegan, W. J., B. B. Schlegelmilch, and Barbara Stottinger. *Globales Marketing-Management: Eine europäische Perspektive*. Munchen Wien, R. Oldenbourg Verlag.

Keegan, Warren J. and Malcolm H.B. McDonald. *Marketing Plans That Work: Targeting Growth and Profitability*, Second Edition. Boston: Butterworth-Heinemann.

2001

Keegan, Warren J., *Global Marketing Management, Seventh Edition*, Upper Saddle River, NJ: Prentice Hall, Inc.

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“Global Income and Population: 2000 and Projections to 2010 and 2020”. Pace University, Lubin School of Business, Institute for Global Business Strategy, 2001.

2000

Keegan, Warren J., & Mark C. Green, *Global Marketing*, Second Edition. Upper Saddle River, NJ: Prentice Hall, Inc., 2000.

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1997

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"Global Income and Population: 1995 and Projected Growth to 2020", Pace University, Lubin School of Business, Institute for Global Business Strategy, 1995.

1994

Keegan, Warren J., and Jean-Marc De Leersnyder. *Marketing sans frontiers*. Paris: InterEditions. 1994.

"The Global Observer", A Weekly Column in "International Business" a core content feature of The Prodigy On- Line Interactive Service, January 6, to June 30, 1994.

"Global Income and Population: 1994 and Projected Growth to 2020", Pace University, Lubin School of Business, Institute for Global Business Strategy.

1993

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1992

Keegan Warren J., and Sandra E. Moriarty and Thomas R. Duncan. *Marketing* Englewood Cliffs, NJ: Prentice Hall, Inc., 1992.

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1991

Advertising Worldwide (with Marieke K. De Mooij), (1991). New York: Prentice Hall, 440 pages.

KTI, Keegan Typen-Anzeiger von Dr. Warren J. Keegan. Translated from the English by S. C. Kitsopoulos, Interconsult Press, 1991.

“Global Income and Population: 1989 and Projected Growth to 2009”; Pace University, Lubin Graduate School of Business, Institute for Global Business Strategy. 1991.

1990

“Global Strategy: Yesterday's Fantasy, Today's Reality”. Training and Management Development, Australian Institute of Management, 1990. March, pages 5-7.

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“Purchasing in the 1990s: The Evolution of Procurement in the Telecommunications Industry”, 1990.

“Competing in Global Industries: The Transnational Advantage,” The Center for International Business Studies, Institute for Global Business Strategy, Lubin Schools of Business, Pace University, Working Paper No. 2, May 1990.

“The Global Business and Its Strategy In the 1990s: Issues, Opportunities, and Challenges”, Advances in Telecommunications Management, Wesley, J. Johnston, JAI Press Inc., Volume 2. 1990.

1989

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“Global Strategy: Yesterday's Fantasy, Today's Reality”, Pace, Vol. 7, No.1, (1989) 8-13.

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Exhibit 3—Other materials (including review of additional studies cited in Hammond (2011))

Introduction

136. As discussed at paragraphs 15 through 18 above, I have reviewed additional materials cited in the Possible Revision and the Impact Assessment that do not have the potential to impact the discussion on potential behavioral effects of an increase to the size of health warnings. I have addressed each study of this type in a brief review below, noting for each the reasons it cannot be considered reliable evidence on the topic of larger health warnings.

137. In addition, I have reviewed studies listed in paragraph 13 which were relied on in Hammond (2011) and Wardle et al. (2010), but which are not directly cited in the Possible Revision or the Impact Assessment. Again, I have addressed each of these studies in a brief review below.

138. I confirm that, in reaching my conclusions set out at paragraphs 131 through 135 above, I have considered all the studies reviewed in this Exhibit.

Additional materials of the type identified at paragraphs 136 through 137 above.

Moodie et al. (2009)

139. This study is largely irrelevant to my analysis as it primarily focuses on various measures of efficacy of text-based health warnings among young people in the UK (prior to the implementation of pictorial health warnings) and does not specifically address size. Comprehensive review of this study is therefore unnecessary.

140. However, this study is cited in the Impact Assessment in support of the following statement about health warnings: “There is evidence that the warnings are more visible if placed on the front panel in the upper part of the package.”⁷⁴

141. This citation seemingly refers to the Moodie et al. conclusion that health warnings should “appear on the front of the pack given that our findings indicates that this is where most

⁷⁴ Impact Assessment, p. 88 (FN 331).

smoking and non-smoking youth focus their attention.”⁷⁵ However, the Moodie et al. study did not specifically seek to test where young people “focus their attention.” This is an inferential conclusion based on the findings of the “memorability” portion of the Moodie et al. study wherein respondents were asked through unaided recall to provide information they could remember from the text warnings on the pack.⁷⁶

142. In my expert opinion, Moodie et al.’s results were weak in this regard, with respondents recalling the content of only two of 16 text health warnings to any meaningful degree.⁷⁷ These warnings were: “Smoking kills” and “Smoking seriously harms you and others around you.”⁷⁸ Moodie et al.’s inferential conclusion is based on the fact that both of these messages appeared on the front of cigarette packages.

143. However, the Moodie et al. study does not provide any actual evidence regarding health warning placement. The authors coded responses by theme⁷⁹ and did not require respondents to exactly recite the health warning. The categories which respondents most often “recalled” (i.e., the categories into which the authors coded the most responses: “Smoking kills” and “Smoking seriously harms you and others around you” are extremely broad, general categories into which many diverse responses regarding the commonly known risks of smoking could fall. There is therefore an inherent bias built into the coding scheme used by the authors.

144. Indeed, the fact that respondents offered answers that fall into these categories says nothing about the efficacy or placement of the health warning message on the package. Rather, it shows that there is a general awareness among respondents that smoking is harmful and that when asked to recall themes about the risks of smoking, many respondents provide a broad, generic answer.

⁷⁵ Moodie et al. (2009), p. 6.

⁷⁶ Moodie et al. (2009), p. 3.

⁷⁷ Moodie et al. (2009), p. 4.

⁷⁸ Moodie et al. (2009), p. 4.

⁷⁹ Moodie et al. (2009), p. 3.

145. Additionally, it should be noted that this study did not test for any potential impact of altering the placement of the health warning on the front of the package (e.g., the upper part of the package as opposed the lower part of the package). Therefore this study provides no specific evidence regarding the positioning of the health warning on the package.

146. Finally, this study was conducted prior to the introduction of pictorial health warnings in the UK among a very limited sub-sample of the population (11 to 16 year olds). It is unknown whether and/or to what extent the findings of this study of text-only warnings 1) are applicable to the current UK policy environment wherein pictorial health warnings are the reality; and 2) are applicable beyond the narrowly-defined sample population.

147. For the reasons stated above, I do not consider this study to be relevant to a discussion of the size of health warnings. Furthermore, I do not consider this study to be reliable evidence regarding health warning placement on cigarette packages.

Gallopel-Morvan et al. (2011)

148. This study consists of focus group research conducted in France with the objectives of gaining information on how participants perceive and understand text and visual health messages on cigarette packages and exploring “the intentional and unintentional consequences of graphic fear appeals”⁸⁰ on participants. The authors conducted six focus group interviews among a total of 50 participants (26 smokers, 24 non-smokers, 25 women, 25 men) ranging in age from 15 to 46.⁸¹ Participants were shown a variety of health warning stimuli (three real Marlboro packs, 12 new European pictorial warnings on risks of smoking, and two new European pictorial warnings on cessation support) and asked, within the group setting, to provide their reactions to the health warnings.

149. I have addressed at length the limitations of focus group research at Exhibit 4 to my 2010 Report.⁸² Among other things, I state in my 2010 Report:

⁸⁰ Gallopel-Morvan et al. (2011), p. 4.

⁸¹ Gallopel-Morvan et al., (2011), p. 4.

⁸² 2010 Report at para. 223-227.

150. Focus group studies do not set out to generate results that can be generalized to populations outside of the focus group itself with statistical confidence, and therefore do not have predictive value. Focus groups provide the researcher insight into individual perceptions and attitudes, and can be a beneficial tool to shape further discussion, development, and research. Accordingly, focus groups do not carry the scientific weight of a representative consumer research study.⁸³
151. Gallopel-Morvan et al. acknowledge the limitations of their focus group research, stating that such research is “suitable for exploring attitudes and perceptions”⁸⁴ but “remains limited due to its exploratory nature. Indeed, we did not measure the effects of warnings on real behavior nor on a larger and more representative sample.”⁸⁵
152. Beyond the general limitations of focus group research, this study suffers from an additional notable limitation. The findings of the Gallopel-Morvan et al. study are described in terms of participants’ “positive” and “negative” reactions to the stimuli that were shown. Such qualitative data simply reflects participants’ attitudinal responses to the variety of stimuli that were shown during the interviews. Such data provides no information about respondents’ recall or depth of processing of existing health messages or the potential impact of changing existing health warnings on smoking behavior. This type of data cannot be used to generate reliable conclusions regarding the potential behavioral impact of a change in the size of health warnings.
153. For these reasons, I do not consider this study to be reliable evidence on the issue of larger health warnings.

Rey Pino et al. (2010)

154. As of the date of the submission of this report, the Rey Pino study is available as a Spanish language publication only. As such, I was unable to conduct a full review of this study. However, the Rey Pino study includes an English language abstract which provides enough information for me to comment on this study.

⁸³ 2010 Report at para. 223.

⁸⁴ Gallopel-Morvan et al. (2011), p. 4.

⁸⁵ Gallopel-Morvan et al. (2011), p. 8.

155. The Rey Pino study consists of focus group research conducted in Spain to assess the potential impact of switching from text only health warning messages (which were in place in Spain at the time of the study's execution) to pictorial health warning messages. I have previously discussed the significant limitations of focus group research,⁸⁶ specifically that focus group findings cannot be projected to the general population.
156. Additionally, the Rey Pino study addresses a potential change from text to pictorial warnings. There is no indication that the study specifically addresses increasing the size of health warnings. In the absence of such a focus, this study is irrelevant to the current debate regarding larger health warnings.
157. For these reasons, I do not consider the Rey Pino study to constitute reliable evidence with regard to the potential impact of larger health warnings.

Studies cited in Wardle et al. (2010) and Hammond (2011)

Fathelrahman et al. (2009)

Introduction

158. This study sought to explore the relationship between the then-current Malaysian text-only cigarette pack warnings and quitting intentions. The study does not examine the impact, if any, of a switch to larger and/or pictorial health warnings, and therefore it is not directly applicable to a discussion on those topics.
159. The authors asked a sample of 1,919 Malaysian male smokers about their impressions of the Malaysian text-only cigarette pack warnings, attempting to link awareness of pack warnings to increased awareness of smoking risks, intention of quitting, and self-perceived efficacy (i.e., how successful the respondent thought they would be in an attempt to quit).

Leading Questions

160. The study questionnaire, which was based on the ITC 4-Country Survey, presents respondents with leading questions. For example, respondents were asked, "In the last

⁸⁶ 2008 Report at p. 12; 2010 Report at para. 223-227.

month...how often, if at all, have you noticed the warning labels on cigarette packages?”⁸⁷
This question tells the smoker that there is a warning label on their pack and asks if they have noticed it. It is difficult to not answer this question affirmatively; to do so would require the respondent to ‘admit’ that he or she has not noticed something that they have just been informed exists. This question also specifically draws the respondent’s attention to the warning label, potentially elevating its importance and/or influence in the minds of consumers and creating the possibility of biased responses.

161. A more objective approach would have included a filter question asking respondents about the types of information they notice on cigarette packs—e.g., “If you can recall, what types of information appear on a cigarette package?” In this unprompted format, only those who mention a warning label would be asked further questions about that topic.
162. Respondents were also asked questions regarding “four kinds of reactions to the warnings.” The authors report that respondents were asked questions regarding “thinking about health risks of smoking because of the warning labels,” “more likely to quit because of the warning labels,” “avoiding looking at labels during last month,” and “stopping from having a cigarette when about to smoke because of the labels.”⁸⁸
163. Again, specifically directing the respondent’s attention to the warning labels in each of these questions creates the potential for biased answers. The authors could have asked, for example, “Have you thought about the risks of smoking?” and, if yes, “What motivated you to do so?” (and employed similar question structure for the other three items) to collect the same data in an objective format.

No Measurement of Actual Behavior

164. Additionally, the study does not contain any data on the impact of cigarette pack warnings on actual smoking behaviors. The authors asked respondents about their intentions to quit smoking—i.e., to predict a future behavior that has not yet occurred. They did not track whether respondents who self-reported noticing or reading the warnings actually make increased quit attempts reduce their cigarette consumption over time. As stated in Exhibit 4,

⁸⁷ The article states that respondents were asked about “noticing warning labels during last month” (p. 250). A review of the ITC 4-Country Wave 1 Survey (4C1-P) (p. 9) reveals the question text reproduced above.

⁸⁸ Fathelrahman et al. (2009), p. 250.

section B of this report, individuals' actual behaviors often differ from their stated behavioral intentions. In other words, people often do not do what they say they are going to do.

Unfounded Directional Assumption

165. An additional limitation of this study is that the authors assume a directional relationship among the variables for which they have no supporting data. Specifically, the authors assume that exposure to cigarette pack warnings leads to awareness of the risks of smoking which leads to behavioral changes (in this case, an intention to quit).⁸⁹ However, it is unknown whether this is the actual progression of thought that occurs among respondents. It is just as likely that people who have an intention to quit are more aware of the risks of smoking and therefore have a heightened awareness of cigarette pack warnings.
166. Indeed, the authors acknowledge this limitation in the discussion portion of the study,⁹⁰ but attempt to dismiss this possibility in favor of their preferred directional hypothesis. In fact, this is a major limitation. While the authors' hypothesis is not ruled out by the data, it is also not specifically supported.

Unsupported Conclusion

167. Finally, the authors state in the last sentence of the study: "Given that the effects were found with the relatively weak Malaysian warnings, it seems likely that even larger effects will be achieved if warnings are implemented in line with the FCTC obligations or recommendations." The current study provides absolutely no evidence in support of this statement. The 'effects' measured in this study have significant limitations as discussed above. Additionally, the authors did not test the effect of larger or pictorial health warnings and therefore have no basis to opine as to what the effects of such a change would be. This statement simply cannot be supported with the data offered in this study.

Not Broadly Applicable

168. This study was conducted in Malaysia, among a sample and within a marketplace which cannot be applied to the EU. Specifically, the study's sampling frame included only

⁸⁹ Fathelrahman et al. (2009), p. 252.

⁹⁰ Fathelrahman et al. (2009), p. 252.

Malaysian male respondents. Accordingly, application of this study's data and/or findings to any market other than Malaysian males should be approached with extreme caution.

Conclusions

169. This study is hindered by several limitations that prevent any reliable conclusions from being drawn from the data:
- The study does not examine the impact, if any, of a switch to larger and/or pictorial health warnings, and therefore it is not directly applicable to a discussion on those topics;
 - Respondents were presented with leading questions that create the potential for biased responses;
 - The study does not contain any data on the impact of cigarette pack warnings on actual smoking behaviors, but rather asks respondents to make predictions regarding their future smoking behaviors;
 - The authors assume a directional relationship among the variables for which they have no supporting data;
 - The authors conclude that implementing larger and/or pictorial warnings would increase smokers' quit intentions, although the current study does nothing to test this hypothesis;
 - The study has limited applicability due to the unique geographic, cultural, and gender makeup of its sample.
170. Accordingly, this study cannot be regarded as reliable evidence in support of implementing larger and/or pictorial warnings.

Hammond et al. (2003)

171. This study reports on the results of a telephone survey of 616 adult smokers residing in western Ontario, Canada, that was conducted in late 2001. Seventy percent of the participants (n=432) completed a follow up survey three months after their initial interview. The study took place approximately nine months after the introduction of new graphic health warnings in Canada.

172. Respondents in this study were asked whether they read, thought about, and discussed the health warning labels on cigarette packs. This “cognitive processing” was correlated with quitting and attempting to quit in a follow-up survey of 432 of these respondents three months later.
173. It should be noted that this study was conducted 12 years ago in a very specific, geographically limited location (western Ontario, Canada). Canada had, at the time of the study, just transitioned from text only health warning messages to pictorial health warning messages on cigarette packages, becoming the first jurisdiction with this requirement. This regulatory measure attracted considerable media attention which likely created a heightened awareness of the cigarette health warning issue among the general Canadian population. For these reasons, the results of this study may not be universally applicable to other jurisdictions (especially in today’s regulatory environment where pictorial health warnings have long been in use in many jurisdictions) and should be interpreted with caution.
174. The authors found that “smokers who read, thought about, and discussed the warning labels in greater depth at baseline were more likely to intend to quit in the next six months”⁹¹ and “were significantly more likely to either quit, attempt to quit, or reduce their smoking”⁹² at the time of the follow up study.
175. The authors note that “the direction of this relationship is unclear—smokers who intend to quit may be more likely to read the labels.”⁹³ In other words, a potential cause of the measured increase in cognitive processing could be the result of smokers, once having decided to engage in a particular behavior (quitting), have a heightened awareness of messaging related to that behavior.
176. In this case, it could therefore be not the messaging that led them to quitting, but quitting that led them to the messaging.

⁹¹ Hammond et al. (2003), p. 393.

⁹² Hammond et al. (2003), p. 393.

⁹³ Hammond et al. (2003), p. 393.

177. This seems especially likely given that this study was conducted “approximately nine months after the introduction of the new graphic warnings”⁹⁴ in Canada. The smokers surveyed had been exposed to these new warnings for nine months. There is no conclusive evidence that health warnings that they had been exposed to for an extended period suddenly compelled them to quit. Rather, it is just as likely that those who decided to quit did so for reasons independent of the health warnings but, having decided to engage in the behavior, took greater notice of the existing health warnings as such warnings were now relevant to their intended behavior.

178. For these reasons, the conclusions presented by the authors are speculative and this study does not provide reliable evidence as to the efficacy of graphic health warnings. The authors have not tested for a directional effect (i.e., reading the label leads to intention to quit or vice versa) and acknowledge the possibility that intention to quit may drive respondents to read the labels. Accordingly, it is not possible to draw an objective conclusion regarding directional effect from this data.

179. Therefore, due to the speculative nature of the findings and conclusions, this study offers no evidence that increased health warnings result in more quit attempts.

Lyle (Centre for Behavioural Research) (1992)

180. In this review study, the author examines 14 studies that present evidence on various aspects of health warnings and labeling on tobacco products. This study was published in 1992 and evaluates research dating back to the 1980s.

181. I have discussed previously the significant limitations of relying on research which is both: 1) outdated and no longer reflective of the current policy environment⁹⁵; and 2) of a secondary nature (i.e., presents no original consumer survey research).⁹⁶ Indeed, both of these limitations apply to the Lyle study.

⁹⁴ Hammond et al. (2003), p. 392.

⁹⁵ 2010 Report at para. 43-44.

⁹⁶ Keegan, W.J. “Third Report concerning Consumer Survey materials relevant to the Display Ban Requirement in England.” November 28, 2011, at para. 27-28; Keegan, W.J. “Analysis of Consumer Survey Evidence Relevant to the Display Ban Requirement in England,” April 28, 2010, para. Ex.5.65.

182. However, notwithstanding these broad limitations, it is notable that the Lyle report is highly critical of the studies which it evaluates, concluding that the studies it examined “provide no evidence that warnings or health information on cigarette packets affect smoking behaviour”⁹⁷ and “it cannot be accepted that these studies provide any evidence of social support for compulsory changes to cigarette packets.”⁹⁸ The Lyle report also concludes that recommendations made in the examined studies “seem to have arisen from preconceived ideas rather than from the experimental data.”⁹⁹ Lyle’s final point is that the studies reviewed do not support any recommended policy actions.¹⁰⁰

183. In light of the general limitations of the Lyle study and the specific objections to the underlying research reviewed within the Lyle study, I do not consider this report reliable evidence on the issue of larger health warnings.

Linthwaite (1985)

184. This study, published in 1985, consists of the findings of focus group research conducted in the UK. The objective of the study was to gather exploratory evidence on the potential impact of introducing additional text-only health warnings onto cigarette packs beyond the one warning (“Cigarettes can seriously damage your health”) that appeared on packs at the time, as well as changing the position of the warning (from the side of the pack to the front).¹⁰¹ The issue of size was not directly investigated in this study.

185. I have previously commented on the importance of considering a study’s age in assessing its relevance to a policy discussion. For example, in my 2010 Report I stated, “Consumer research generally has a limited lifespan in that one is provided a snapshot of the social,

⁹⁷ Lyle (1992), p. 5.

⁹⁸ Lyle (1992), p. 5.

⁹⁹ Lyle (1992), p. 5.

¹⁰⁰ Lyle (1992), p. 5.

¹⁰¹ Linthwaite (1985), p. 218.

market, and regulatory environments as they existed at the time of data collection. To the extent that these factors change over time, a study may become less applicable.”¹⁰²

186. Indeed, the Linthwaite study is so outdated that it can have limited relevance to the current policy debate regarding larger health warnings. In 1985, the regulatory environment in the UK with regard to tobacco was entirely different. For example, at that time, cigarette packs bore a single text-only warning on the side of the pack and tobacco advertising in magazines was permitted. This is reflected in the stimuli used in the Linthwaite study:

Mock-up cigarette packs and advertisements were produced by sticking the five new health warnings over the existing warning, and also separately on the front of packs to test for position. Real cigarette packs and magazine advertisements were used to create the mock-ups.¹⁰³

187. Today, cigarette packs in the UK have rotating pictorial warnings on both the front and back of the pack and tobacco advertising in magazines (and elsewhere) has been banned. Public smoking bans are in place and a myriad of other tobacco control measures have been introduced. Any relevance that the Linthwaite study may have once had has been eclipsed by the sweeping changes in UK cigarette labeling policy and wider tobacco control regulation that have been implemented since its publication nearly 30 years ago.

188. Beyond the critical age limitation, the Linthwaite study is focus group research. I have previously described the considerable limitations of focus group research.¹⁰⁴ Foremost among these is that focus group research is not designed to be statistically reliable and therefore the results of which cannot be generalized to broad populations beyond the study participants. The Linthwaite study is bound by this limitation.

189. In light of the considerable limitations of the Linthwaite study, I do not consider it reliable evidence with regard to the current discussion of larger health warnings.

¹⁰² 2010 Report at para. 44.

¹⁰³ Linthwaite (1985), p. 218.

¹⁰⁴ See for example my 2010 Report at para. 223-227.

Exhibit 4—Research Types

Introduction

190. This exhibit categorizes different types of consumer studies based on their research designs. Other information sources on consumer behavior, such as psychological evidence, consumer expert opinions, or other types of consumer analyses, are outside of the scope of this assignment.

(A) Focus Groups

191. Focus group studies report on informal exploratory conversations held between an interviewer and a group of respondents. Because they can provide insight as to individual preferences among consumers, focus group studies are used by businesses for commercial market research purposes. However, focus group studies do not set out to generate results that can be generalized to populations outside of the focus group itself with statistical confidence, and therefore do not have predictive value. Focus groups provide the researcher insight into individual perceptions and attitudes, and can be a beneficial tool to shape further discussion, development, and research. Accordingly, focus groups do not carry the scientific weight of a representative consumer research study.

192. In other words, focus group studies are exploratory in nature and generate hypotheses rather than findings that can be generalized to a wider population.¹⁰⁵ The reported findings of focus groups have no statistical significance due to the small sample size and exploratory nature of the responses.¹⁰⁶ There is also significant opportunity for the moderator to influence

¹⁰⁵ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. The Dryden Press, Orlando, FL, p. 81-85.

¹⁰⁶ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 263.

the discussion or for group members to influence each other,¹⁰⁷ which, if not designed properly, can generate misleading results.¹⁰⁸

193. For these reasons, focus group studies cannot be used as a basis to discuss the broader applicability of the results.¹⁰⁹ Rather, when properly conducted, the information gained from a focus group setting can assist in coloring a discussion on a particular issue.

194. In a statistical sense, focus group participants are not representative of any larger population, which prevents qualitative findings of this type from being generalized. In fact, Canadian Market Research and Intelligence Association (MRIA) guidelines preclude researchers from using any quantifiable terms (e.g. “40 percent”) to describe findings from this type of research.¹¹⁰

195. Thus, while focus group research may prove beneficial in a commercial setting—for example, by identifying issues of interest to be researched further—it does not meet the minimum threshold of statistical reliability and should not be considered predictive of any particular outcome.

(B) Opinion / Attitudinal

196. Opinion research collects data whereby respondents are asked to express their opinions or attitudes about a particular topic or range of subjects. Opinion research can be informal (e.g., an opt-in online survey collecting opinions regarding a product) or follow a more rigorous sampling and survey design, allowing the researcher to project the results to comment on the opinions of a defined population.

197. Opinion research may provide insight into respondents’ thoughts and beliefs about a particular subject area; however, it is difficult to determine the extent to which opinions

¹⁰⁷ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 142.

¹⁰⁸ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 263.

¹⁰⁹ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 142.

¹¹⁰ <http://www.mria-arim.ca/STANDARDS/CODEindividualsFAQ.asp#8>.

offered by respondents reflect their or others' actual or intended behavior.¹¹¹ Opinion data, therefore, cannot be used to draw inferences that reach beyond the question asked of respondents.

198. Opinion data is often collected and published by news organizations. For example, a newspaper may poll its readers to determine what proportion believes the local sports team will win a championship. However, even if a large proportion of respondents answer affirmatively, this does not provide reliable information as to which franchise will win the title. Opinion data is simply a measure of respondents' belief about a topic.
199. There are two types of opinion data. The first type consists of information regarding respondents' beliefs about a particular subject, issue or design—e.g. “I prefer cardboard packaging.” The second type of opinion data consists of respondents' beliefs regarding how others will react to a particular subject, issue, or design—e.g. “I think people will prefer cardboard packaging.” The first type of opinion data informs the reader as to what people are reporting about their own beliefs; the latter informs the reader as to how people believe others will think or behave.
200. Neither type of opinion data, however, provides a reliable measure of what people will do—e.g., which type of packaging will result in higher sales. For example, whereas a respondent may report feeling a certain way when asked about a particular topic, his or her behavior on the issue may be contrary to that belief. Indeed, people do not always do what they say they are going to do and in fact can behave in ways contrary to their own predictions.¹¹²
201. Additionally, research that asks respondents to predict what they or others around them may think or do have little predictive value, in that respondents are only offering a guess as to the public response.¹¹³ Lay respondents without specialized knowledge in the field are simply

¹¹¹ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 275-276.

¹¹² Stephanie Clifford, “Never Listen to Céline? Radio Meter Begs to Differ.” *New York Times*, 12/16/2009.

¹¹³ As stated by Groves et al., “Surveys can only provide useful information if respondents can answer the questions with some degree of accuracy.” See Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 268-269.

not qualified or trained to predict how people around them will react to a particular policy change. Therefore, opinion data merely provides information about the sample's opinions and, to the extent that statistical projection is possible, the opinion of the wider population.

202. Opinion data is subject to several common limitations. It has been shown that when respondents do not have a clear view on a particular topic, answers offered to attitudinal questions can be strongly affected by the wording or context of the question itself, leading to unreliable, biased answers.¹¹⁴ Additionally, opinion research can contain errors wherein respondents who hold the same opinion (e.g., that a product is good) report them differently (e.g., one respondent may rate the product an eight while another rates it a 10).¹¹⁵

(C) Self-Reported Behavioral

203. Self-reported behavioral data is commonly used in business and academic settings in attempts to measure the impact of a change—e.g., a business decision or policy shift—based on information provided by subjects regarding their behavior. For example, researchers in a jurisdiction that has implemented an increase in the duty on alcohol within the past year might ask the following self-reported behavioral question: “Would you say you drink more alcohol, less alcohol, or the same amount of alcohol per week as compared to last year?” The answer to this question may give the researcher insight as to whether the subjects have reduced their intake of alcohol since the tax went into effect. This self-reported data may also be inconsistent with actual sales of alcohol over the relevant time period, raising a question about the validity of the self reported behavior.

204. Self-reported behavioral data can provide researchers with an indication as to how people have changed their behavior over time. However, it is limited in that the behavioral data is provided by the subjects themselves and not independently observed, collected or verified. Furthermore, there may not be a link between any reported change in behavior and the policy change being assessed. For example, even if it is found that alcohol consumption decreases among the sample after the implementation of a higher duty, this decrease could be

¹¹⁴ See Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 237.

¹¹⁵ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 80.

attributable to factors other than the duty—e.g., ongoing educational campaigns, a general decline in the popularity of alcohol, etc.

205. In self-reported behavioral research, subjects make an on-the-spot self-assessment of their past behavior. It is well established that consumer recall of past behaviors can be inaccurate, as the time elapsed between the event and the time of reporting can distort respondents' perceptions.^{116, 117}

206. Additionally, depending on the level of sensitivity of the question being asked, self-reported behavioral data can be subject to bias related to “social desirability”—that is, a respondent's tendency to provide a socially acceptable answer to an uncomfortable question.¹¹⁸ These limiting factors should be considered when evaluating this type of research.

(D) Observed Behavioral

207. Observed behavioral data allows the researcher to observe, in a firsthand manner, respondents' actions as they occur. Observed behavioral data is collected at the time and place where a behavior occurs. For example, shoppers can be observed by researchers as they interact in a retail environment. Such subjects may not even be aware that they are being observed.

208. In other instances, researchers may conduct intercept interviews with customers exiting a store to ask them questions about the products they just purchased. Observed behavioral data largely eliminates respondent recall bias, as the recording of the data occurs contemporaneously (or nearly so) with the respondent's behavior.

209. Observed behavioral data is valuable for assessing consumer behavior in a natural environment and is not subject to the limitations of self-reported data.

¹¹⁶ Floyd J. Fowler, Jr. (2009). *Survey Research Methods, 4th Edition*. Thousand Oaks, CA: Sage Publications, p. 107.

¹¹⁷ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. Orlando, FL: The Dryden Press, p. 240.

¹¹⁸ Floyd J. Fowler, Jr. (2009). *Survey Research Methods, 4th Edition*. Thousand Oaks, CA: Sage Publications, p. 108.

(E) Experimental

210. Experimental research puts subjects into an experimental condition—e.g., exposes them to a product, photo, video, etc.—and asks them questions related to that condition. Properly designed experimental data can be useful in providing insight into the potential impact of factors (represented by the experimental condition) on respondents' behaviors,¹¹⁹ provided other variables are adequately controlled.
211. In an experimental research project, a subject might be presented with a mock-up of a new product package—for example, of a laundry detergent. After examining the packaging, the subject might be asked questions regarding whether they considered the detergent's packaging to be appealing or unappealing and whether the packaging might motivate them to purchase the product. By controlling for extraneous variables, the researcher can collect data on the expected impact of altering a particular independent variable. When executed properly, experimental data can provide information on a cause and effect relationship that may exist between the independent and dependent variables.¹²⁰

(F) Longitudinal

212. Longitudinal data refers to like data that is collected over two or more points in time. Sometimes referred to as “wave studies,” longitudinal research collects data at a “baseline” and then uses the same or similar data collection methods to collect data again at a later point or points in time, often after an event—e.g., a policy change, a new pricing strategy, or simply the passage of time—has occurred.
213. Longitudinal data can be valuable in that it provides researchers with a point of comparison. For example, if a jurisdiction implements an increase in the duty on alcohol, a researcher may be able to assess whether there has been any correlating change in consumer behavior. If confounding variables are properly controlled and a proper study design is employed, the researcher may be able to make a determination as to the policy's effectiveness by collecting consumer-reported consumption data both before and after the policy goes into

¹¹⁹ As stated by Ghauri and Grønhaug, “A key purpose of the experimental design is to isolate and estimate the effect(s) of potential cause(s).” See Ghauri and Grønhaug (2005). *Research Methods in Business Studies*, 3rd Edition. England: Pearson Education Limited, p. 65.

¹²⁰ Ghauri and Grønhaug (2005). *Research Methods in Business Studies*, 3rd Edition. England: Pearson Education Limited, p. 59-65.

effect. Because longitudinal data allows researchers to measure change over time, it can be a powerful tool in evaluating the effectiveness of business decisions, policy measures, etc.

214. There are two types of longitudinal research:

- Cohort studies track the same group of respondents over time. In medicine, randomized controlled trials are cohort studies. Because this allows researchers to objectively observe changes in specific medical conditions in patients over time, such a design is considered the gold standard of medical research. However, tracking the same group of respondents over time can be problematic when the study repeatedly seeks information regarding self-reported behaviors and/or opinions from respondents on the same topic. In such cases, participation in the cohort can raise the respondent's overall awareness of the issue of interest, creating the potential for a non-representative sample.
- Cross-sectional longitudinal studies use random selection of the population of interest at repeated waves and compare the data resulting from these sets of representative samples.

(G) Market Response

215. Market response data are unit and/or dollar measures of sales of a product by consumers or channel members. This is a measure of what people have done. For instance, sales data collected at the point of purchase can inform a retailer as to the effectiveness of a marketing campaign. Market response data is "hard data"—e.g. data that is collected at the point of sale that does not rely on any reporting or recall by the consumer. Market response data lends itself to econometric analyses aimed at determining the economic or social impact after the implementation of a business decision or policy measure, provided other factors or variables are properly controlled.