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

Submitted by:

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Summary of Assignment

1. I have prepared this report for Japan Tobacco International in which I review publicly available consumer survey studies and papers which are cited as relevant to the European Commission's Directorate General for Health and Consumer Affairs ("DG SANCO") proposal identified in Option 2a of Section 3 of the *Possible Revision of the Tobacco Products Directive 2001/37/EC—Public Consultation Document* to increase the size of health warnings on tobacco packaging (the "Proposal"). I understand that a report prepared by RAND Europe for DG SANCO, dated September 2010, and entitled *Assessing the Impacts of Revising the Tobacco Products Directive* (the "RAND Report") is described as an input into DG SANCO's evaluation of the evidence base. In preparing this report, I have relied upon my expertise regarding consumer research in general and specifically related to the packaging of tobacco products.

2. Among the topics presented in the DG SANCO Consultation are potential revisions to the way in which consumers are presented with information on cigarette packages. Specifically, Section 3 of the Consultation sets out several options for the presentation of health information to consumers:

- A. Option One – No Change: This option would require no modification to labeling procedure across the EU Member States.
- B. Option Two – Improve Consumer Information: Of the four identified sub-options under Option Two, the relevant proposal (2a) reads "picture warnings would become mandatory in all Member States. They would be **enlarged**; required on both sides of the package and placed toward the top of the pack" (emphasis added).
- C. Option Three – Introduce Plain or Generic Packaging: This option would standardize labeling across the Member States through the use of unbranded cigarette packages.

3. I have been asked to prepare the current report in regard to Option 2a above. 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—a proposed change under Option 2a—is likely to result in changes in smoking behavior among consumers.¹

4. DG SANCO cites no evidence to support the Proposal. Therefore, in undertaking this task, I have examined each study on the topic of increasing the size of health warnings cited in the RAND Report. I have done so to determine the extent to which these studies provide reliable evidence in support of the proposition that increasing the size of cigarette pack health warnings, as proposed in Option 2a of Section 3, would impact smoking behavior among consumers.

5. The remainder of this report (a) provides an overview of the supporting documents on the topic of increasing the size of health warnings cited in the RAND Report; (b) provides an overview of the different types of survey research and the varying degrees of reliability thereof, this being important background for the analysis that follows; (c) reviews studies on the topic of increasing the size of health warnings that provide evidence that the Proposal may not impact consumer behavior; and (d) details the results of my analyses of the studies cited in the RAND Report on the topic of increasing the size of health warnings.

6. I have also been asked to review two studies relevant to plain packaging of tobacco products. This review supplements existing reports that I have previously undertaken in this regard.² The two studies are entitled “Tobacco Branding and Plain Packaging: The New Frontier of Tobacco Control?” (“Hoek et al. (2009)”) ³ and “Effects of Dissuasive Packaging on Young Adult Smokers” (“Hoek et al. (2010)”).⁴ My analysis of these studies is set out in detail in Exhibit 7. In

¹ DG SANCO does not, in the Consultation, put forward specific goals that it wishes to achieve though updating the policy language of the Directive.

² Exhibit 7 sets in more detail the previous reports I have prepared in this regard.

³ Hoek, J. Gendall, P. and Louviere, J. (2009). “Tobacco Branding and Plain Packaging: The New Frontier in Tobacco Control?” In Moore, B., Pappalardo, J and Wilkie, W. (Eds.), Proceedings of the American Marketing Association Marketing and Public Policy Conference, Washington DC, May 28-30.

⁴ Hoek et al. (2010). “Effects of Dissuasive Packaging on Young Adult Smokers.” *Tobacco Control*. Published online 10/21/2010 in advance of the print edition.

summary, I conclude that both of these studies suffer from considerable methodological limitations and I therefore do not consider either study to provide reliable evidence regarding the potential impact of plain packaging on smoking behaviors.

Executive Summary of Findings

7. DG SANCO cites no evidence to support the Proposal. The RAND Report cites a variety of different types of research studies on the topic of increasing the size of health warnings. As discussed in more detail below at paragraphs 19 through 23, none of the work undertaken to date by DG SANCO or RAND Europe is primary research. Their work to date is secondary or tertiary research.

Studies with Potential to Inform the Debate

8. Some of the studies cited in the RAND Report have the *potential* to inform the debate regarding possible behavioral impacts of increasing the size of health warnings on cigarette packs. Such studies include those that collect or examine primary data and have a behavioral element—i.e., attempt to measure potential way(s) in which an increase in the size of health warnings could impact consumers' smoking behaviors.

9. 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 variables it sets out to measure, whether data collection is undertaken objectively, whether results are presented and interpreted objectively, the degree to which the study is statistically rigorous, and whether the authors' conclusions are supported by the data. I have undertaken this task in preparing this report.

10. A listing of the studies which I analyzed in full appears at paragraph 75 below and in Exhibit 6. My findings, in brief, for each of those studies are as follows:

- A. **The ITC Project/ ITC Summary Document (2009):** My ability to assess the ITC Project and all studies that are based on ITC data is significantly impeded by the ITC's policy of selective disclosure of its survey data. This presents the opportunity for selective inclusion of favorable results, as the reader does not have the ability to independently review the full ITC data set. Therefore all studies based on ITC data should be considered with caution.

- Additional methodological limitations of the ITC project include inappropriate use of the cohort study design, an inconsistent questionnaire across study waves, country comparisons which do not adequately account for inherent differences between compared populations, leading questions, and potentially biasing data collection procedures.
- B. **Hammond et al. (2006)**: This study relies on ITC data, which is unavailable for review. Additionally, it fails to account for cultural differences that may exist between its samples, and does not directly test for any specific impact of an increase in the size of health warnings on consumers' smoking behaviors.
- C. **Hammond et al. (2007)**: This study relies on ITC data, which is unavailable for review. It also makes inappropriate use of the cohort design and makes uncontrolled country comparisons. The only relevant behavioral question in this study shows no link between behavioral change and warning label changes, and therefore does not provide insight as to the impact of larger warning labels on consumer behavior.
- D. **Elliot & Shanahan (2008)**: This study suffers from a number of limitations, including excessive passage of time between data collection waves, significant question design issues, and subjective, potentially misleading presentation of the study results.
- E. **Environics (2008)**: This study, which is comprised of a youth survey and a separate adult survey, suffers from significant limitations. It largely reports on attitudinal (i.e., opinion) data, which has no bearing on potential behavioral outcomes of an increase in health warning label size. Additionally, the questionnaire presents potentially biasing information to respondents and presents respondents with poorly constructed questions; the only behavioral question presented to respondents is without context and, therefore, wholly uninformative.
- F. **Joossens (2004)**: A significant limitation of this study is that the questionnaire is not provided; it is therefore unknown what was asked of respondents. This study also suffers from an inappropriate study design and leading questions.
11. Upon conducting a full analysis of the studies listed above, I have found that no study provides reliable evidence as to the potential behavioral impact of increasing the size of health warning labels on cigarettes.

Studies with No Potential to Inform the Debate

12. The RAND Report also cites studies that do not have the potential to inform regarding the potential behavioral impacts of increasing the size of health warnings.

13. 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 of 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.

14. 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).

15. I have reviewed the studies cited by the RAND Report which fall into this category. A brief review of studies relied upon by the RAND Report, but which do not impact the current debate on increasing the size of health warnings on cigarettes, is presented in Exhibit 5 of this report. None of these studies provide reliable evidence as to the potential behavioral impact of increasing the size of health warning labels on cigarettes.

Conclusion

16. I have reviewed and analyzed the studies relied on by the RAND Report in support of the proposition that increasing the size of health warnings on cigarette packs will impact smoking behaviors among consumers.

17. Upon completing my review, I have found that no study provides reliable evidence as to the potential behavioral impact of larger health warnings.

Qualifications

18. My full qualifications, current CV, and publications list are included as Exhibits 1 through 3, respectively, to this report.

Overview of EU Consultation and RAND Report

19. It is my understanding that DG SANCO has commissioned a report prepared by RAND Europe—*Assessing the Impacts of Revising the Tobacco Products Directive*—which is stated to be “a study to support a DG SANCO impact assessment.”⁵ A review of the RAND Report shows that, on the topic of larger health warnings, RAND Europe cites a variety of primary studies—i.e., studies that collect and/or evaluate original consumer survey research—rather than presenting its own original survey research. Thus, the RAND Report is considered a secondary source on the topic of larger health warnings.

20. Additionally, the RAND Report repeatedly cites a report by Sambrook Research International—*A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages*, published on May 27, 2010 (the “Sambrook Report”)—regarding its findings on larger health warnings. The Sambrook Report is a secondary source as well, reviewing existing research rather than presenting original market or consumer survey data.

21. In light of the above, the Proposal is several steps removed from the original research studies that provide the underlying support regarding larger health warnings. Like a set of Russian matryoshka dolls continually revealing new layers, it becomes necessary to peel away the various layers of supporting documents to uncover the primary data on which the Proposal actually relies.

22. 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. I address this issue on a study-by-study basis throughout the remainder of this report.

23. It is notable that the RAND Report does not contain a comprehensive analysis of the available evidence on the potential impacts of increasing the size of health warnings on cigarette packs, nor does it comprehensively evaluate the evidence that it has identified and relied upon. Restrained by the broad range of topics addressed, the RAND Report states that it conducted “rapid reviews” of the available evidence, rather than comprehensive “systematic evidence

⁵ Rand Europe, *Assessing the Impacts of Revising the Tobacco Products Directive*, p. i, front cover.

reviews.”⁶ Contrary to RAND, I have conducted in-depth comprehensive analyses of the relevant studies (i.e., studies on the topic of increasing the size of health warnings) identified regarding the Proposal.

Consumer Research Overview

24. 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.

25. 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.

26. 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

27. 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.

⁶ Ibid., p. 253.

International Standards of Survey Research

28. 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.

29. In order to promote research of acceptable integrity and reliability, international research organizations have developed standards of practice which researchers follow.⁷ 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.

30. A variety of professional organizations have compiled standards for researchers engaging in survey research. Such organizations include the Market Research Society (MRS),⁸ the American Association for Public Opinion Research (AAPOR),⁹ the World Association for Public Opinion Research (WAPOR),¹⁰ the Council of American Research Organizations (CASRO),¹¹ the International Statistical Institute (ISI),¹² the Market Research and Intelligence Association (MRIA),¹³ and the European Society for Opinion and Marketing Research (ESOMAR).¹⁴

⁷ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 371-372.

⁸ Market Research Society, *MRS Code of Conduct* (2005). <http://www.mrs.org.uk/standards/downloads/code2005.pdf>.

⁹ American Association for Public Opinion Research, *AAPOR Code of Professional Ethics & Practices* (2005). <http://www.aapor.org/aaporcodeofethics>.

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

¹¹ Council of American Research Organizations, *Code of Ethics and Standards for Survey Research*, (2008). <http://www.casro.org/pdfs/CodeVertical-FINAL.pdf>.

¹² International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>.

¹³ Market Research and Intelligence Association, *Code of Conduct for Members* (2007). <http://www.mria-arim.ca/STANDARDS/CODE2007.asp>.

31. 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.

32. 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;
- Respondents are not led toward a particular answer;
- Answers are capable of being interpreted in an unambiguous way.¹⁵

33. 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

¹⁴ 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.

¹⁵ Market Research Society, *MRS Code of Conduct* (2005). <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, paragraph B.14.

selecting methods designed to produce misleading results, or in misrepresenting statistical findings by commission or omission.¹⁶

34. 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.¹⁷

35. 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,”¹⁸ and that “researchers shall always be prepared to make available the technical information necessary to assess the validity of any published findings.”¹⁹ 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.”²⁰ The International Statistical Institute’s *Declaration on Professional Ethics* states that researchers “should provide adequate

¹⁶ International Statistical Institute, *Declaration on Professional Ethics* (1985). <http://isi.cbs.nl/ethics.htm>.

¹⁷ American Association for Public Opinion Research. *AAPOR Code of Professional Ethics & Practice* (2005). www.aapor.org/AAPOR_Code.htm.

¹⁸ http://www.iccwbo.org/uploadedFiles/ICC/policy/marketing/Statements/ICCESOMAR_Code_English.pdf, p. 4.

¹⁹ *Ibid.*, p. 6.

²⁰ <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, p. 16.

information to colleagues to permit their methods, procedures, techniques and findings to be assessed.”²¹

36. 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.”²²

37. 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.

38. 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.²³ 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 prepare a manual to assist judges in managing cases involving complex scientific and technical evidence.²⁴

39. 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,²⁵ 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

²¹ <http://isi.cbs.nl/ethics.htm>.

²² American Association for Public Opinion Research. *AAPOR Code of Professional Ethics & Practice* (2005). www.aapor.org/AAPOR_Code.htm.

²³ The FJC Manual is available at <http://www.fjc.gov/pdf/nsf/lookup/sciman00.pdf>.

²⁴ FJC Manual, page v.

²⁵ 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).

information.”²⁶ 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;²⁷
- (b) questions in the survey should be clear, precise and unbiased, and filter questions should be included to reduce guessing;²⁸
- (c) in order to test a causal proposition, the survey should include an appropriate control group or question;²⁹
- (d) the survey report should include complete and detailed information on all relevant characteristics;³⁰ and
- (e) interviewers should be appropriately selected and trained.³¹

40. 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.

²⁶ FJC Manual, Chapter 6, Reference Guide on Survey Research, p. 231.

²⁷ Ibid., p. 239.

²⁸ Ibid., p. 248-249.

²⁹ Ibid., p. 256.

³⁰ Ibid., p. 270.

³¹ Ibid., p. 264.

Methodological Limitations

41. 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.

42. 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

43. 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.³² This is determined, in part, by when the research was executed.

44. 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.

³² Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 63.

Question Design

45. 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.³³

46. 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.³⁴

47. 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' 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.

48. 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

³³ 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.

³⁴ Rea & Parker (2005). *Designing & Conducting Survey Research: A Comprehensive Guide, 3rd Edition*. San Francisco: John Wiley & Sons, Inc., p. 52-60.

neutrality and therefore would be expected to yield results that are less than a true measure of the phenomenon.

49. 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.

50. 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.

51. 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

52. 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.³⁵ 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

53. 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

³⁵ 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.

study.^{36,37} 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.³⁸ 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.

54. 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.

55. 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

56. As is explained in more detail in paragraphs 24 through 26 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.³⁹ In consumer research, the gold standard

³⁶ World Association for Public Opinion Research, *WAPOR Code of Professional Ethics and Practices*, <http://www.unl.edu/WAPOR/ethics.html>, paragraph II.A.10.

³⁷ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 124.


³⁸ Bradburn, Sudman & Wansink (2001). *Asking Questions: The Definitive Guide to Questionnaire Design*. San Francisco: Jossey-Bass, p. 11.

³⁹ 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>.

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.

57. 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
	Prediction of others’ future behavior	Opinion / Attitudinal
Least reliable		

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

Age of Respondents

59. Conducting research among youth presents particular issues that must be accounted for to ensure the reliability of the data collected.⁴⁰ Young respondents are more likely to feel pressured during an interview situation; such pressure can result in answers that are inaccurate.⁴¹

60. 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.

⁴⁰ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. The Dryden Press, Orlando, FL, p. 387-390.

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

61. 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.

62. 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.⁴²

Cross-Cultural Applicability

63. 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, 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

64. 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.

65. 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

⁴² Ibid., p. 42-47.

larger population or market and proper adjustments (e.g., weighting) have been made.⁴³ 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.

66. 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.⁴⁴

67. Researchers must be careful to only draw those conclusions that are supported by the data; conclusions that stray beyond this are speculative.⁴⁵ 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.

Evidence that the Proposal May Not Impact Behavior

68. I have examined the studies on the topic of increasing the size of health warnings cited in the RAND Report (see detailed analysis below) and have found that they do not provide reliable evidence regarding larger health warnings.

⁴³ 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.

⁴⁴ Thompson, Bruce (1994). “The Concept of Statistical Significance Testing.” *Practical Assessment, Research & Evaluation*, Vol. 4, No. 5.

⁴⁵ 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.

69. In fact, there is some evidence that suggests that the Proposal may not be effective in impacting smoking behaviors among consumers. Specifically, a series of wave studies conducted in Canada have shown that increasing the size of the health warning message on cigarette packages has not lead to any discernible reduction in smoking behaviors attributable to those larger warnings. The Canadian wave surveys are discussed in detail below.

Canadian Wave Surveys

70. In 2001, Health Canada increased the size of health warnings on tobacco packaging from 25 to 50 percent of the principal display areas of the pack, and introduced pictorial warnings. A series of wave surveys were conducted, starting with a baseline in 2000 (before the new 50 percent pictorial health warnings were introduced) and continuing yearly from 2001 to 2007. These wave surveys assessed consumer smoking behavior and attitudes toward health warnings.

71. I have seen JTI-Macdonald's submission in response to Health Canada's Proposal for Changes to Packaging Health Information, dated 12 June 2009, which discusses the Canadian wave surveys at pages 15 through 17. I have reviewed the Canadian wave surveys in order to assess the points made in those pages. In light of this review, I agree with the various points raised in JTI's submission regarding the Canadian wave surveys. In particular, the following points, in my opinion, flow from the wave surveys and support the conclusion that the Proposal may not achieve its intended goal:

- While self-reported awareness, motivation and self-characterized behavior (e.g., awareness of health effects of smoking, smoking less around others, desire to quit, perception of cigarette consumption) has improved with the 50 percent pictorial warnings over the 25 percent text warnings, these self-assessments did not impact actual smoking behaviors. This is not surprising, given that, as discussed in more detail at paragraph 56 above and in Exhibit 4, 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;
- Daily cigarette consumption did not decrease between 2000 (baseline) and 2002;

- The 50 percent pictorial warnings were no more effective than the text warnings in motivating smokers to actually make a quit attempt;
- While the percentage of smokers who have tried to quit at least once has increased slightly over time, there is no specific effect associated with the 50 percent pictorial warnings in motivating smokers to quit;
- Canadian perceptions of smoking as a health problem have remained stable between 2000 and 2007 and do not appear to be affected by the 50 percent pictorial warnings;
- Fewer smokers reported reading the 50 percent pictorial warnings on a regular basis as compared to the prior text-only warnings.

72. In considering the factors listed above, the JTI submission concludes that while there has been a decrease in the prevalence of smoking over time, there is no evidence that this continuation of a downward trend in smoking rates is in any way attributable to the 50 percent pictorial warnings.

73. Regardless of the self-reported data, an examination of actual smoking behaviors among Canadian adults and youth shows that behavioral trends have been relatively stable over the time period covered by the Wave Studies. Accordingly, it is not justified to conclude that this data shows that the 50 percent pictorial warnings have had an actual impact on smoking behaviors in Canada since their introduction in 2001.

Review of Specific Studies

74. As discussed above at paragraph 4, DG SANCO cites no evidence in support of the Proposal. I have reviewed each of the studies cited in the RAND Report on the topic of increasing health warnings 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.

75. 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. I set out below my findings in respect of each of the following studies:

- A. International Tobacco Control (ITC) (2009). “FCTC Article 11 – Tobacco Warning Labels: Evidence and Recommendations from the ITC Project” (ITC Summary Document (2009)).
 - B. 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)”).
 - C. Hammond, D. 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, p. iii19-iii25 (“Hammond et al. (2006)”).
 - D. Hammond, D. 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, p. 210-217 (“Hammond et al. (2007)”).
 - E. Joossens, L. (2004). “Investigation into the effect of health warnings on cigarette packets in Belgium.” *Belgian Minister of Public Health and Social Affairs*. p. 1-18 (“Joossens (2004)”).
 - F. Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers.” Prepared for Health Canada (“Environics (2008)”).
 - G. Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth.” Prepared for Health Canada (“Environics (2008)”).
76. Studies that do not have the potential to impact the discussion on potential behavioral effects of an increase to the size of health warnings are reviewed in Exhibit 5.

The ITC Project/ITC Summary Document (2009)

77. The RAND Report cites certain studies on the topic of increasing the size of health warnings that draw data from the International Tobacco Control (ITC) Project, including the ITC

Summary Document (2009). The ITC Project is an international cohort study on smoking that began in 2002 with four countries (Canada, United States, United Kingdom, Australia) participating. Twenty countries currently participate in the annual national-level administration of a common questionnaire consisting of over 200 questions.⁴⁶

78. The ITC Summary Document (2009) cited in the RAND Report is an example of the summary-format documents that are periodically released by ITC through its website (www.itcproject.org) to report on select data from the ITC Project's various study waves. Additionally, the ITC allows researchers to analyze its data and produce studies on their findings (see Hammond et al. (2006) and Hammond et al. (2007) reviews below). I set out below some of the overarching limitations which are inherently ingrained in the ITC project as a whole, and which therefore also apply to studies that rely upon ITC data (including the ITC Summary Document (2009)).

Unavailable Data

79. My ability to review studies that are based upon data collected by the ITC Project, including the ITC Summary Document (2009), was significantly impeded by the ITC's policy of selective disclosure of its survey data.

80. ITC does not provide consistent information across participating countries, nor does it provide unrestricted public access to the underlying data upon which its various summary reports and tables are based. According to the ITC published data sharing policies, the ITC Project only shares data on an as-approved basis and states that access "will not be approved for use by the tobacco industry, or any person affiliated with the industry."⁴⁷

81. Therefore, the only data I am able to review is that which is revealed in the ITC ad-hoc publications or in other published research.⁴⁸ In none of these cases is the full data set available for

⁴⁶ The ITC website <http://www.itcproject.org/> and materials available therein has been used as a source throughout this review.

⁴⁷ <http://www.itcproject.org/datarequ>.

⁴⁸ See, for example, Hammond et al. (2006) and Hammond et al. (2007) discussed in more detail below, and selected materials published regarding the ITC Southeast Asia Project discussed below.

review. Unfortunately, without full disclosure of the data, the reader is presented with selective study results proffered by ITC. Thus, an independent review is not possible and the reader is left in the difficult position of being presented with a particular interpretation of the data with no opportunity to independently audit those findings.

82. This policy stands in contrast with recommended data transparency procedures as reflected in various international codes of accepted survey research practices. For example, 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,”⁴⁹ and that “researchers shall always be prepared to make available the technical information necessary to assess the validity of any published findings.”⁵⁰ 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.”⁵¹ Further, 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.”⁵²

83. The structure that the ITC has established regarding its data collection and dissemination lacks the accountability that is required for an international research project supported and funded by governmental health agencies around the world. Typically, a researcher makes available all the data collected for a particular project, rather than selectively publishing only the data that supports a specific finding. In this way, the research is transparent such that those outside the research project can corroborate the effort. Documenting and sharing data with the research community—a process known as full disclosure—is a basic principle of the scientific method, which, through allowing others to examine a study’s data, helps to promote sound, objective research.

⁴⁹ http://www.iccwbo.org/uploadedFiles/ICC/policy/marketing/Statements/ICCESOMAR_Code_English.pdf, p. 4.

⁵⁰ *Ibid.*, p. 6.

⁵¹ <http://www.mrs.org.uk/standards/downloads/code2005.pdf>, p. 16.

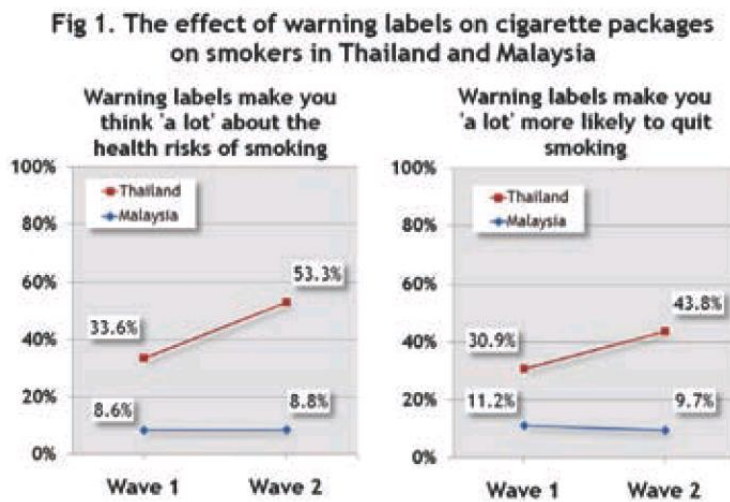
⁵² <http://isi.cbs.nl/ethics.htm>.

84. The ITC model has created a separation between those publishing research on various issues and those collecting the data (the ITC). This allows a researcher to selectively isolate data on which to report. When this is done, I (and others) have no ability to review the more comprehensive data set to evaluate whether the selectively chosen data is, for example, representative of the issue under evaluation or an anomaly.

85. A prime example of the difficulty that can arise in this circumstance emerges upon analyzing ITC Southeast Asia (Malaysia and Thailand) materials. Unlike with other ITC country-specific projects, ITC has released a limited amount of study data (including questionnaires and selected results) with its Southeast Asia summary reports. An examination of this, albeit limited, data shows inconsistency between the findings presented by ITC in its Thailand summary report and the limited underlying data released by ITC.

86. Specifically, ITC reported that “increasing the size and adding graphic images to warning labels greatly increases their effectiveness”⁵³ and offered select Thailand and Malaysia data as supporting evidence. The ITC Thailand Summary Report, as well as the ITC Summary Document (2009), present the following results (see Figure 1 below):

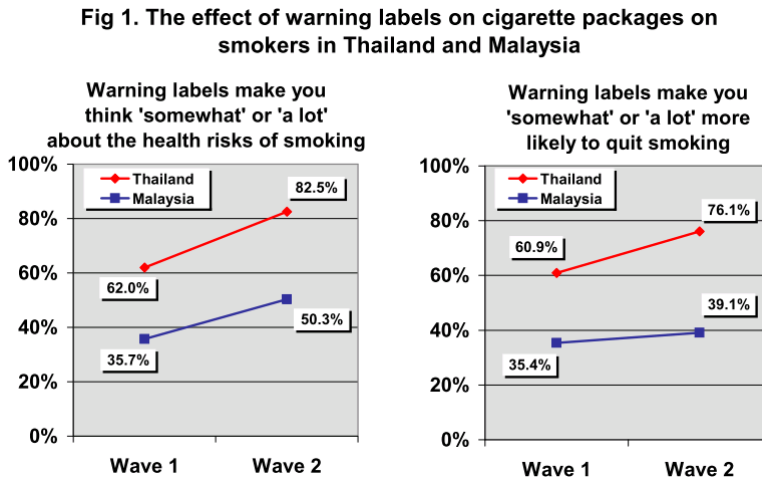
Figure 1. Thailand and Malaysia data as presented by ITC⁵⁴



⁵³ ITC Summary Document (2009), p. 8; ITC Thailand Summary Report, February 2009.

87. Thailand had introduced larger pictorial warnings between ITC data collection waves, whereas Malaysian warnings remained unchanged over that period. However, the impact of this change is selectively presented through the inclusion of only those respondents who reported being affected “a lot” by the warning labels. Reconstructing the graphs to also include those respondents who were “somewhat” affected by the warning labels—a task made possible by the limited underlying data provided by ITC for the Southeast Asian study—provides a markedly different result (see Figure 2).

Figure 2. Reconstruction of Thailand and Malaysia data to include “somewhat” responses⁵⁵



88. As shown in Figure 2 above, including participants who responded that they were “somewhat” affected by the warning labels causes the data to present entirely differently. In this case, inclusion of this additional group of respondents results in rising awareness of health risks of smoking and intention to quit in both Thailand and Malaysia from the first to the second wave of data collection. This stands in contrast to ITC’s presentation of the data in the ITC Thailand Summary Report, which leaves a different impression of the impact of larger health warnings.

89. The broader implication is that, as illustrated in the example above, large data sets can be selectively presented to advocate a particular perspective that may not be representative of the data

⁵⁴ Ibid.

⁵⁵ Data gathered from ITC Thailand Summary Report, February 2009, Appendix A: Frequency Tables for ITC Thailand Four Page Summary, p. 12-15.

set as a whole. That ITC publishes the majority of its “findings” in summary documents without providing the reader access to the underlying data calls into question the objectivity of all of the results and conclusions so presented.

90. The unavailability of the ITC data also presents issues regarding data integrity. For example, because ITC released a limited amount of study data in the ITC Southeast Asia (Malaysia and Thailand) study, I discovered a potentially biasing factor in the data collection procedure. ITC enlisted the assistance of the Malaysian Ministry of Health to complete data collection.⁵⁶ In this capacity, fieldworkers often used Ministry of Health vehicles to commute to fieldwork sites.⁵⁷ This is potentially problematic in that the government vehicles would have informed respondents that the government was involved in the project. Such knowledge could have significantly impacted the responses offered by participants.

91. Indeed, ITC acknowledges that the involvement of the Malaysian Ministry of Health impacted data collection efforts:

The enumerators' familiarity with the local respondents, as well as their authenticity, as seen from their uniforms and vehicles, facilitated the approach process and therefore increased the response rate.⁵⁸

92. Because the interviewers in the Malaysian portion of the study could have been viewed as authoritative figures collecting data in an official governmental capacity, such data is potentially biased and should be considered with caution.

93. This important information regarding the integrity of the Malaysian data would have remained unknown but for the ITC's decision—in this particular, and rare, instance—to release details regarding the data collection process.

⁵⁶ ITC Thailand and Malaysia Technical Report Wave 1, p. 8., ITC Thailand and Malaysia Technical Report Wave 3, p. 17-18.

⁵⁷ ITC Thailand and Malaysia Technical Report Wave 1, p. 8.

⁵⁸ ITC Thailand and Malaysia Technical Report Wave 3, p. 18.

94. The lack of transparency of the ITC's data sharing policy prohibits a full review of the data and, consequently, my review of any study relying on ITC data is incomplete. If ITC data is generally reliable, informative, and objective, one would expect the ITC to make it available for full review.

Cohort Design

95. Country level cohort sampling is used for all ITC surveys. A group of adult smokers is selected, then that same group is tracked and sampled again every year.

96. Cohort sampling is not suitable for this type of research where, as discussed below, the questionnaire itself has the potential to influence the respondents' beliefs and behaviors. Cohort designs are more appropriately used to measure factual variables, such as rates of disease or weight, which can be corroborated.

97. The ITC questionnaire, however, often measures the respondents' reported behaviors or beliefs. The behaviors and beliefs held by respondents have the potential to be influenced by the questionnaire as the same respondents are exposed to the same questionnaire every year. This results in increasing conditioning over the years.

98. For example, respondents are asked, "how often, if at all, have you noticed the warning labels on cigarette packages?" After the first year, a respondent's awareness of the subject matter of this question is heightened as compared to individuals outside of the cohort. In the second year, and increasingly so in each successive year, the cohort is tainted with this increased awareness as compared to those not in the cohort that are not being asked about the warning label every year.

99. In addition to the questionnaire influencing the behavior or beliefs of the cohort, there is also the risk that participants in the cohort will attempt to please the interviewer or show what they perceive to be "progress" in successive years. Because respondents know what they will be asked and how they answered in previous years, they may feel social or other external pressure to report modifications in their smoking behavior or beliefs.

100. Individuals in survey conditions are vulnerable to external influences. Ideally, the researcher controls for external conditions to a point where their influence is immaterial. In this way, the respondents, as a group, are reflective of the larger population from which they are

sampled. However, when external influences are allowed to materially impact the respondents' behaviors and beliefs then those respondents are no longer reflective of any larger population.

101. The respondents' participation in the annual survey has the potential to impact their behaviors and beliefs. However those not participating in the cohort are not subject to the influences of the survey. Therefore, the ITC cohort design itself contributes to the lack of representativeness of the cohort.

102. For these reasons, the ITC study is better suited to a cross-sectional longitudinal design, whereby a fresh, randomly-selected sample is interviewed at each data collection wave. Such a sample would be free of the biasing influences that the cohort design introduces.

Expanding Questionnaire

103. The problems with the cohort design identified above are compounded by the fact that the ITC questionnaire has been modified from wave to wave, gradually increasing the length of the questionnaire. For example, whereas the Thailand Wave 2 Adult Recontact Smokers Survey contained approximately 97 single and multi-part questions, the Wave 3 version of this questionnaire contained approximately 131 single and multi-part questions.

104. When comparing data sets—for example wave 1 data compared to wave 2 data—the questionnaires ideally should contain as few changes as possible from Wave to Wave. This ensures that the same item has been measured in the same way across multiple data collection points. In this way, any variance in a measurement from Wave to Wave can be attributed to factors outside of the interview process itself.

105. When the questionnaire is changed, however, a comparison across different data collection waves becomes problematic, as the researcher is no longer comparing 'apples to apples.' The questionnaire itself is now a potential confounding variable that must be considered when evaluating the resulting data.

106. It should also be noted that the ITC questionnaire is particularly lengthy. I estimate the time to complete an interview based on the current questionnaire to be at least one hour.⁵⁹ The mere

⁵⁹ See ITC Thailand and Malaysia Technical Report Wave 3, p. 14 for ITC's discussion of this topic.

willingness to participate in a study of this length year after year suggests that an ITC country cohort respondent may not be representative of the broader population from which he or she is drawn.

Country Comparisons

107. Often the ITC data is used to compare country cohorts. Inherent in this design is an assumption that existing differences between the country cohorts is not a contributing factor to any measured effect(s) in the data. The ITC questionnaire does not provide a mechanism by which the researcher can properly control for the innumerable cultural, political, economic and other differences between countries; therefore, cross-country comparisons must be conducted with extreme caution and take into account the vast array of confounding variables present.

108. For example:

- The U.S. has no pictorial health warnings. According to the ITC data, compared to other countries, few in the U.S. notice the health warnings but many plan to quit. It is important to distinguish here causality from mere correlation. It is unlikely that the low recognition of health warnings in the U.S. is the cause of the high intent to quit. Unique county variables, independent of health warnings, are likely influencing the intent to quit variable.
- France is another example of the unreliability of country-to-country comparisons due to the many confounding cultural and other variables. France has no pictorial health warnings, yet according to the ITC data, measures the highest awareness of health warnings among the participating ITC countries. The awareness measured may be the result of cultural influences, limiting the ability to compare these results across various countries.
- Mass media campaigns are another variable that may influence or skew the results of the ITC study. For example, in 2001 Health Canada commenced a five-year \$480 million campaign to further support existing Canadian tobacco control campaigns. This massive effort was the largest ever by the Canadian government and separates the Canadian cohort from the other country cohorts not exposed to this influence.

109. It should also be noted that the questionnaire is the same in all countries participating in the ITC data collection and, has not changed since it was introduced in 2002.⁶⁰ Whereas this is done to make comparisons between countries easier and uniform, the drawback is that the individuality of each country is not accounted for in a one size fits all questionnaire. The use of a single, non-customized data collection instrument—designed in Canada in 2002—could have profound effects on data collected in places far removed in time and location, such as China and Uruguay in 2010.

Leading Questions

110. The reliability of the ITC Project data is uncertain due to the fact that some of the questions asked of respondents are leading in nature—that is, the wording used could have elicited answers from respondents that were biased or otherwise impacted by the wording of the question itself.

111. For example, respondents are asked “In the last month, how often, if at all, have you noticed health warnings on cigarette packages?”⁶¹ This question informs the respondent that a health warning exists and then asks them how many times they have noticed it. This creates a situation whereby it is difficult for a respondent to offer a “not at all” answer. This question also focuses the respondent’s attention directly on health warning messages, potentially coloring the respondent’s memory of their past experience with health warnings. A more neutral way of asking this question might be “What information, if you recall, appears on cigarette packs?” A mention of health warning messages in response to this question would indicate that the respondent notices health warnings on cigarette packages.

112. Additionally, respondents are asked “In the last month, have the health warnings stopped you from having a cigarette when you were about to smoke one?”⁶² Again, this question draws the

⁶⁰ While the basic set of questions included in the questionnaire have not been reworded from one wave to another, a number of additional questions have been added to the questionnaire over time. As discussed at paragraphs 103 to 105, the insertion of any new question in the questionnaire can taint the comparability of responses to the basic set of questions which have not changed.

⁶¹ See, for example, Wave 2 Thailand Smokers Recontact Questionnaire, Question 25.

⁶² Ibid., Question 27.

respondent's attention directly to the health warnings and presupposes they have the ability to stop a smoker from doing something that he or she would otherwise have done. This potentially elevates the impact of the warnings. This question could have been presented to respondents more neutrally, for example, "In the last month, have you stopped yourself from having a cigarette when you were about to smoke one?" and, if yes, "What factors impacted this decision?"

113. The presence of leading questions in the ITC questionnaire is problematic in that it introduces the opportunity for bias into the survey results. By presenting respondents with questions that place undue emphasis on health warnings, the survey potentially impacts the answers offered by respondents, such that the resulting data is not a true reflection of the respondent's opinions and/or behavior.

Conclusions

114. The ITC Project data has significant limitations that should be considered when evaluating any study based on this data:

- ITC's withholding of full access to its data raises questions as to why, if the data is reliable, such access is not willingly granted;
- Analysis of the data provided by ITC for the Southeast Asia study shows inconsistency in ITC's presentation of the study results;
- The cohort design used is not appropriate for this type of research where the survey has the potential to influence the behavior and beliefs of the cohort over time;
- The expanding length of the ITC questionnaire creates the potential for data comparability and reliability problems;
- Country to country comparisons are subject to a multitude of confounding variables that typically prevent a finding of causation between variables;
- The use of an aged survey instrument across multiple cultures for which it has not been tailored results in potentially unreliable data; and

- The questionnaire contains leading questions that are likely to introduce bias into the results.

115. Whereas each study based on ITC data should be reviewed on its own merits, any such study should first be evaluated in light of the limitations of the ITC Project discussed here.

Hammond et al. (2006)

116. This study uses data from the first wave of the International Tobacco Control Four Country Survey (ITC-4) in 2002.⁶³ The ITC-4 study encompassed interviews of 9,058 adult smokers across four countries: Canada, Australia, United Kingdom, and the United States. The current analysis attempts to show, among other things, that cigarette package warning label size in these countries correlates with knowledge of the health risks of smoking. It should be noted that no attempt is made in this study to connect awareness of health risks and behavior, and indeed none is shown.

Unavailability of Data

117. As described at paragraphs 79 through 94 above, the underlying data of the ITC Project—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.⁶⁴ 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.

118. Notwithstanding this limitation, my best efforts analysis of this study follows in the sections below.

⁶³ The data used by the researchers in this analysis has not been made publicly available. The ability to properly audit the researchers' work for computational errors as well as misinterpretation or misrepresentation of results is therefore severely limited.

⁶⁴ <http://www.itcproject.org/datarequ>.

Cultural Differences Between Samples

119. The analysis employed here is a comparison between countries. As discussed above at paragraph 107, such a comparison assumes that existing differences between the citizens of these countries is not a contributing factor to any measured distinction in the data. We know, however, that a respondent in Quebec is not the same as a respondent in Queensland. The innumerable variations between the experiences of respondents from different countries is usually so great as to prevent the attribution of any one factor to be the cause of a measured difference among these groups. Therefore between-country comparisons must be done with extreme caution and take into account the vast array of confounding variables present.

120. In 2001, one year prior to the collection of the data used in this study, Health Canada commenced a five-year \$480 million campaign to further support existing Canadian tobacco control campaigns.⁶⁵ This massive effort was the largest ever by the Canadian government⁶⁶ and, in particular, separates the Canadian sample from the other country samples in the data reviewed here. In fact, for the past decade, Canada has been at the forefront of stricter tobacco controls and public education measures, more so than any of the other countries in this study.

Size of Warning is Not Directly Tested

121. The authors claim to have found a “significant association between the strength of the package health warning...and the likelihood of citing packages as a source of health information.”⁶⁷ However, this does not demonstrate that larger pictorial health warnings are more effective at increasing awareness of the health risks of smoking.

⁶⁵ Siahpush et al. (2006). “Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey.” *Tobacco Control*. Vol. 15 (Supp. III), p. iii69, Footnote 32.

⁶⁶ “Two Thumbs Down – Canada’s Tobacco Control Mass Media Campaign.” Available at: www.nsra-adnf.ca/cms/file/pdf/twothumbs.pdf.

⁶⁷ Hammond, D. 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, p. iii23.

122. In fact, this study does not provide any evidence as to what extent, if at all, the size of a health warning impacts its effectiveness as a source of information. The study does not experimentally isolate and test the warning size variable; rather it is considered in concert with the content variable, and from this it is inferred that larger warnings are more effective in communicating health information than smaller warnings.⁶⁸

123. In other words, the authors have assumed that there is a causal link between the size and design of health warnings and the likelihood of citing packages as a source of health information. There is no basis for this assumption. To the extent that Canadian consumers were more likely to cite cigarette packages as a source of information than consumers in other countries, this could have been attributable to differences between the samples rather than any warning label effect. Possible differences include cultural differences, the extent of anti-smoking campaigns through other media, or the substantial difference in the content of the health warning messages themselves.

The Impact of Health Warnings on Knowledge of Health Risks

124. The authors further claim that “health warnings on cigarette packages are strongly associated with health knowledge.”⁶⁹ This is based on the finding in the study that Canadian respondents were aware of a greater number of health risks than those in other countries. It should be noted that no attempt is made in this study to connect awareness of health risks and behavior, and indeed none is shown.

125. We know that just prior to the data collection in this study Canada was in the midst of a significant public education campaign on this issue. The authors of this study attempt show that in jurisdictions with larger pictorial health warnings respondents are more knowledgeable of health effects of smoking. However, this ignores the likelihood that it was the unique experiences of Canadians at the time this data was collected, including the comprehensive Health Canada education effort, which makes the Canadian sample different from the others. It is possible that this massive educational campaign created the appearance of a link between health warnings and

⁶⁸ Ibid.

⁶⁹ Ibid.

knowledge, when in fact unique environmental factors, which were not controlled for, may also be a cause.

126. Moreover, this study does not provide the reader with any information regarding the impact of the relative size or pictorial content of health warnings. As discussed above, the samples that are compared in this study are composed of respondents with unique cultural experiences. That one country's warning is a different size than the others does not necessarily mean that any difference in risk awareness between the samples is attributable to the difference in warning label size or pictorial content. Indeed, these variables were not directly tested in this study. Therefore, any findings on the effect of health warnings on respondents' awareness of specific risk issues cannot be specifically linked to the size or graphic content of the health warning.

127. Respondents were asked about smoking behavior. So while this study attempts to link knowledge of health effects with warning label size and intention to quit, the lack of a significant difference in reported smoking prevalence between countries would indicate that if knowledge of health effects and the size and pictorial content of the warning label on cigarette packs did influence smoking behavior, then those connections must not be supported here.

128. The authors report that the study is "limited to respondents from Wave 1 [of ITC-4 data collection], conducted between October and December 2002." In other words, this is a cross-sectional study, which collects and examines data only at one specific point in time. Accordingly, while this study provides a snapshot of inter-country awareness of the health effects of smoking at the time of data collection, it provides no evidence as to changes in intra-country awareness and smoking prevalence over time.

129. As discussed above at paragraph 120, Canada implemented larger pictorial health warnings in 2001, a year prior to the current study's data collection phase. Because this study does not present any longitudinal data from before the implementation of the larger warnings, it does not provide any evidence as to how, if at all, awareness of health warnings and smoking prevalence in Canada changed from before to after the implementation of the larger health warnings. Consequently, the extent to which, if at all, the larger pictorial health warnings impacted higher awareness and intention to quit in Canada cannot be determined from this study.

Conclusion

130. This study is hampered by a variety of limitations which impact its reliability. These limitations include the following:

- This study relies on ITC data which is unavailable to me and therefore impedes a full review of the findings reported by the authors;
- Inherent cultural differences between the samples in this study have not been controlled for and their impact on the resulting data is unknown;
- The study fails to experimentally isolate and test the warning size variable to determine what impact, if any, warning size has on respondents' awareness of the health risks of smoking; and
- The study's cross sectional design prevents an examination of the extent to which, if at all, awareness of health warnings and smoking prevalence in Canada changed from before to after the implementation of larger pictorial health warnings.

131. In light of these significant limitations, I do not consider this study to provide credible evidence regarding the impact of larger tobacco health warning labels.

Hammond et al. (2007)

132. This study sought to examine the effectiveness of the health warnings on cigarette packages across four countries (Canada, Australia, the UK, and the US) in terms of impacting smoking behaviors and exposure and response to health warnings.

133. The study examined data from the first four waves of the ITC Four Country Survey conducted in Canada, Australia, the UK, and the US. The samples consisted of 14,975 adult smokers: Canada (n=3,687), US (n=4,273), UK (n=3,634), and Australia (n=3,381). Data was collected prior to and at three waves following the implementation of a new health warning in the UK.

134. It should be noted that this study makes complex statistical claims. Given my conclusions below regarding this study, I do not comment on these statistical claims.

Unavailability of Data

135. As described at paragraphs 79 through 94 above, the underlying data of 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.⁷⁰ 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.

Country Comparisons

136. As described above at paragraphs 107 to 109, ITC data is often used to compare country cohorts. Indeed, the present study compares samples across four different countries. Such comparisons are problematic because the ITC questionnaire does not control for the many cultural, political, economic and other differences between countries. This is a significant limitation of this study.

Cohort Design

137. The ITC study design is inherently flawed in that it collects cohort longitudinal data (see paragraphs 95 through 102 above). In cohort studies, the researcher follows the same group of people over time, collecting data at various points, or “waves.” While cohort data is not in itself problematic as a research tool—in fact it is appropriately utilized in, for example, medical research—its use in the ITC study is inappropriate.

138. The ITC study seeks to “evaluate the psychosocial and behavioural effects of national-level tobacco control policies throughout the world,”⁷¹ including respondents’ awareness and understanding of cigarette health warnings. By administering the same questionnaire to the same group of respondents at multiple waves, the sample becomes accustomed to the questions that will be asked of them. This awareness can bias respondents’ answers at the second and future waves of data collection.

⁷⁰ <http://www.itcproject.org/datarequ>.

⁷¹ www.itcproject.org.

Results

139. Respondents were asked a series of questions regarding their exposure to health warnings: how often they had noticed the warning labels on cigarette packages in the past month, whether they had read or looked closely at the warning labels in the past month, and whether they had noticed advertising or information about the dangers of smoking or encouraged quitting on cigarette packages. These questions do not provide any data on the impact of larger or pictorial health warnings on smoking behaviors; therefore results generated by these questions are irrelevant to my analysis.

140. The sole relevant behavioral question—“In the last month, have the warning labels stopped you from having a cigarette when you were about to smoke one?”—shows no link between the responses to this question and warning label changes, and therefore does not provide insight as to the impact of larger warning labels on consumer behavior.

141. As stated by the authors:

It is not possible to estimate the influence of the new UK warnings or the Canadian pictorial warnings on prevalence rates using the current data. National prevalence rates are determined by a constellation of individual, social, and environmental factors, including other policy measures as well as “secular” trends in marketing and pricing.⁷²

142. Additionally, the authors do not explore the apparent disconnect between the level of respondents who noticed warnings often and the level of respondents that make quit attempts. Indeed, UK respondents show the lowest level of quit attempts in the past year.

⁷² 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, p. 216.

Conclusions

143. In summary, this study has material limitations, namely:
- This study relies on ITC data which is unavailable to me and therefore impedes a full review of the findings reported by the authors;
 - The cohort design is inherently flawed for the purpose of evaluating tobacco control policy.
 - This survey contains questions that are purely attitudinal and therefore cannot be used to comment on behavioral change.
 - A link between smoking behavior and warning label changes has not been established.
 - Although a behavioral question is asked, no attempt has been made to analyze changes in this behavior over time.
 - The country to country comparisons are unreliable.
144. For the reasons stated above, this study does not provide reliable evidence in support of any initiative to introduce larger health warnings.

Elliott & Shanahan (2008)

145. This is an Australian study which includes a literature review, focus group findings, and a telephone survey of 1,304 Australians 15 and older completed in 2008. The telephone survey data is compared to data from a similar study done in 2000. Larger health warnings were introduced in Australia in between these telephone survey research waves in 2006.

146. The authors reach several conclusions based on the telephone surveys that are discussed below. The literature review and focus group findings do not provide data that is projectable to a larger sample and are therefore not discussed herein. For a more detailed discussion of these types of data and their lack of applicability to a discussion of behavioral impact, please see Exhibit 4 of this report.

Passage of Time

147. The authors conclude that “the graphic health warnings communicated potential health effects; improved consumer knowledge; discouraged smoking; and have contributed to behavioural change.”⁷³ However, this conclusion is unfounded, not least due to the extensive passage of time that has occurred between the two data collection points of this study.

148. For example, the authors claim that health warnings have been effective in informing consumers. The percentage of respondents that claim the Health warnings have improved their knowledge “a lot” saw a slight increase from the 2000 study to the 2008 study. However, given the extensive passage of time, the modest change reported could be due to any number of factors including the wide ranging tobacco control and education efforts that have occurred over this period. The authors have not sufficiently controlled for such confounding variables and therefore cannot accurately claim that consumers are better informed as a result of the health warnings.

149. The authors further report that the health warnings have led to an overall increase in consumers’ knowledge of the health consequences of smoking.⁷⁴ Thirty-eight percent of smokers responded that the health warnings had improved their knowledge “a lot” in the 2008 study, while a lower 32 percent provided this response in 2000. This measurement alone tells the reader very little. A respondent’s claim as to the effectiveness of the health warnings is merely an opinion that may be influenced by a wide range of variables, only one of which may be the actual degree to which the health warnings have increased their knowledge of the health consequences of smoking. Accordingly, a more accurate interpretation of this result is that there was a small percentage increase in the number of smokers that *believe* that the health warnings have increased their knowledge of the health consequences of smoking.

150. Additionally, the impact of any reported increase in knowledge on smoking behavior is unknown. Even if the survey results are correct, this does not provide any information about the impact of that knowledge on their behavior.

⁷³ 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. 15.

⁷⁴ *Ibid.*, p. 105.

151. Given the passage of so much time between the two measurements, it cannot be said that the health warning is the determining (or even a) factor in that reported increase in knowledge. It is my understanding that many tobacco control variables have been introduced over this extended period of eight years. For example, some of the tobacco-related initiatives that took place over this period include:

- Tobacco Advertising Prohibition Amendment Act, phasing out tobacco advertising at international sporting or cultural events (November 2000);
- Tobacco (Amendment) Act 2000, enacting certain bans on smoking in restaurants and eateries (effective 1 July 2001);
- Tobacco Product Regulation (Further Restrictions) Amendment Act, enacting certain public smoking bans (December 2004);
- Australian Consumer and Competition Commission (ACCC) implemented descriptor bans (November 2005);
- Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004 (effective 1 March 2006), includes regulations on larger and pictorial health warnings, pack size, yield levels;
- Anti-smoking television campaign which coincided with World No Tobacco Day (May 2007); and
- Anti-tobacco advertisements aimed at a younger generation of smokers aired for two months. (October 2007).

152. The examples listed above are just a few of many tobacco control measures that have occurred in Australia over the period spanned by this study. As such, it is impossible to attribute any reported increase in respondents' knowledge to any one factor such as the health warnings on cigarette packs.

153. This study also measured a higher intent to quit smoking in 2008 among smokers when the 2000 data is compared to the 2008 data. This is not surprising given the changed environment for smoking over this period, as discussed above. Given the multitude of smoking control measures

and educational efforts that have occurred over this period, any measured increase in smokers' intent to quit cannot be attributed even partially to graphic health warnings without clearly controlling for the impact of these other variables. This has not been done in this study.

Question Design Issues

154. In addition to the extensive passage of time that impacts a comparison between these two data waves, material question design issues present throughout the study further weaken the data presented. These question design issues are discussed below.

Noticeability

155. This study includes some self-observed data, such as claiming to have noticed changes in health warnings⁷⁵ and being aware of health warnings.⁷⁶ There is limited value to this data as it does not measure observed behavior, but rather asks for respondent recall. As described at paragraphs 56 through 58 above, respondents do not always recall past events accurately. Indeed, simply asking the question, "Have you noticed..." can influence the respondent's answer. Additionally, because this study did not utilize control questions, the reader cannot discern to what degree the study itself influenced the answers given by respondents.

156. The Quitline survey questions suffer from being entirely leading and suggestive to the point of rendering the resulting data unusable. Question 18, the first direct Quitline question reads:

Are you aware of a Quitline telephone number which is included with the health messages on tobacco packs?⁷⁷

157. Within the question itself, the respondent is told that the Quitline number is present on packs, and is then asked if they have noticed it. It is difficult for a respondent to reveal that he or she has not noticed something when they are being told that it exists. Indeed, the "awareness" measured here ranged from 56 percent to 90 percent depending on the classification reported. Prior

⁷⁵ Ibid., p. 61.

⁷⁶ Ibid., p. 63.

⁷⁷ Ibid., p. 208.

to this leading question, unaided awareness of the Quitline number reported in this study ranged from 1 percent⁷⁸ to 8 percent.⁷⁹ The unaided—and less suggestive—measurement illustrates the material impact that question design can have.

Effectiveness

158. The authors also conclude that the health warnings prevent non-smokers from taking up smoking and ex-smokers from taking up smoking again. This is based on a measurement of the *perceived* effect of the health warnings on behavior.⁸⁰ Responding ‘yes’ or ‘no,’ non-smokers were asked if the health warnings “have helped you from taking up smoking.”⁸¹ Twenty-two percent claimed it had. As discussed below, the answer format of this inclusive statement results in a built-in bias that impacts the validity of the data.

159. Both non-smokers and ex-smokers were asked if the health warnings “would help prevent people from taking up smoking.” Sixty-three percent of non-smokers and 54 percent of ex-smokers indicated ‘yes.’ For this question, what a respondent thinks about what hypothetical ‘people’ may do is not a valid predictor of what consumers will actually do. Such data is attitudinal and should be assigned very little weight in terms of its predictive value.

160. The yes/no answer format used in both of these questions above should also be evaluated closely. A loosely designed statement—such as, health warnings “have *helped* you from taking up smoking”—is difficult to completely rule out with a ‘no’ answer, but easy to respond to with a ‘yes’ answer. Even assuming that the answers given by respondents to this question were accurate, what is not measured at all is the magnitude of the role, relative to other factors, that health warnings may have had in “helping” respondents from taking up smoking. Hence, this question design suffers from a built-in bias for the respondent to answer ‘yes.’ Its failure to measure the degree to which the belief is held renders it over-inclusive and unable to produce valid results. Therefore this data should not be relied upon.

⁷⁸ Ibid., p. 62, Table 9.

⁷⁹ Ibid., p. 68, Table 16.

⁸⁰ Ibid., p. 108, Table 50.

Reaction

161. The authors conclude from their data that smokers have adopted behaviors to avoid the health warnings and that this suggests that the warnings are making smokers uncomfortable. Smokers were asked if they had ever, in the past two years, “avoided buying packs with particular health warnings or concealed or hid the health warnings on your pack in some way?”⁸²

162. Eight percent of smokers indicated that they had avoided buying packs with particular health warnings, 12 percent reported that they had concealed or hidden the pack in some way, and four percent reported that they had done both. Therefore, eight percent reported that they avoided but didn’t conceal, while 12 percent reported that they concealed but didn’t avoid, and four percent reported that they did both.

163. There are a number of issues with the conclusion drawn from this data:

- Those reporting having engaged in the behavior is very low. Only four percent of respondents report that they engaged in both behaviors measured.
- The answer category stated is very broad, capturing almost any circumstance; therefore, respondents are much more likely to answer affirmatively. The questions “Have you ever avoided” or “have you ever concealed or hid” over a two year time span include a broad range of possible behaviors.
- The range of behaviors covered in this question includes behaviors that do not necessarily rise to the level of making smokers uncomfortable about their habit.
- The answer categories do not measure magnitude at all. Thus, in addition to being overly inclusive, these questions do not provide a measure of the degree to which respondents engage in the target behaviors.

⁸¹ Ibid., p. 108.

⁸² Ibid., p. 117, Table 58.

Other Effects

164. The authors concluded that “the graphic health warnings have raised concerns about smoking and encouraged smokers to think about quitting and to quit, and assisted recent quitters to stay quit.”⁸³

165. Because respondents are read prompted answers, responses to the question from which this conclusion is based give little insight into the issue of the impact of health warnings. The prompted nature of the question makes it very easy for the respondent to offer an affirmative response. The question reads:

In terms of the way you feel about your own smoking behaviour would you say the health warnings on packs of cigarettes and tobacco have... [read list]⁸⁴

166. One of the list items reads: “Raised your concerns about smoking.”⁸⁵ Rather than asking the question in this way, a more fundamentally sound way to measure that variable would be, for example, to first ask if the respondent has a raised concern about smoking and, if they have, ask what has contributed to that raised concern. The unprompted responses to this type of question carry much greater weight than the prompted question asked in this survey.

167. Subject to this design weakness, smokers in the 2008 survey indicated an overall greater impact of the health warnings as measured in the question above. However, given the extended passage of time between these two data collection points (as discussed above), the health warning variable has not been sufficiently isolated to draw any conclusions from this data. There are simply too many potentially confounding factors that could have influenced this variable over the eight year period between data collection waves. The isolated impact of any one of these factors, including health warnings, cannot be known any degree of reliability from the data presented.

⁸³ Ibid., p. 118.

⁸⁴ Ibid., p. 119.

⁸⁵ Ibid.

Quitting

168. The authors conclude that “the graphic health warnings have contributed toward smokers quitting and encouraged others to consider quitting in the future.”⁸⁶ As support for this conclusion, the authors cite the responses of former smokers to the question “which, if any, of the following factors helped you decided to quit smoking.” A list of 13 factors is then read to them, including health warnings.

169. As a prompted response, the measurement here does not provide much insight as it is a leading design that elevates the impact of the very factors presented. A more valid design would collect unprompted answers to this question. Such a design would provide a more valid gauge of respondents’ uninfluenced perceptions. The tendency to affirmatively respond to the factors presented is shown by the fact that recent quitters selected most of the prompted reasons for quitting.⁸⁷

Attitudes

170. The authors conclude that the “graphic health warnings have had a positive effect on attitudes in terms of raising concern and increasing knowledge about the effects of smoking on health and encouraging quitting.”⁸⁸

171. The support for this conclusion is drawn from a series of statements read to the respondents whereupon they were asked if they agree a little or a lot or if they disagree a little or a lot with each statement. Although the responses are entirely subjective, the 2008 data is compared to the 2000 data.⁸⁹

172. Given the passage of eight years, and, as discussed above at paragraph 151, the multitude of smoking control measures implemented over this period, the authors have not sufficiently isolated the health warnings variable in their study to conclude that the changes in respondents

⁸⁶ Ibid., p. 120.

⁸⁷ Ibid., p. 121.

⁸⁸ Ibid., p. 126.

⁸⁹ Ibid., p. 127, Table 69.

reaction to the statements presented to them is the result of the health warnings on cigarette packs or one or a combination of many other confounding factors.

173. Additionally, the presentation of this data is incomplete. Respondents indicated whether they agree a little or a lot or disagree a little or a lot. Yet “all agree” and “all disagree” responses are not shown, nor is their revealed statistical testing for these combined categories. For a few of the statements cited as supporting the authors’ conclusion, there is a statistically significant difference in the “a lot” figures and that is discussed, yet no such difference in the “a little” figures and that is ignored.

174. A statistical analysis of the “all agree” and “all disagree” data is not shown in the table but in two instances discussed in the text as significant.⁹⁰ The “all agree” and “all disagree” groupings should be shown as they are a better measurement of agreement or disagreement than the more subjective designation of “a little” or “a lot.” Indeed, the authors selectively use these combinations in two instances, yet do not allow the reader to review and evaluate the data for the entire “all agree” and “all disagree” groupings.

Presentation of Findings

175. Interlaced throughout the presentation of results from the telephone survey is a discussion of the focus group findings (see full discussion of the limitations of focus group research at paragraphs 223 through 227 below). This appears to be an attempt to bolster survey findings or interpret ambiguous survey findings in a particular way. An objective evaluation of the data from the telephone survey would be aided by a clear presentation of those results, unencumbered by an infusion of non-compatible data. In this study, the reader is left to filter out the quantitative telephone survey data and findings that are mixed with qualitative focus group discussion excerpts.

176. Additionally, comparisons to the earlier telephone survey are piecemeal, with no explanation of why some data is compared to the earlier study and some is not. A systematic approach to the longitudinal comparisons is preferred so that the reader is satisfied that all comparisons are shown, not just those that support the author’s perspective.

⁹⁰ Ibid., p. 127.

Conclusions

177. In summary, this study does not provide reliable data on the issue of the impact of increased health warning messages for the following reasons:

- The extensive passage of time between the two studies precludes the health warning variable from being sufficiently isolated as a cause of any of the changes measured.
- Material question design issues present throughout the study further weaken the data presented.

Environics (2008)

178. This study was conducted among separate samples of Canadian youth and Canadian adult smokers. Both the adult and youth studies are reviewed in the sections that follow.

Review of Adult Study⁹¹

179. In this study the authors sought to test the effectiveness of different sized health warning messages among Canadian adult smokers. The authors interviewed 1,000 adult smokers across 14 Canadian communities in the spring of 2008.

180. The introduction of this study reveals that respondents were informed that Health Canada was the sponsoring party prior to any data collection.⁹² As discussed at paragraphs 53 through 55 above, accepted international standards of consumer survey research caution against providing respondents with information regarding the study sponsor, as such knowledge can introduce bias into the study results.

181. In this case, informing the respondent that Health Canada was the study's sponsor could have influenced respondents to provide answers (whether consciously or unconsciously) which

⁹¹ On January 7, 2010, JTI-Macdonald submitted a letter to the Canadian Controlled Substances and Tobacco Directorate that included a discussion of some of my concerns with this study. In addition to the discussion contained in that letter I submit this review.

⁹² Envionics Research Group (2008). "Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers." Prepared for Health Canada. Appendix B – Questionnaires, p. 1.

exaggerate the impact that the health warning messages have had on them, whereas otherwise they may have answered the questions differently—a phenomena known as “pleasing the interviewer.” Maintaining a double-blind⁹³ protocol is essential in this type of study to help prevent the study design from influencing the results. From the outset, this study deviates from that practice.

Attitudinal Data

182. Much of the survey findings are limited to the respondents’ attitudes toward a variety of smoking issues. For example, the study reports that “58 percent say increasing the size of messages would be very or somewhat effective in making the message more noticeable,”⁹⁴ and that “almost all adult smokers (98%) agree that smoking is bad for their health.”⁹⁵

183. These types of findings are attitudinal. At best,⁹⁶ they simply inform the reader as to what this group of respondents think or believe about a particular subject. Critically, attitudinal findings like these do not inform us of the behavioral impact of any regulatory or marketplace adjustments related to these issues.

184. For example, someone may say that, *in their opinion*, increasing the size of the health warning message on cigarette packs would be effective in making the message more noticeable. However, this opinion does not inform the reader as to the actual behavioral impact of an increase in warning size, whether it be actually noticing the new warning more or impacting their smoking behavior. Therefore, while public opinion polls serve a purpose in some circumstance, they are not reliable when used to predict the behavioral outcome of a policy or marketplace change.

⁹³ Double-blind refers to the practice of data collection where neither the interviewer nor the respondent is aware of the purpose or sponsor of the study. Maintaining this protocol prevents the interviewer from influencing the respondent to achieve a particular result, and helps prevent the respondent from considering anything other than his or her beliefs are on the subject.

⁹⁴ Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers.” Prepared for Health Canada. p. 3.

⁹⁵ *Ibid.*, p. 2.

⁹⁶ There are other significant issues with the attitudinal questions in this survey, such as leading question design and unbalanced question sets and answer categories, which further weaken the data. However, since this attitudinal data is of limited use in this circumstance I will not detail these additional concerns in this section of the review.

185. Indeed, if predicting marketplace outcomes were simply a matter of asking people what they think, the discipline of marketing would be much simpler. In practice, however, predicting behavior is more complex and often requires different types of market research and data.

Poor Question Design

186. Outside of the experimental section of this study (discussed below), there is one question that purports to measure respondents' behaviors. Question 17 asks if the health warning messages have "been very, somewhat, not very or not at all effective in each of the following ways."⁹⁷ Five attributes are listed:

- Getting you to smoke less
- Getting you to smoke less around others than you used to
- Increasing your desire to try to quit smoking
- Getting you to try to quit smoking
- Informing you about the health effects of cigarette smoking

187. This question asks about the individual's own behavior and is therefore more informative on the issue of future behavior than merely collecting data about the individual's attitude or beliefs about what he or she thinks others will do. However, this question does suffer from a lack of an internal control that makes the results difficult to interpret with any accuracy.

188. The five attributes measured here are positive. There could be external influences, such as question wording or interview atmosphere, that influence respondents to answer this question more toward "Very effective" than "Not at all effective," or vice versa. Without the inclusion of a negative attribute in the answer set, such as "Decreasing your desire to quit smoking," there is no relative reference for the data collected. Hence, the reader does not know the level of influence of

⁹⁷ Environics Research Group (2008). "Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers." Prepared for Health Canada. Appendix B – Questionnaires, p. 5.

external factors and cannot have any confidence that this question is measuring phenomena external to the potential influence of the study itself.

Experimental Design

189. Among other issues, the experimental design section of the study also addressed the issue of larger health warnings.⁹⁸ This study sought to test four health warning size options: 50%, 75%, 90%, and 100% of pack coverage. The study calls for the respondent to be shown each of the four pack designs and after each one asked to measure the pack's effectiveness in "Informing Canadians about the health effects of tobacco," and "In encouraging Canadians to reduce their tobacco use."⁹⁹

190. This is a poor design. Once a respondent views one pack size option and is asked the questions, a standard has been set with that individual. When a second pack is shown and the same questions are asked, the respondent must answer those questions relative to that now existing standard. Therefore one would expect respondents to rate health warnings that are relatively larger than the ones they had previously seen as more effective, and relatively smaller health warnings as less effective. The respondent is constrained by his or her own ranking.¹⁰⁰

191. Removing this influence could have easily been accomplished in the design by dividing the sample into four distinct cells and showing each cell only one size option. The ratings established in each cell would then be true to the health warning size shown and not the result of their prior rating of a relatively smaller or larger warning. The data from the four cells could then be compared to determine relative effectiveness.

⁹⁸ Plain packaging was also addressed in the experimental design and is not relevant to this review.

⁹⁹ These questions and the others that follow in this section are attitudinal and are subject to the restrictions discussed earlier in this review. However, the design flaw is such that the data produced by these questions is irrelevant.

¹⁰⁰ The questionnaire gives the instruction to "RANDOMIZE ORDER SHOWING 11, 12, 13, 14." However, the process of randomizing is notoriously difficult for humans to do and is indeed a great burden on the data collection personnel in this circumstance. The tendency would be to simply show the packs in order and not randomize. If this was done it would exacerbate the issue discussed here. There is no way of knowing in what order the stimuli were presented to respondents because the researchers, unfortunately, did not capture that information in their design.

192. The next three questions in the experimental design section show the respondent all four packs designs together and ask attitudinal questions regarding which pack would be most effective. For example, the study asks, “Which of these 4 packages do you think would be most effective in informing Canadians about the health effects of tobacco?”¹⁰¹

193. This design produces data that is utterly without insight. The questions are, essentially, a logic test that has no relevance to the actual effect of any of the design options presented. Of the choices given, respondents will overwhelmingly select the bigger one in this circumstance on the lay assumption that bigger is better.

Behavioral Section

194. The final section of the study shows respondents the pack design with the 100 percent warning and asks what the impact would be on them personally. The responses to this question are not informative because they lack any relative foundation. For example, 15 percent said they would smoke less,¹⁰² yet we have nothing to compare that to. What percentage of respondents would have answered they would smoke less if shown the 50 percent design?

195. A more informative design would have included the other health warning size options in distinct cells. Had this design been employed, one could have compared the results obtained in each cell and form a better understanding of the influence, if any, of the health warning size as a factor motivating behavioral change. Without this comparison, the data from this single question is not informative.

Review of Youth Study

196. The adult study reviewed above was repeated on a Canadian youth population. The youth study was identical to the adult study in all respects except that instead of interviewing adult

¹⁰¹ Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers.” Prepared for Health Canada. Appendix B – Questionnaires, EX7, p. 8.

¹⁰² Ibid., p. 51.

smokers, 1,000 youth aged 12 to 18 were interviewed.¹⁰³ In the youth sample, 10 percent were smokers and 90 percent were non-smokers.¹⁰⁴

197. Employing the same study design, the youth component of this study suffers from the same shortcomings as the adult component discussed above. Additionally, because this study interviewed young respondents, it is subject to the additional methodological limitations discussed in the “Age of Respondents” section at paragraphs 59 through 62 above.

Conclusion for Adult and Youth Studies

198. For the reasons outlined above, these studies cannot be viewed as credible support for the conclusion that larger health warnings would increase awareness and/or impact on smoking behavior.

Joossens (2004)

199. Belgium introduced new larger text health warnings in October 2003 that covered an average of 55 percent of the front and back of cigarette packs. A survey of Belgians aged 15 and over was completed in January 2004, a few months after the introduction of the new warning labels. Smokers comprised about one-third of the sample.

Analysis

200. The complete questionnaire is not provided in this report. Even the wording of individual questions used in this survey is often absent. As the survey instrument can have a material effect on the participant’s responses, the unavailability of the questionnaire limits my ability to review the methodology sufficiently to have confidence that the results are an accurate measurement of the issues probed. Considering this significant limitation, I will discuss the results provided to the greatest extent possible.

¹⁰³ Environics Research Group (2008). “Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth.” Prepared for Health Canada. p. 1.

¹⁰⁴ Ibid., p. 9.

201. The study found that 79 percent of packaged cigarette smokers noticed the new warnings.¹⁰⁵ However, this is a cross-sectional study in which data was collected only once. There is no point of comparison with the prior warnings (i.e., no baseline measurement) and therefore the data is not informative of the *relative* noticeability of the new warnings over the old warnings.

202. Those that had noticed the new warnings were asked to indicate their level of agreement with a number of assertions, such as, “I have discussed the new warnings with friends or family.”¹⁰⁶ Again, there is no point of comparison with the prior warnings, so the measurements here are not informative of any impact of the new warnings over the old.

203. When asked if they are smoking more or less as a result of the new warnings, eight percent of respondents indicated that they smoked less, two percent more, and 88 percent said the warnings had no effect on their smoking.¹⁰⁷ There is a leading nature to this inquiry in that it directly focuses the respondent’s attention on the new warnings and makes it convenient—if indeed that respondent believes he or she is smoking less—to attribute this behavioral change, at least in part, to the health warnings.

204. A neutral approach to this question would be to ask respondents if they have noticed a change in their smoking behavior over the last three months, and, if yes, whether they are smoking more or less. The respondent could then be asked to list the factors that have contributed to this change in behavior. This sequence, properly executed, will yield a reliable measure of the influences impacting a change in behavior. This was not done here.

205. Additionally, as before, there is no equivalent measurement of behavioral impact of cigarette health warnings collected prior to the introduction of the new health warnings with which to compare these findings. Therefore the relative influence of the new warnings on respondents’ smoking behavior as compared to the old is unknown.

¹⁰⁵ Joossens, L. (2004). “Investigation into the effect of health warnings on cigarette packets in Belgium.” *Belgian Minister of Public Health and Social Affairs*. p. 10.

¹⁰⁶ *Ibid.*, p. 12.

¹⁰⁷ *Ibid.*, p. 14.

206. Finally, respondents were shown a pack with a Canadian pictorial warning and the new Belgian pack with the text warning and asked their opinion regarding which of the two warnings were “more convincing.”¹⁰⁸ There was no difference between the two, with 30 percent selecting the Canadian pack and 29 percent selecting the Belgian pack.¹⁰⁹

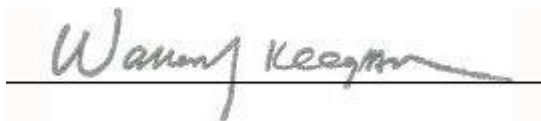
Conclusion

207. This survey attempted to measure a number of variables regarding the then current Belgian text-only cigarette pack warning labels. However, given that no baseline measurements for these variables exist for the prior health warning, it cannot be determined from these results to what degree, if any, the new warnings have had an impact on the variables measured here. I therefore conclude that this study provides no reliable evidence as to the impact of increasing the size of health warnings.

Conclusions

208. DG SANCO cites no evidence in support of the Proposal. I have reviewed and analyzed the studies relied on by the RAND Report in support of the proposition that increasing the size of the health warnings on cigarette packs will impact smoking behaviors among consumers.

209. Upon completing my review, I have found that no study provides reliable evidence as to the potential behavioral impact of increasing the size of health warning labels on cigarettes.



Dr. Warren J. Keegan

November 24, 2010

Date

¹⁰⁸ Ibid., p. 14.

¹⁰⁹ Even if there was a measurable difference between the two pack designs here, the question design used is problematic. Using ambiguous terms such as “convincing” leaves the reader unsure as to what respondents believed they were responding to. This is also an attitudinal measurement with no obvious bearing on behavioral impact.

Exhibit 1 – Qualifications of Dr. Keegan

Warren J. Keegan, DBA

Biographical Sketch

210. I am a Visiting Professor of Marketing and International Business and Distinguished Professor of Marketing and International Business Emeritus at the Lubin School of Business, Pace University, New York.

211. My educational background includes a B.S. (1958) and M.S. (1959) in Economics from Kansas State University, and a Master of Business Administration (1961) and doctorate (1967) from the Harvard Business School.

212. During a leave of absence from the Doctoral Program at Harvard, I was employed by the Boston Consulting Group. I worked with the founders of the firm on major strategy assignments and participated in the early stage development of the first major strategy boutique firm in the global consulting industry.

213. After obtaining my doctorate, I was appointed Assistant Professor at Columbia Business School in New York City, taught in the MBA program, served on the doctoral faculty, and was promoted to Associate Professor. I then joined the faculty of Baruch College in New York where I taught in the MBA program, served on the doctoral faculty of the City University of New York, and was promoted to full Professor.

214. In 1976, I was appointed full Professor at The George Washington University. After four years at The George Washington University, I returned to New York as a visiting professor at the Stern School of Business, New York University. In 1982, I was appointed Professor of Marketing and International Business at Pace University in New York.

215. I have taught MBA and doctoral courses at the University level for over 35 years at these schools and have been a visiting professor and lecturer at leading business schools in the U.S., Europe, Africa, Asia and Latin America. I teach in the marketing, international business, organization strategy and strategic management areas and was the founder and director of the Center for Global Business Strategy at Pace University.

216. I have extensive experience in the area of research design and methodological analysis. As a member of the doctoral research faculty, I directed and participated in seminars on research methodology and design at Harvard University, Columbia University, George Washington University, and New York University. At Pace University I offered a special research methodology seminar as part of the research methodology curriculum in the doctoral program. Over the course of my career I have supervised and advised hundreds of students on research design and methodology.

217. As a faculty member, I have engaged throughout his career in discussion and collaboration with faculty colleagues about research methodology and design. As a member of editorial review boards, and as an author of articles that have been published in refereed journals, I have engaged in ongoing dialog and discussion of research design and methodology best practices.

218. Additionally, I have taken numerous graduate and doctoral level courses in research methodology and design including statistical analysis. My consulting assignments have included the design and implementation of nationwide field surveys of consumer awareness and purchase interest in client consumer products.

219. I have published in the leading business journals in his field including the Journal of Marketing, Harvard Business Review, Administrative Science Quarterly, Journal of International Business Studies, the Columbia Journal of World Business, and many others. I am on the editorial advisory board of the Cranfield School of Management and Financial Times Management Monograph Series and on the editorial review board of leading marketing and international business journals.

220. I have published over thirty books including *Offensive Marketing*, *Global Marketing Management*, now in the Seventh Edition; *Marketing Plans that Work*, now in the Second Edition; *Global Marketing*, now in the Sixth Edition; *Marketing*, now in the Second Edition, *Globales Marketing-Management: Eine Europäische Perspektive* and *Judgments, Choices and Decisions: Effective Management through Self-Knowledge*.

221. In my consulting practice, I have focused on marketing and business strategy. I am the founder of Keegan & Company LLC., a consulting consortium of experts in marketing and global

strategic management. I have prepared reports and testified as an expert on a variety of issues in U.S. federal and state courts, in arbitration, and before the International Trade Commission.

Exhibit 2 – 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, Fifth Edition*. Englewood Cliffs, NJ.: Pearson Prentice Hall, 2008.

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.

Global Marketing, Fourth Edition, with Mark C. Green, Upper Saddle River, NJ, Prentice Hall, Inc., 2004.

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.

Global Marketing, Second Edition, with Mark C. Green, Prentice Hall, Inc., 2000.

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, Member, Financial Advisory Board, 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.

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Exhibit 3 – Selected Publications of Dr. Keegan (1965-2010)



Publications of Dr. Warren J. Keegan

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.

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

2004

Keegan, Warren J. *Global Marketing Management, Seventh Edition*, Chinese Simplified Translation, Pearson Education Asia Ltd and Tsinghua University Press, 2004.

Keegan, Warren J. *Forward. Consumer Behavior Concepts, Applications and Cases*. By: M S Raju and Dominique Xardel. Vikas Publishing House PVT LTD 2004.

Keegan, Warren J. and Hugh Davidson. *Offensive Marketing: An Action Guide to Gaining the Offensive in Business*, Elsevier, Butterworth Heinemann, 256 pages, 2004, ISBN No. 0750674598.

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

2003

Keegan, Warren J. *Manajemen Pemasaran Global*, Indonesian Edition. Prentice Hall, 2003.

Keegan, Warren J., *Global Marketing Management*, Chinese Edition, Prentice Hall, 2003.

Keegan, Warren J. *Strategic Marketing Planning: A 21st Century Perspective*. IMR, Vol. 21, Issue 1, 2003.

Keegan, Warren J. "The New Landscape of Global Marketing: Winners and Losers in the 21st Century." Singapore Nanyang Business Review (SNBR): WMA edition. Guest editors - Philip Kotler and Hermawan Kartajaya. Volume 2 Number 1 (January-June 2003): pp. 75-82.

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 europaische 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.

Keegan, Warren J., *Global Marketing Management, Third Edition*, Traditional Chinese Translation, Prentice Hall International (Taiwan), 2001.

Keegan, W. J. and B. B. Schlegelmilch. *Global Marketing Management: A European Perspective*. Prentice Hall International, 2001.

“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.

Global Marketing Management, Sixth Edition. Englewood Cliffs, NJ: Prentice Hall, Inc., 1999.

Keegan, Warren J., & Mark C. Green. *Princípios de Marketing Global*. São Paulo, Brasil: Editora Saraiva, 1999.

“Global Income and Population: 1998 Revised Edition and Projections to 2000 and 2010.” Pace University, Lubin School of Business, Institute for Global Business Strategy. 1998.

1998

Keegan, Warren J., & Mark C. Green. *Fundamentos de Mercadotencia Internacional*. (Primera edición ed.) Naucalpan de Juárez, Edo. de México: Prentice-Hall Hispanoamericana, S.A., 1998.

“Global Income and Population: 1997 and Projections to; 2000 and 2010”. Pace University, Lubin School of Business, Institute for Global Business Strategy, 1998.

1997

Keegan, Warren J. *Manajemen Pemasaran Global* (Bahasa Indonesia Edition of *Global Marketing Management*, Fifth Edition). Englewood Cliffs, NJ: Prentice Hall, Inc., 1997.

Keegan, Warren J. and Malcolm H. B. McDonald. *Marketing Plans That Work: Kiat Mencapai Pertumbuhan dan Profitabilitas Melalui Perencanaan Pemasaran yang Efektif*. Jakarta: Butterworth-Heinemann, 1997.

Keegan, Warren J. and Malcolm H.B. McDonald. *Marketing Plans That Work: Targeting Growth and Profitability*. Boston: Butterworth-Heinemann, 1997.

Keegan, Warren J. (1997). *Márketing Global*, quinta edición. Madrid: Prentice Hall, 532 pages.

Keegan, Warren J. & Mark C. Green (1997). *Principles of Global Marketing*. Upper Saddle River, NJ: Prentice Hall, Inc., 421 pages.

Keegan, Warren J. and Michael Friedman, "Global Market Segmentation: Strategic Alternatives and Issues", *AMA Winter Marketing Educators' Conference*, St. Petersburg Beach, Florida, 1997.

1996

Keegan, Warren J. and F.H. Rolf Seringhaus. *Global Marketing Management*, Canadian Edition. Scarborough, Ontario: Prentice-Hall Canada Inc., 1996.

"Strategic Alliances in International Retailing: An Exploratory Survey of European Collaboration" Conference Proceedings, *AMA Winter Marketing Educator's Conference*, Hilton Head, South Carolina, February 1996.

"Global Income and Population: 1996 and Projected Growth to 2020" Pace University, Lubin School of Business, Institute for Global Business Strategy. 1996.

1995

Global Marketing Management, Fifth Edition. Englewood Cliffs, NJ: Prentice Hall, Inc., 1995. .

Keegan, Warren J., Sandra E. Moriarty and Thomas R. Duncan. *Marketing*, Second Edition. Englewood Cliffs, NJ: Prentice Hall, Inc., 1995.

Keegan, Warren J., Sandra E Moriarty, Thomas R. Duncan and Stanley Paliwoda. *Marketing*, Canadian Edition. Scarborough, Ontario: Prentice Hall Canada, 1995.

Dictionary of Marketing Terms: Second Edition, Peter D Bennett (Ed) (Chicago: American Marketing Association, 1995, 316 pages. (Contributor).

Chapter Seven, "Global product management: strategic alternatives" in Stanley J. Paliwoda and John K. Ryans Jr. *International Marketing Reader*, New York: Routledge, 1995.

"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

“Global Product Planning: Strategic Alternatives,” The MNC in Transition, Fourth Edition Editors. Philip D. Grub and Dara Khambata, Princeton, NJ: The Darwin Press, Inc., 1993.

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

1992

Keegan Warren J., and Sandra E. Moriarty and Thomas R. Duncan. *Marketing* Englewood Cliffs, NJ: Prentice Hall, Inc., 1991.

Keegan, Warren J., *The Marketing Connection*, “Three Key Marketing Principles”, A Prentice Hall Publication, Volume 1 No. 1, Fall 1992.

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.

Introduction, *Medunarodni Marketing - kooperacioni koncept, pristup i oblici*, by Dr. Mile Jovic, *Savremena Administracija*, Izdavacki sektor, Beograd, Crnotravska 7.9, 1990.

“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

Global Marketing Management, Fourth Edition, (1989). Englewood Cliffs, NJ: Prentice Hall, Inc., 783 pages.

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

1988

Going Global in Frank Caropreso, ed. *Getting Value from Strategic Planning*, The Conference Board, Research Report No. 915, (1988) 67-73.

Author of Global Marketing terms in *Dictionary of Marketing Terms*, Peter D. Bennett, Editor, American Marketing Association, 1988, 220 pages.

Globalni konkurencija: Strateske alternative, *Marketing*, Vol. 19 (4), 245-332, 1988, pages 259-263.

1987

“Transferability and Adaptability of Products and Promotion Themes in Multinational Marketing - MNCs in LCDs” (with Richard R. Sill and John S. Hill), *Journal of Global Marketing*, (1987) pages 85-104.

“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.

1986

“International Marketing,” in Victor P. Buell, Editor, *Handbook of Modern Marketing*, Second Edition, New York: McGraw-Hill Book Company, 1986.

“The Decline and Fall of the Multinational Corporation: A Typology of Stages of Corporate Development,” Center For Applied Research, Lubin Schools of Business, Pace University, Working Papers, No. 62, September 1986.

1984

“International Marketing: Past, Present and Future,” in *Marketing Aspects of International Business*, Gerald M. Hampton and Art P. Van Gent, (Ed.), Kluwer-Nijoff Publishing, 1984, pages 1-14.

Judgments, Choices and Decisions, New York: John Wiley and Sons, 1984.

Multinational Marketing Management, Third Edition, Englewood Cliffs, NJ: Prentice-Hall, Inc. 1984.

“How to Cultivate Your Management Style,” *Office Administration and Automation*, October, 1984.

“International Competition: The Japanese Challenge,” *Journal of International Business Studies*, (1984) 189-193.

1983

“Strategic Market Planning: The Japanese Approach,” *International Marketing Review*, (August 1983).

1982

“Approaches to Assessing International Marketing Opportunities for Small and Medium-Sized Companies”, (with Susan P. Douglas and C. Samuel Craig), *Columbia Journal of World Business*, (Fall 1982) 26-32.

“Managing the Personality Puzzle,” *Planning Review*, Vol.10, No.2, March 1982, pages 12-25.

“KTI, Keegan Type Indicator, Form B,” Rye, NY: Warren J. Keegan Press, 1982.

1981

“Multinational Product Planning: Strategic Alternatives,” in *The Great Writings in Marketing*, Howard A. Thompson (Ed.), Second Edition, Tulsa, Oklahoma, Penwell Books, 1981.

1980

Multinational Marketing Management, Second Edition, Englewood Cliffs, NJ: Prentice-Hall, Inc., 1980.

“Guide to Type - A Users Manual For the Keegan Type Indicator,” Warren J. Keegan Associates Press, 1980.

1979

“The Rise of the Third World Multinationals” (with David A. Heenan), *Harvard Business Review*, (January / February 1979) 101-109.

“KTI, Keegan Type Indicator, Form A,” Warren J. Keegan Associates Press, 1979.

“The Future of the Multinational Manufacturing Corporation: Five Scenarios,” *Journal of International Business Studies*, (1979), 98-104.

1978

“Psychological Types and Management,” School of Government and Business Administration, The George Washington University, Working Paper, 87-1, 1978, 66 pages.

“The Future of Multinational Marketing,” *Executive*, Vol. 4, No. 3, pages 33-35.

“The Multinational Corporation and Its Future: From the American Viewpoint,” in *A Multinational Look at the Transcontinental Corporation*, Michael T. Skully (ed.), Dryden Press, Sydney, Australia, 1978.

1977

Multinational Product Management (with Charles S. Mayer). Chicago, IL: *American Marketing Association*, 1977, 184 pages.

“Psychological Types and Organization Strategy,” School of Government and Business Administration, The George Washington University, Working Paper 77-1, November, 1977, 59 pages.

“Strategic Marketing: International Diversification vs. National Concentration,” *Columbia Journal of World Business*, (Winter 1977) 119-129.

1976

“Multinational Product Planning: New Myths and Old Realities,” Introduction to Multinational Product Management, Proceedings, American Marketing Association / Marketing Science Institute Research Workshop, 1976, 360 pages.

“La politique de produit a l'echelle internationale: quelle strategie adopter?” *Techniques commerciales / Encyclopedie du Marketing Editions Techniques*, 123, rue d'Alesia, 75014 - Paris. 1976.

1975

“Meppam Land Incorporated,” with Michael Ghertman in Frank Paine and William Naumes, *Organizational Strategy and Policy Formation*, W.B. Saunders Co., 1975.

“Productivity: Lessons from Japan,” *Long Range Planning*, April, 1975.

Forward to David A. Heenan, *Multinational Management of Human Resources: A Systems Approach*, Austin, TX: Bureau of Business Research, U. of Texas at Austin, 1975.

1974

Multinational Marketing Management, Englewood Cliffs, NJ: Prentice-Hall, 1974,

“Multinational Scanning - A Study of the Information Sources Utilized by Headquarters Executives in Multinational Companies,” *Administrative Science Quarterly*, September, 1974, pages 411-421.

“Strategies for Investment in Japan,” (with Shigera Masuda) *Columbia Journal of World Business*, summer, 1974.

1972

“A Conceptual Framework for Multinational Marketing,” *Columbia Journal of World Business* (November/December 1972) 67-76.

“Global Business Information - The Foundation of Multinational Enterprise, Proceedings of the 1st International Conference On Communications, October 24-26, 1972, sponsored by: Research Institute of Telecommunications and Economics, Japan Management Association.

“Multinational Marketing Control,” *Journal of International Business Studies*, Fall, 1972, pages. 33-47. Also published in C.G. Alexandries, *International Business Systems Perspectives*, School of Business Administration, Georgia State University, 1973.

“What's in the Future? New Approaches to New Realities,” *Worldwide P & I Planning*, January / February, 1972, (with Nathaniel Leff and David Zenoff).

1971

“Multinational Marketing: The Headquarters Role,” *Columbia Journal of World Business*, January / February, 1971. Also published in Phillip D. Grub and Mika Kaskimies, *International Marketing in Perspective*, Sininen Kirja Oy, 1971. Also published under the title, “Headquarters Involvement in Multinational Marketing,” in H.B. Thorelli, (Ed.), *International Marketing Strategy*, Penguin, 1973.

1970

“Five Strategies for Multinational Marketing,” *European Business*, January, 1970, pages. 35-40. Also published in H.B. Thorelli, *International Marketing Strategy*, Penguin Books, 1973. Helmut Becker and Hans B. Thorelli (Eds.), *International Marketing Strategy*, Pergamon Press, 1980.

“Multinational Marketing Management,” Marketing Science Institute Working Paper, January, 1970, 58 pages.

“Key Questions in Multinational Marketing Management,” *Worldwide P & I Planning*, July / August, 1970.

1969

“Multinational Product Planning: Strategic Alternatives,” *Journal of Marketing*, Vol. 33 (January 1969) 58-62.

Also published in Gordon E. Miracle and Gerald S. Album, *International Marketing Management*, Richard D. Irwin, Inc., 1970; D. Maynard Phelps (Ed.), *Product Management: Selected Readings*, (1960-69), American Marketing Association, 1970; S. Beamin Prasad, *International Business Management*, Apagesleton-Century-Crofts, 1971; James F. Robb and Jack L. Taylor, *Fundamentals of Marketing: A Collection of Readings in Marketing Management*, Prentice-Hall, 1971; S. Prakish Sethi and Jagdish N. Seth, *Multinational Business Operations*; Goodyear Publishing Company, 1971; Phillip D. Grub and Mika Kaskimies (Eds.), *International Marketing in Perspective*, Sininen Kirja Oy, 1971. David W. Ewing (Ed.), *Long Range Planning for Management*, Harper & Row, 1972; A. Kapoor and Phillip D. Grub, (Eds.), *The Multinational Enterprise in Transition*, The Darwin Press, Inc. 1972; Stewart Henderson Britt and Harper W. Boyd, Jr., *Marketing Management and Administrative Action*, Third Edition, McGraw-Hill, 1972; John K. Ryans, Jr. and James Baker, *The World Marketplace: Readings for the International Marketer*, Grid, Inc., 1974; Z.E. Shipchandler, (Ed.), *Selected Academic Readings*, Simon & Schuster, Inc. 1974; Howard A. Thompson (Ed.), *The Great Writings in Marketing*, Tulsa, OK, The Petroleum Publishing Company, 1976; Subhash Jain and Lew Tucher, *International Marketing: Managerial Perspectives*, Boston, MA, CBI Publishing Company, Inc., 1979; Philip Kotler and Keith Cox, *Marketing Management and Strategy: A Reader*, Englewood Cliffs, , Prentice-Hall, Inc., 1980.

“Multinational Pricing: How Far Is Arm's Length?” *Columbia Journal of World Business* (May/June 1969). Also published in Courtney Brown, (Ed.) *World Business: Promise and Problems* as Chapter 13, “Multinational Pricing Is A Complex Task: The Case of the U.S.,” MacMillan, 1970 and in Phillip D. Grub and Mika Kaskimies, *International Marketing In Perspective*, Sininen Kirja Oy, 1971.

1968

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

“Global Intelligence: A Framework for Action,” Worldwide P & I Planning, July/August, 1968.

“Acquisition of Global Business Information,” *Columbia Journal of World Business* (March/April 1968) 35-41.

1967

“Multinational Marketing Strategy and Organization: An Overview,” Changing Marketing Systems, R.S. Moyer (Ed.), Chicago, American Marketing Association, 1967. Also published in Taylor W. Meoloan, Samuel Smith and John Wheatly (Eds.), Marketing Management: Policies and Decisions, Houghton Mifflin, 1960; Louis E. Boone, Management Perspectives in Marketing, Dickenson Publishing Company, Inc., 1971; and Betsy D. Gelb, Insights for Marketing Management, Goodyear Publishing Company, 1974.

1965

“Tanganyka's Five Year Development Plan,” Financing African Development, Tom J. Farer (Ed.), Cambridge, MA: M.I.T. Press, 1965.

Book Reviews by Warren J. Keegan

Foreign Market Entry Strategies by Franklin R. Root, New York, Amacon, 1982, in *Journal of International Business Studies*, Spring 1986, pages 140-141.

“A Spirited Call for Collaboration,” a review of *The Re-United States of America* by David A. Heenan, Reading, MA, Addison Wesley Publishing Company, 1982, in *Columbia Journal of World Business*, Fall 1983.

“A Spirited Call for Collaboration,” a review of *The Re-United States of America* by David A. Heenan, Reading, MA, Addison Wesley Publishing Company, 1982, in *Sloan Management Review*, Spring 1983.

Sovereignty at Bay: The Multinational Spread of U.S. Enterprises, by Raymond Vernon (New York, Basic Books, Inc., 1971) in *Columbia Journal of World Business*, March / April, 1972, pages 79-80.

The Japanese Marketing System: Adaptations and Innovations, by M.Y. Yoshino (Cambridge, MA, MIT Press, 1971) in *Journal of Marketing*, January, 1972, pages 111-112.

“Japan Adjusts to Mass Merchandising,” a review of *The Japanese Marketing System: Adaptation and Innovations*, by M.Y. Yoshino, in *Columbia Journal of World Business*, September / October, 1971.

“Poverty: A Behavioral Problem,” a review of *The Abolition of Poverty*, by David Horowitz, and *On Understanding Poverty: Perspectives From the Social Sciences*, Daniel P. Moynihan, (Ed.), in *Journal of International Affairs*, Vol. XXIV, No. 2, 1970.

Exhibit 4 – Research Types

Introduction

222. 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

223. 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.

224. In other words, focus group studies are exploratory in nature and generate hypotheses rather than findings that can be generalized to a wider population.¹¹⁰ The reported findings of focus groups have no statistical significance due to the small sample size and exploratory nature of the responses.¹¹¹ There is also significant opportunity for the moderator to influence the discussion or

¹¹⁰ Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. The Dryden Press, Orlando, FL, p. 81-85.

¹¹¹ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 263.

for group members to influence each other,¹¹² which, if not designed properly, can generate misleading results.¹¹³

225. For these reasons, focus group studies cannot be used as a basis to discuss the broader applicability of the results.¹¹⁴ Rather, when properly conducted, the information gained from a focus group setting can assist in coloring a discussion on a particular issue.

226. 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.¹¹⁵

227. 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

228. 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.

¹¹² Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 142.

¹¹³ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 263.

¹¹⁴ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 142.

¹¹⁵ <http://www.mria-arim.ca/STANDARDS/CODEindividualsFAQ.asp#8>.

229. 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 offered by respondents reflect their or others' actual or intended behavior.¹¹⁶ Opinion data, therefore, cannot be used to draw inferences that reach beyond the question asked of respondents.

230. 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.

231. 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.

232. 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.¹¹⁷

233. 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.¹¹⁸ Lay respondents without specialized knowledge in the field are simply not

¹¹⁶ Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 275-276.

¹¹⁷ Stephanie Clifford, "Never Listen to Céline? Radio Meter Begg to Differ." *New York Times*, 12/16/2009.

¹¹⁸ 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.

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.

234. 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.¹¹⁹ 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).¹²⁰

(C) Self-Reported Behavioral

235. 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.

236. 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

¹¹⁹ See Robert M. Groves, et al. (2009). *Survey Methodology, 2nd Edition*. Hoboken, NJ: John Wiley & Sons, Inc., p. 237.

¹²⁰ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 80.

after the implementation of a higher duty, this decrease could be attributable to factors other than the duty—e.g., ongoing educational campaigns, a general decline in the popularity of alcohol, etc.

237. 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.^{121, 122}

238. 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.¹²³ These limiting factors should be considered when evaluating this type of research.

(D) Observed Behavioral

239. 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.

240. 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.

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

¹²¹ Floyd J. Fowler, Jr. (2009). *Survey Research Methods, 4th Edition*. Thousand Oaks, CA: Sage Publications, p. 107.

¹²² Churchill and Iacobucci (2005). *Marketing Research: Methodological Foundations, 9th Edition*. Orlando, FL: The Dryden Press, p. 240.

¹²³ Floyd J. Fowler, Jr. (2009). *Survey Research Methods, 4th Edition*. Thousand Oaks, CA: Sage Publications, p. 108.

(E) Experimental

242. 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,¹²⁴ provided other variables are adequately controlled.

243. 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.¹²⁵

(F) Longitudinal

244. 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.

245. 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,

¹²⁴ 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.

¹²⁵ Ghauri and Grønhaug (2005). *Research Methods in Business Studies, 3rd Edition*. England: Pearson Education Limited, p. 59-65.

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 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.

246. 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

247. 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.

Exhibit 5 – Other Materials

Introduction

248. As discussed above at paragraphs 12 through 15, the RAND Report cites various studies 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.

249. A table of all studies cited by the RAND Report that are relevant to the issue of increasing the size of health warnings appears as Exhibit 6 to this report.

Créatec (2008)¹²⁶

250. In this study the authors sought to test the effectiveness of a variety of different sized cigarette pack health warning messages—ranging in size from the current 50 percent warning to a 100 percent warning—among a sample of Canadian respondents. Specifically, the authors conducted interviews among a sample of adult smokers (N=730) and a sample of youths consisting of both smokers and non-smokers (N=746). Interviewing took place in February 2009.

Attitudinal Data

251. From the outset, this study is incapable of providing objective data on whether larger health warnings are in fact more effective, since its conclusions are based on attitudinal rather than behavioral data. For the reasons detailed above in Exhibit 4, paragraph (B), attitudinal data is not a reliable indicator of potential behavioral change associated with a policy shift.

Respondent Bias

252. Respondents in this study were given information which was likely to bias them towards responding that new, larger health warnings were likely to be more effective. Specifically,

¹²⁶ On January 7, 2010, JTI-Macdonald submitted a letter to the Canadian Controlled Substances and Tobacco Directorate that included a discussion of some of my concerns with this study. In addition to the discussion contained in that letter I submit this review.

respondents were informed that “the government is thinking of making cigarette companies sell cigarettes using new types of warnings.” There was no reason to inform respondents of the government’s intentions in this way. If this statement has any effect at all, it would be to bias respondents towards some form of change in the warning design.

Flawed Research Objectives

253. Respondents were asked to speculate on how effective mock pack designs featuring health warnings covering (respectively) 50 percent, 75 percent, 90 percent and 100 percent of primary pack surfaces would be in influencing and/or changing the smoking behavior of “the public,” “smokers,” or “people like you” and other types of people. Respondents were not asked direct questions about how they themselves would react in response to the proposed health warnings.

254. The study is therefore purely attitudinal in nature. It does not observe or address how health warnings of differing sizes in fact influence smoking behavior, but rather how the respondents perceived the effectiveness of health warnings in influencing the behavior of others. Respondents were ordinary Canadian citizens that had no specialized knowledge of this issue. Their subjective opinions, however sincerely held, about how indeterminate groups of Canadian consumers might or might not react to a given design do not provide reliable evidence of how consumers are in fact likely to respond. The results of this study have no bearing on how effective one size of warning compared to another will be, and the study falls at the least reliable end of the research types identified at paragraph 57 above.

Experimental Design and Survey Methodology

255. Respondents were shown a series of mocked-up cigarette packs, which differed in terms of the size of the health warnings that they bore.

256. Whether this was intentional or not, the experimental design operated so as to predetermine the results in favor of larger health warnings, particularly considering that the respondents were told at the outset of the study that the Canadian government is in favor of introducing larger health warnings (see paragraph 252 above). When shown different sized warnings, lay, non-expert respondents are naturally inclined to rate bigger as better regardless of the order in which the warnings are shown. There is thus a logical progression to the stimuli which favors larger health warnings. A lay respondent who has assessed a pack with one warning size and who is then asked

to assess another with a larger warning is likely to say that the latter design, bearing the larger warning, is either equally or more effective at meeting a given objective. Conversely, when shown a pack with a smaller warning than the one that he or she has just seen, the respondent is likely to rate it as being equally or less effective at meeting a given objective. This methodological flaw would be expected to result in data that shows larger warnings to be more effective.

257. A more reliable study design would have been to divide respondents into four cells, one of which would see and be asked to rate the effectiveness only of 50 percent warnings, the next of which would see and be asked to rate the effectiveness only of 75 percent warnings, and so on for 90 percent and 100 percent warnings. This would permit a far more objective assessment of how effective respondents perceived a given size warning to be, removing the possibility of respondents being cued into giving expected answers. (Such an experimental design would not, however, remedy the wider defects in the Créatec study, and in particular the attitudinal nature of the data sought—see paragraph 251 above).

258. This fundamental flaw in research approach was compounded by two other factors. First, the order in which different pack designs were shown was not randomized. Only four different rotations were used, two of which followed the natural order of progression from largest to smallest or smallest to largest (i.e. 50% - 75% - 90% - 100% and 100% - 90% - 75% - 50%). This would have further inclined respondents to give the larger warnings a higher effectiveness rating.

259. Secondly, the authors of the study failed to include a design featuring a health warning that was smaller than the current 50 percent warning. It would have been sound experimental practice to include a smaller design, which would have acted as a control stimulus. By including a smaller design (for example, one featuring a 40 percent warning), the researchers could have made a determination as to whether the perceived changes in effectiveness were actually due to the size of the design (in which case, it would be expected that the smaller design would rank as less effective than the current warning and proposed larger warnings) or whether respondents were influenced by confounding factors (such as the novelty of a change in warning size), which would be suggested if the smaller warning outperformed any of the larger warnings and would warrant further investigation.

Flawed Question Design

260. This study also suffered from a serious flaw in the question design. Respondents were not given the option of responding “don’t know” or “no opinion” to questions about the effectiveness of certain health warnings. Such options are typically provided, so as not to force respondents into making a choice that does not reflect their true opinion. In other words, the “don’t know” or “no opinion” option acts as a filter to reduce guessing and inaccurate results, and to increase the validity and reliability of the data. In other words, the conclusions drawn by Créatec are flawed because they did not provide for these options.

Conclusions

261. Based on the analysis above, I have reached the following conclusions regarding the Créatec study:

- Irrespective of the flaws in the experimental design, this study was not capable from the outset of providing objective data on whether larger health warnings are in fact more effective, since its conclusions were based on attitudinal rather than behavioral data;
- The experimental design of this study was flawed in a number of ways. Respondents were instructed that the study had been commissioned for public health purposes, conditioning them to give the “right” answer, and were cued—as a result of being presented with differing sizes of design in turn—to answer that larger health warnings are more effective. The effect of these flaws was to predetermine the results obtained.

262. Therefore, this study cannot credibly be said to support the conclusion that larger health warnings would increase awareness and/or impact on smoking behavior.

Flash Eurobarometer 253, European Commission (2008)

263. This study was conducted among citizens aged 15 years and over in the 27 European Union Member States and Norway in December 2008. Over 26,000 (n=26,582) respondents were randomly selected and interviewed via telephone or an in-person interview. Respondents were asked questions on a range of topics concerning tobacco, including smoking habits, exposure to tobacco in the home and workplace, attitudes regarding smoke-free places, perceived effectiveness

of health warnings on tobacco packs, purchasing tobacco online, tobacco pricing, and tobacco smuggling.

Analysis and Conclusion

264. This study does not contain any data that is relevant to the issue of larger health warnings. In the only potentially relevant section of this report—i.e., the section that evaluated the perceived effectiveness of health warnings on tobacco packs—respondents are asked about their beliefs regarding the effectiveness of health warnings as an information vehicle and as an impetus to change smoking behaviors:

Thinking about the health messages that are on tobacco packs, have these messages been very effective, somewhat effective, not very effective or not effective at all in each of the following ways?

- Informing you about the health effects of tobacco
- Getting you to smoke less
- Getting you to try to quit smoking¹²⁷

265. They are also asked to give their opinion regarding the potential effectiveness of pictorial health warnings:

In your opinion, how effective has adding a colour picture illustrating the health effects of smoking been in strengthening the text-only health warning?¹²⁸

266. As none of these questions directly relate to the issue of larger health warnings, this study does not provide any evidence regarding the potential impact of larger health warnings on smoking behaviors.

¹²⁷ Flash Eurobarometer #253, “Survey on Tobacco: Analytical Report.” European Commission (2009), p. 96.

¹²⁸ Ibid.

O'Hegarty et al. (2008)

267. This focus group study consists of interviews of 95 participants (54 smokers and 41 nonsmokers) aged 18-24 years from the Detroit-metropolitan area. Participants were broken out into 11 separate focus groups based on whether they were current college students or recent graduates (four groups) or not in college or not recent grads (seven groups). Participants were shown six Canadian pictorial warning labels and were asked questions regarding “reactions and perceptions of the visual and contextual format of these labels,”¹²⁹ and the potential value of listing cigarette ingredients on the label. Smokers were asked whether “warning labels would motivate them to quit and whether they thought warnings would deter young people from smoking.”¹³⁰

Analysis

268. This is a focus group study and cannot be generalized to a broader population outside of this study. A detailed discussion of focus groups and the limitations thereof appears above at Exhibit 4 paragraph A.

269. Specifically, this is a qualitative study that gauges the opinions of the particular respondents in this sample. Because this study reports on informal discussion sessions rather than data collected through a controlled experimental design, it cannot be viewed as an accurate, broadly applicable measurement of the concepts examined. The use of qualified, non-specific language in this report (e.g., “many participants,” “a majority of focus group participants”)¹³¹ as well as language specific to a single respondent (e.g., “one woman participant who was a smoker and college educated stated...”)¹³² and the absence of any quantifiable numeric data illustrate the exploratory nature of this study.

270. The script used by the moderator to facilitate discussion is not provided. The degree of influence that the moderator was afforded during the discussions, therefore, is unknown. Little

¹²⁹ O'Hegarty M., Pederson L., Yenokyan G., Nelson D., Wortley P. (2007). “Young adults’ perceptions of cigarette warning labels in the United States.” *Preventing Chronic Disease*, Vol. 4, No. 2. p. 4.

¹³⁰ Ibid.

¹³¹ Ibid., p. 4-5.

¹³² Ibid., p. 5.

information is given about the moderators themselves; it is unknown whether the authors took part in moderation and, if not, the extent to which the moderators were informed about the purpose of the study.

Conclusion

271. The data from this study cannot be generalized to a broad population. It was collected through focus group interviewing, which yields qualitative results. The data provides no statistically reliable information about potential behavioral changes associated with larger health warnings. For these reasons, I do not consider it to be reliable evidence on the topic of larger health warnings.

UK Department of Health (2007)

272. This is not an original research study, but a consultation document issued by the UK Department of Health on the issue of implementation of pictorial health warnings on tobacco packages. This consultation document discusses the costs and benefits of requiring pictorial health warnings within the context of the 40 percent health warning requirement established by the European Commission in 2001 and implemented in the UK in 2003. It does not address, by discussion or reference, the topic of larger health warnings.

Conclusion

273. This consultation document does not propose increasing the size of health warning messages and does not cite any materials that appear directly relevant to the topic of larger health warnings. Because it presents no original research and does not address or in any way reference the topic of larger health warnings, this document does not provide any reliable evidence regarding the potential impact of larger health warnings on smoking behaviors.

BRC Marketing and Social Research (2004)

274. This report presents the findings from eight “mini-group discussions”¹³³—i.e., focus groups—commissioned by the New Zealand Ministry of Health on the potential presentation of pictorial and text health warning messages on cigarette packages. In total, 37 current smokers from various demographic backgrounds participated in the study. Respondents were separated into eight groups, each of which was shown a different pack design. Package designs differed in terms of type of warning (text vs. pictorial), warning size, and colors used.

Analysis

275. As discussed above at Exhibit 4 paragraph A, focus group research is qualitative and cannot be generalized to broad populations. It is typically used as an informal information-gathering tool to generate questions for further research. Sample sizes are small—for example, in this case, only 37 subjects participated—and therefore do not provide results that can be statistically validated. Interviewing is conducted in a group setting as an informal dialog facilitated by the interviewer; accordingly, the interviewer has considerable control and influence over the direction and content of the discussion.

276. Indeed, in this study interviewing was conducted by BRC, the research firm hired by the New Zealand Ministry of Health to complete the project. Consequently, the interviewers were aware of the purpose of the study. Interviewers used probing questions to clarify responses and obtain additional information from respondents. This, along with the fact that this was a face-to-face interview, affords the interviewer considerable influence in the data collection process.

277. In this study, the informal nature of the interviews combined with the fact that informed, interested parties (i.e., the researchers themselves) conducted the interviews results in data that must be interpreted with caution.

¹³³ 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 (2004), p. 4.

Conclusion

278. The various limitations of focus group research are discussed in detail above at Exhibit 4 paragraph A. This focus group research is not applicable to the wider population and conclusions regarding larger health warnings can not be drawn from it. For these reasons, I do not consider this report as reliable evidence regarding the potential impact of larger health warnings on smoking behaviors.

Zatonski et al. (2003)

279. This article provides an historical overview of smoking behaviors, health trends among smokers, and tobacco control measures in Poland since the Second World War. It is a policy paper that examines the tobacco issue in Poland from a regulatory and public health perspective. It does not collect or evaluate any primary data. The author of this article cites an outside source to support statements regarding the potential effectiveness of larger health warnings.¹³⁴ Such underlying sources should be evaluated and cited directly if they are thought to provide evidence supportive of a policy change.

Conclusion

280. Because this article presents no original research, it offers no reliable evidence as to the potential behavioral implications of larger health warnings on tobacco packages.

Ministry of Health, Romania (2008)

281. This study, cited in the Sambrook Report, does not appear to be publicly available and I have therefore been unable to conduct a review.

¹³⁴ Zatonski, W., Przewozniak, K., and Porebski, M.,(2000). "Large Cigarette Pack Warnings Change Smoking Behaviours in Poland." In "Workshop and Poster Session on Challenges to Tobacco Control for Eastern Europe in the 21st Century, August 8, 2000. Eleventh World Conference on Tobacco or Health—Promoting a Future Without Tobacco, August 6-11, 2000, Chicago, Ill." Abstracts: vol. 3: 777.

Exhibit 6 – Chronological List of Studies Considered for the Purpose of Preparing This Report

Year	Citation	Current Report Citation (para)	Source Citation
2009	International Tobacco Control (ITC) (2009). "FCTC Article 11 – Tobacco Warning Labels: Evidence and Recommendations from the ITC Project."	78	RAND Report, p. 129-130
2008	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.	145	RAND Report, p. 130
2008	Environics Research Group (2008). "Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers." Prepared for Health Canada.	178	Sambrook Report, p. 43, 118.
2008	Environics Research Group (2008). "Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth." Prepared for Health Canada.	178	Sambrook Report, p. 43, 118.
2008	Créatec report prepared for Health Canada (2008). "Effects of Modified Packaging Through Increasing the Size of Warnings On Cigarette Packs. Quantitative Study of Canadian Youth Smokers And Vulnerable Non-Smokers."	250	Sambrook Report, p. 43, 118.
2008	Créatec report prepared for Health Canada (2008). "Effects of Modified Packaging Through Increasing the Size of Warnings On Cigarette Packs. Quantitative Study of Canadian Adult Smokers."	250	Sambrook Report, p. 43, 118.
2008	Flash Eurobarometer (2008). "Survey on Tobacco – Analytical Report." European Commission, #253.	263	Sambrook Report, p. 118.
2008	Ministry of Health, Romania (2008). "Evaluation of the impact of diverse control measures."	281	Sambrook Report, p. 119.
2007	Hammond, D. et al. (2007). "Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study." <i>American Journal of Preventive Medicine</i> . Vol. 32, No. 3, p. 210-217.	132	Sambrook Report, p. 118.

Year	Citation	Current Report Citation (para)	Source Citation
2007	O'Hegarty, M., et al. (2007). "Young Adults' Perceptions of Cigarette Warning Labels in the United States and Canada." <i>Preventing Chronic Disease – Public Health Research, Practice, and Policy: Centre for Disease Control and Prevention, Atlanta. Vol. 4, No. 2, p. 1-9.</i>	267	Sambrook Report, p. 118.
2007	UK Department of Health (2007). "The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment." London.	272	RAND Report, p. 130.
2006	Hammond, D. 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." <i>Tobacco Control. Vol. 15, Suppl III, p. iii19-iii25.</i>	116	RAND Report, p. 130.
2004	Joossens, L. (2004). "Investigation into the effect of health warnings on cigarette packets in Belgium." <i>Belgian Minister of Public Health and Social Affairs. p. 1-18.</i>	199	Sambrook Report, p. 118.
2004	BRC Marketing and Social Research (2004). "Smoking Health Warnings Study – Optimising Smoking Health Warnings Stage 2 – Text, Graphics, Size and Colour Testing," Prepared for the New Zealand Ministry of Health, p. 1-27.	274	RAND Report, p. 131; Sambrook Report, p. 118
2003	Zatonski, W. (2003). "Democracy and Health: Tobacco Control in Poland. In <i>Tobacco Control Policy: Strategies, Successes and Setbacks. Six Country Case Studies</i> , ed. W. De Beyer. World Bank, Washington, DC.	279	Sambrook Report, p. 118.

Exhibit 7 – Plain Packaging Study Reviews

Introduction

282. I have previously prepared the following reports for Japan Tobacco International in which I review, amongst other things, publicly available survey evidence cited in support of plain packaging of tobacco products:

- A. “Analysis of Consumer Survey Evidence Relevant to the UK Department of Health Consultation on the Future of Tobacco Control” dated 2 September 2008; and
- B. “Analysis of Consumer Survey Evidence Relevant to the UK Department of Health Consultation on the Future of Tobacco Control – a supplemental report” dated 18 June 2009.

283. In this appendix, I refer to these two documents collectively as “the Reports.”

284. I concluded in the Reports there was no reliable evidence to suggest that plain packaging of cigarettes will lead to a reduction in youth smoking uptake, or that it will have any other impact on smoking behaviour more generally.

285. I have prepared this report for Japan Tobacco International in which I review two recent studies regarding plain packaging, namely, “Tobacco Branding and Plain Packaging: The New Frontier of Tobacco Control?” (“Hoek et al. (2009)”) ¹³⁵ and “Effects of Dissuasive Packaging on Young Adult Smokers” (“Hoek et al. (2010)”) ¹³⁶ I discuss the extent to which they offer reliable evidence on whether plain packaging will lead to a reduction in youth smoking uptake, or that they will have any other impact on smoking behaviour more generally. As I set out below, I have concluded that these studies offer no reliable evidence as to the potential behavioral implications of plain packaging.

¹³⁵ Hoek, J. Gendall, P. and Louviere, J. (2009). “Tobacco Branding and Plain Packaging: The New Frontier in Tobacco Control?” In Moore, B., Pappalardo, J and Wilkie, W. (Eds.), Proceedings of the American Marketing Association Marketing and Public Policy Conference, Washington DC, May 28-30.

¹³⁶ Hoek et al. (2010). “Effects of Dissuasive Packaging on Young Adult Smokers.” *Tobacco Control*. Published online 10/21/2010 in advance of the print edition.

286. For the purposes of preparing this appendix, I have adopted the same methodological approach that I applied in the Reports and an additional report which I have previously prepared for JTI entitled “Analysis of Consumer Survey Evidence Relevant to the Display Ban Requirement in England,” dated April 28, 2010. Whereas my April 2010 report is not relevant to the issue of plain packaging, (1) the evaluation criteria adopted is consistent with the approach undertaken in the Reports; and (2) the evaluation criteria is explained more fully in the April 2010 report and is therefore informative in the assessment of Hoek et al. (2009) and Hoek et al. (2010) as undertaken in this appendix.

287. This appendix is intended to be read in conjunction with those Reports.

Hoek et al. (2009)

288. This study exposed 245 students at a university in New Zealand to various combinations of six cigarette pack designs and recorded their preferences as to which pack they would be most and least likely to buy to share with their friends.¹³⁷

Analysis

289. The packs used in this study were a combination of three brands and two warnings. The brands were Holiday, the most popular young adult brand in New Zealand, Kool, a brand not sold in New Zealand, and a plain pack.¹³⁸ The warnings were the same size; however one was a pictorial warning label showing a dissected human brain with text and the other was a text-only warning.¹³⁹

¹³⁷ Hoek, J. Gendall, P. and Louviere, J. (2009). “Tobacco Branding and Plain Packaging: The New Frontier in Tobacco Control?” In Moore, B., Pappalardo, J and Wilkie, W. (Eds.), Proceedings of the American Marketing Association Marketing and Public Policy Conference, Washington DC, May 28-30, p. 15.

¹³⁸ Ibid., p. 13.

¹³⁹ Ibid.

290. The study found that the packs with the pictorial warning were chosen less often for all pack brands as compared to the text warnings for those brands,¹⁴⁰ and that participants favored generic packages less often than branded packages.¹⁴¹

291. The authors conclude that “the PWL decreased the attractiveness of tobacco packages...and generic packages were markedly less attractive than branded packages.”¹⁴² The terms “attractiveness” or “attractive” are not defined by the authors and indeed were not used in the questionnaire. As such, to the extent that these terms apply to the results, the reader must speculate as to the importance of these terms.

292. Despite the undefined terms used by the authors, there are other equally viable explanations for the results of this study. Specifically, this study’s design encourages participants to respond based on their degree of familiarity with the package designs presented. The pack with highest participant ranking is the familiar Holiday brand with the also familiar (then current) text warning in New Zealand. The packs with the lowest participant rankings are the unfamiliar Kool brand and unfamiliar generic design coupled with the unfamiliar picture warning. The middle-ranking packs presented a mix of familiar and unfamiliar design components.

293. The conclusion that “branding reduces the impact of health warning information”¹⁴³ is speculative based on the results of this study. In other words, the authors have not isolated the impact of branding upon the dissemination of health warning information, but have merely shown that respondents choose the familiar more often than they do the unfamiliar. Accordingly, whereas the authors have attributed the respondents’ selections solely to the presence of branding elements, alternative and equally reasonable factors could be the cause of the measured selection tendency.

294. Without knowing what caused the measured effect, it is not possible to attribute any particular behavioral outcome to a change in pack design.

¹⁴⁰ Ibid., p. 18.

¹⁴¹ Ibid.

¹⁴² Ibid., p. 18.

¹⁴³ Ibid., p. 16.

295. Moreover, in employing this design, the authors have asked the subjects to perform an artificial exercise—i.e., rank a variety of cigarette packages bearing different designs. Such a choice, however, does not reflect any marketplace reality. Tobacco control measures, whatever they may be, apply to all brands in a particular jurisdiction equally. Consumers are never put in a marketplace situation where they have an opportunity to select one pack design over another.

296. Therefore the potential impact, if any, which the designs tested here will have on actual consumer behavior is unknown. There are multiple factors that could impact the subjects' rankings of the packages. The choices presented in this study are arbitrary and would never occur in the reality of the marketplace. Therefore no insight as to whether pictorial warnings or plain packaging will reduce smoking consumption or initiation can be gleaned from these results. As the authors note, "our study estimated the perceived appeal of different options, not actual behavior."¹⁴⁴

Conclusion

297. Given the limitations of the research presented here, this study offers no reliable evidence as to the potential behavioral implications of plain packaging.

Hoek et al. (2010)

298. In this study, 292 young adult smokers (aged 18 to 30) were surveyed via face-to-face interviews in New Zealand. Respondents were exposed to a two-part experiment.

299. First, respondents were shown 13 cards bearing different combinations of 13 cigarette pack mock-ups, shown four to a card. The packs displayed were a mix of "test" cigarette pack designs which varied by the warning size and the level of branding elements present. The warning sizes used were 30, 50 or 75 percent of the front of the pack. The branding imagery present for each pack mock-up was the current Holiday branding ("the most popular young adult brand in New Zealand"¹⁴⁵), the logo only, the unstylized name only, or the generic term "cigarettes" only. A

¹⁴⁴ Ibid., p. 18.

¹⁴⁵ Hoek et al. (2010). "Effects of Dissuasive Packaging on Young Adult Smokers." *Tobacco Control*. E-pub ahead of print, 10/25/2010, p. 2.

“control” pack, which featured neither branding nor a warning and was simply labeled “cigarettes,” was also shown on some cards.

300. For each card they were shown, respondents were asked “Which pack would you be most likely to choose?” and “Which pack would you be least likely to choose?”¹⁴⁶

301. The second part of the experiment was designed to test cessation-related responses. Respondents were shown a fully branded pack that featured a 30 percent graphic health warning or a pack that featured the brand name in a standardized font and had a 75 percent graphic health warning.¹⁴⁷ Respondents were then asked to imagine that the cigarettes they usually smoke were only available in a pack like the one they just saw. They were then asked to estimate the chances that they would seek cessation support, reduce the number of cigarettes they smoke, and/or make a quit attempt.

302. The authors conclude that “removing brand imagery and increasing graphic health warning size has a marked and significant effect on the attractiveness of cigarette packaging to young adult smokers and increases the likelihood that they will engage in cessation-related behaviours.”¹⁴⁸ As in Hoek et al. (2009), this study does not define the terms “attractiveness” or “attractive” and indeed these terms were not used in the questionnaire. As such, to the extent that these terms apply to the results, the reader must speculate as to the importance of these terms.

303. Despite the undefined terms used by the authors, there are design and methodological limitations of this study that result in the authors’ conclusions not being supported by the reported results. These are discussed in detail below.

Measured Familiarity

304. This study appears to simply measure respondents’ familiarity with the pack design. Specifically, as in Hoek et al. (2009) above which addresses the same issue and uses a similar

¹⁴⁶ Ibid., p. 2.

¹⁴⁷ Ibid., p. 2.

¹⁴⁸ Ibid., p. 5.

design,¹⁴⁹ this study's design encourages participants to respond based on their degree of familiarity with the package designs presented. The packs identified in Table 3¹⁵⁰ with highest participant ranking are those that display the familiar normal brand imagery and those with the familiar text warning size in New Zealand. The packs with the lowest participant rankings are those with the unfamiliar standardized branding and the unfamiliar 75 percent picture warning. The middle-ranking packs presented a mix of familiar and unfamiliar design components.

305. The conclusion that "removing brand elements and increasing the graphic warning size would significantly decrease the attractiveness of tobacco packaging"¹⁵¹ is speculative given the design of this study. The authors have not isolated the impact of branding and health warning size on the attractiveness of packaging, but have merely shown that respondents choose the familiar more often than they do the unfamiliar.

306. Accordingly, whereas the authors have attributed respondents' selections solely to the level of branding and warning label size, alternative and equally reasonable factors could be the cause of the measured selection tendency, such as respondents' tendency to choose what is familiar to them as smokers.

307. This familiarity effect is exacerbated by the fact that the Holiday brand used on the branded pack is the most popular brand among the age group that participated in this study and the warning used was a new and unfamiliar warning to study participants.¹⁵² Therefore, to the extent that respondents tend to choose what is familiar to them, this mix of familiar brand and unfamiliar warning favors the selection of more branded packages and smaller warning sizes in this experiment. What may appear to be an impact of decreased branding and increased warning may

¹⁴⁹ Hoek, J. Gendall, P. and Louviere, J. (2009). "Tobacco Branding and Plain Packaging: The New Frontier in Tobacco Control?" In Moore, B., Pappalardo, J and Wilkie, W. (Eds.), Proceedings of the American Marketing Association Marketing and Public Policy Conference, Washington DC, May 28-30.

¹⁵⁰ Hoek et al. (2010). "Effects of Dissuasive Packaging on Young Adult Smokers." *Tobacco Control*. E-pub ahead of print, 10/25/2010, p. 4.

¹⁵¹ Ibid., p. 4.

¹⁵² Ibid., p. 2.

merely be a measurement of the impulse to select the more familiar design when given a choice to do so.

308. Without knowing what caused the measured effect, it is not possible to attribute any particular behavioral outcome to a change in pack design. Additionally it should be noted that a decrease in the “attractiveness” of cigarette packaging, even if it occurred, does not necessarily result in a decrease in smoking behavior.

Choice

309. In employing this design, the authors have asked the subjects to perform an artificial exercise—i.e., pick their most and least favorite out of a variety of cigarette packages each bearing different levels of branding and warning size. Such a choice, however, does not reflect any marketplace reality. Tobacco control measures, whatever they may be, apply to all brands in a particular jurisdiction equally. Consumers are never put in a marketplace situation where they have an opportunity to select one pack design over another.

310. Therefore the potential impact, if any, which the designs tested here will have on actual consumer behavior is unknown. There are multiple factors that could impact the subjects’ rankings of the packages. The choices presented in this study are arbitrary and would never occur in the reality of the marketplace. Therefore, no insight as to whether larger warnings or plain packaging will reduce smoking consumption or initiation can be gleaned from these results. As the authors note, this experiment “involve[s] choice behavior, not actual behaviour.”¹⁵³

Cessation Component

311. The cessation component of this study presented the respondents with a scenario that was overwhelmingly suggestive to the extent that the results are not reliable. When shown the control pack, which was simply the pack design available in New Zealand at that time (branded with a 30 percent health warning), between 23 and 32 percent of respondents claimed that they would either reduce the number of cigarettes smoked, seek help to quit, or make a quit attempt.¹⁵⁴

¹⁵³ Ibid., p. 4.

¹⁵⁴ Ibid., p. 5.

312. It is simply not credible that one exposure to the current pack design would result in this dramatic level of self-predicted behavior. This is “higher for the control pack than is suggested by their current behaviour,”¹⁵⁵ the authors note. While the authors attribute this to the novel warning used, the more likely culprit of this discrepancy is the leading nature of the design.

313. This suggestive design is exacerbated further when the test pack is used. The test pack was comprised of a standardized brand name and 75 percent warning.¹⁵⁶ The measured cessation intentions then increased to between 36 and 40 percent for the three variables measured.¹⁵⁷ This pack design increased the suggestiveness of the questions presented and therefore the measurements increased. The test pack became a measurement for the impact of the suggestiveness of the test design rather than for the impact of the pack design.

314. The inherently suggestive design of the cessation component of this study renders the cessation-related results reported by the authors unreliable.

Sampling Method

315. A non-random sampling procedure was used for this study, thereby limiting the ability to generalize the results to any wider representative sample. Participants were recruited by soliciting observed smokers at various locations.¹⁵⁸ This sampling procedure allows for a biased selection of respondents. For example, interviewers may have tended to approach potential subjects that were of the same gender as themselves. If such bias selection occurred, the ways and extent to which it may have impacted the sample is unknown. It is for this reason that the current study results cannot be generalized to a wider population, as can be done in studies which employ a more rigorous random selection procedure.

316. Although the authors recognize this limitation, their discussion nevertheless frames the results as applicable to a wider population. The authors posit “whether the response patters we

¹⁵⁵ Ibid., p. 5.

¹⁵⁶ Ibid., p. 4.

¹⁵⁷ Ibid., p. 5.

¹⁵⁸ Ibid., p. 2.

have identified can be generalized *beyond* young adults”¹⁵⁹ (emphasis added). In fact, this study cannot be generalized even *among* young adults. As noted by the authors and discussed above, “representativeness cannot be assumed.”¹⁶⁰

Conclusion

317. This study is hampered by considerable methodological limitations that render its findings unreliable. I therefore do not consider this study reliable evidence regarding the potential behavioral impact of implementing plain packaging of cigarettes.

¹⁵⁹ Ibid., p. 5.

¹⁶⁰ Ibid., p. 2.