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Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0867

My name is Joel B. Cohen. I am Distinguished Service Professor Emeritus at the University of Florida, where I previously served as Distinguished Service Professor of Marketing, Director of the Center for Consumer Research and Adjunct Professor of Anthropology from 1988 - 2008. From 1974 until 1983, I served as chairman of the Marketing Department at the University of Florida and created the Center for Consumer Research in 1975. From 1972-74, I was Vice President and Director of Social Science Research at National Analysts, a major survey research organization which became part of Booz, Allen & Hamilton. Prior to that, I was a tenured member of the marketing faculty at the University of Illinois.

Attached hereto is a statement of my specific experience relevant to the issues addressed in these comments.

Section 904(d) requires the Secretary to publish a list containing an enumeration and quantification of the harmful and potentially harmful constituents in each tobacco product, by brand and subbrand (compiled pursuant to Section 904(e)). I will address the risks associated with this action prior to considering the type of research necessary under Section 904(d)(2) to "ensure that the list published under paragraph (1) is not misleading to lay persons."

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Publication of a list that enumerates and quantifies harmful constituents of tobacco products is a positive step that is likely to provide significant information to the scientific community that will contribute to its ability to conduct important research and will also provide relevant data for those who might wish to work toward development of tobacco products with acceptably low risk profiles. Consumers are also entitled to have access to a scientifically accurate list of this type, since they have a right to know what is in the cigarettes that are being sold to them. As shown below, putting this massive amount of data on FDA's website would provide access to the information for scientists and professionals. While it would, theoretically, provide consumers with access to the information as well, it is doubtful that many consumers would choose to access the information or, if they did, would be capable of drawing meaningful conclusions from it. However, departures from this scientifically-accurate content and presentation format in order to simplify the presentation and make it more "consumer friendly" (as will be discussed further below) can have significant adverse consequences.

People do not typically value information for its own sake but because the information is functional in helping to make decisions and take actions they believe are likely to benefit them. That often requires people to group or categorize (see the 1987 Journal of Consumer Research article by Cohen and Basu) both objects and people in functionally meaningful ways: from "things to take on a picnic" and "trustworthy people vs. untrustworthy people" to "better for you vs. not better for you." Strong evidence that smokers did exactly that when low tar and "light" cigarettes were marketed can be found in company documents as well as my national survey published in NCI Monograph 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes and in the *American Journal of Public Health* article "Smokers' knowledge and understanding of FTC tar numbers: Health policy implications." Simply put, very few consumers knew or could accurately approximate the actual tar numbers of the cigarette they smoked. Instead people rely on their categorization of cigarettes when making

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judgments about them. Consumers are not well equipped to make distinctions based on the varying shades of grey bound up in a potential "lower risk" category of tobacco products and to understand the reasons why many such products may present substantially the same health risk. They lack adequate knowledge for making these important distinctions, and so any presentation of constituent information in a form that facilitates comparisons may also increase the likelihood of promoting dangerous misunderstandings.

We have observed smokers' selective processing of information when it helps them deal with internal conflicts caused by the difficulty of quitting and the desire to see themselves as making sensible, health-wise choices. This was well illustrated in the marketing of low tar cigarettes where numerous company documents demonstrate the tobacco companies' recognition that smokers interested in quitting smoking were instead switching to low tar cigarettes under the mistaken belief that doing so would either help them quit or be better for their health. A 1969 R.J. Reynolds survey, for example, suggested that filter cigarette smokers were more conscious of a possible relationship between smoking and health, and indicated that there was a "willingness of an increasing number of smokers to compromise -- to smoke what they considered to be a less harmful cigarette rather than give up smoking entirely." Since it is inherently risky to provide any constituent information that could be processed in a relative manner (i.e., promoting a ranking of products according to a criterion of whether they are relatively better or worse for health) it follows that facilitating broad disclosure of the constituent list on a brand and sub-brand basis could mislead consumers about the relative safety of different products or about the significance of different constituents and level of constituents in different products.

LESSONS LEARNED FROM ATTEMPTING TO PROVIDE CONSUMERS WITH TAR AND NICOTINE INFORMATION

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As already mentioned above, there have been painful lessons learned from a well-intentioned effort simultaneously to provide consumers with standardized tar and nicotine information and encourage the development of less harmful cigarettes. Because of the relevance and importance of the first of these to the present matter, I will devote some additional space to that history.

On March 24, 1966, the Federal Trade Commission notified cigarette manufacturers that they would be permitted to advertise tar and nicotine yields provided they used the Cambridge Filter Method. This was done to achieve the two goals listed above and driven, in part, by the welter of advertising claims (e.g., for miraculous filters and lower tar deliveries) that lacked adequate substantiation. Health authorities had no reasonable way to anticipate that cigarette manufacturers, instead of actually developing less harmful products, would modify products to "defeat" the machine measured yields, in the knowledge that consumers would categorize cigarettes with lower numbers as "safer." A 1977 research company document (from Hawkings, McCain & Blumenthal, Inc) stated that, "Almost all smokers agree that the primary reason for the increasing acceptance of low 'tar' brands is based on the health reassurance they seem to offer." Nor would the required warning label sufficiently counteract such consumer assessments. As the Tobacco Institute put it in 1967: "The suggestion that less nicotine is 'safer' is not avoided by the warning now on cigarette packages. The warning would only remind the smoker that the lower nicotine cigarette is not necessarily completely safe. Obviously, the warning would not stop him from concluding that it is 'safer.'"

At the time these regulatory decisions were made, health authorities did not appreciate (probably until the early 1980's, according to an author of the 1981 Surgeon General's Report) that virtually all smokers compensate for nicotine. Because every smoker smokes to obtain a

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preferred amount of nicotine, they ended up taking in essentially the same amount of nicotine, as well as the associated tar, from cigarettes with quite different tar and nicotine numbers. Company documents demonstrate that cigarette manufacturers were aware of this behavior long before regulatory authorities became aware of it. For example, a February 4, 1976 memorandum from Ernest Pepples, Senior Vice President at Brown & Williamson . . . reveals the company's knowledge that the low tar and filter cigarettes they were marketing as less harmful were not producing less tar and less nicotine to the smoker and were not likely to actually be less harmful . A September 17, 1975 Philip Morris document sent to Leo F. Meyer, Philip Morris Director of Research, reports results of the company's studies with its human smoker simulator, indicating that, due to compensation, smokers got as much tar and nicotine from Marlboro Lights as from full-flavor Marlboros Obviously reality was at odds with smokers' categorizations of cigarettes and assessments of their relative safety.

In a 2006 *Journal of Consumer Research* paper with Lisa Bolton and Paul Bloom, I explained the effects of marketing a product to make it sound like a remedy for a potential problem that consumers believed they could not easily avoid (or way to avoid the most adverse consequences). That is exactly how, first, high filtration and, second, "Light" cigarettes were marketed. "….the remedy signals that the risk is manageable, leading to a boomerang effect on risk perceptions and risky behavior. Put simply, remedy messages suggest that a 'get out of jail free card' is available to take the risk out of risky behavior…. Whenever some aspects of a behavior (e.g., peer approval of smoking) are seen as attractive and behavior is held in check by perceived risks (e.g., dying of smoking related illnesses), promoting an alternative as 'reduced risk' can shift the balance of approach-avoidance forces. Interestingly, our conceptualization suggests that the presence of a brand that is promoted in this way can lead people into a product category they otherwise might not have entered."

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As our experience with providing seemingly useful tar and nicotine numbers makes clear, the unintended consequences of such well-meaning efforts can be dramatic. Rules in place seem intended to prevent a repeat of cigarette company efforts to convey relative “safety” or reduced risk (although the subtlety of such successful efforts---via the use of colors and other symbols should not be underestimated). So my focus is on smokers themselves, and in particular those who can’t easily quit. Many want to believe that some cigarettes are less damaging to their health so that they can feel less fear and anxiety about potential negative consequences from smoking, feel less personal guilt and shame about smoking, and feel less social disapproval from others who want them to quit.

COMMENTS ABOUT THE NATURE OF THE INFORMATION TO BE COMMUNICATED

In balancing the desire to provide consumers with accurate constituent information against the dangers of unintended consequences in transmitting such information, it may make sense to separate the issues into “what information is presented,” “how the information is presented” and “where/when the information is presented.” Let’s discuss the “what information” issue first, though they are related issues. Ironically, the availability of the information as a detailed list in its complete form is likely to carry few risks to consumers. It is doubtful that very many consumers have the background to read and comprehend the constituent information or reach any risk conclusions from it. The highest probability takeaway from seeing the list would be greater certainty that these are very harmful products.

However, if the contemplated consumer research reveals that, as expected, few have the background to make much out of this highly technical information, there may be resulting

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pressure to present information in a reduced and simplified form. Therein lies the problem. Smokers have a built in incentive to use this information in a relative manner i.e., (by comparing constituent quantities in one brand to those in another) to confront the pressures they are facing. It would be a grave mistake to conduct research that would reveal a substantial inability for the public to understand such highly technical information and then to use those results to create alternative presentations that misled consumers into drawing erroneous inferences about relative risk..

The issue of “how the information is to be presented” is almost a non-issue if we are talking about presenting the constituent information in full detail. Such information can be presented in a number of table formats, and these formats can be compared in research to determine what form of organization is preferred. Research regarding consumer understanding of such data is likely to reveal that consumers had little understanding of the highly technical information. If, as expected, research leads to these conclusions, there may be pressures to develop and publish a convenient summary of the information. If such a summary communicates risk in some fashion, the likelihood of unintended consequences is far higher. It is very difficult to communicate risk in the absence of some way to represent both the probability and the severity of consequences associated with the presence of a constituent. It is not clear that existing scientific knowledge allows for these assessments since they are linked to the absolute level of a constituent, its interaction with other constituents and how these are modified by heat as well as smoking parameters (e.g., aeration, intake and duration of smoke). So any attempt to reproduce the detailed list information in a form that is more convenient and understandable for consumers is likely to generate a high level of controversy in the scientific community and has the potential to produce unintended and undesirable consequences due to smokers’ desire to draw inferences that will help them make decisions among alternatives.

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The issue of "where/when the information is to be presented" is closely linked to the prior two discussions. Clearly, comparatively few consumers are likely to see such a list on an FDA (or some other) website unless they are highly motivated to do so. One would expect media reports to help bring the existence of this information to people's attention (as might physicians who wish their patients who smoke to access such information). This is not the sort of information to be "forced upon" people. Attempting to increase access to the information by repackaging it in a more convenient, reader friendly fashion (and making it available in various types of signage and locations) carries the substantial risks discussed above.

COMMENTS ABOUT THE GOALS OF THE PROPOSED RESEARCH

Prior to conducting research it is always a good idea to ask how the results are likely to be used. Yes, questions can be asked out of simple curiosity or for the inherent value of having certain types of knowledge. The lengthy list of respondent understandings presented in the Federal Register Notice (as research goals) suggests there may be added value in rethinking how this information is likely to be used. For example, what different actions would be taken if consumers knew (or did not know) that the tobacco leaf was the source of certain chemicals, or what Federal law requires of tobacco companies? If it turned out that most people did not have the science education needed to understand that the amount of a chemical (or the number of chemicals) listed for a tobacco product did not equate to the likelihood of experiencing a health problem, what would be done differently? Is it even beneficial for people to have a deep enough level of understanding that they realize that the information presented on the list may not even be important to them personally: "*the number of possible health outcomes listed for a tobacco product does not necessarily indicate the likelihood of experiencing a health problem*"?

What, exactly, is it that this research should be designed to do? Before contemplating the details of the research, let's return to FDA mandate. The FDA is charged with publishing "*in a format that is understandable and not misleading to a lay person, and place on public display (in*

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a manner determined by the Secretary) the list [of harmful or potentially harmful constituents] established under [section 904(e)] of the FD&C Act." That burden should be met in two ways: first, by surveying respondents' comprehension of what the list is in plain language---indicating harmful or potentially harmful constituents of tobacco products. To expect more from consumers would require a major overhaul in science education in the United States or even a required graduate degree. Second, the "not misleading" aspect of the burden should be met if survey respondents do not report that the list helps them determine which cigarettes now offered for sale are safer or less risky. This analysis is also consistent with the notice appearing in the Federal Register (Vol. 76, No. 240): "The research goals are to evaluate the impact of different list formats on the public's ability to understand HPHC information, and to assess the potential for certain unintended consequences resulting from exposure to the lists."

In summary, the FDA should take to heart the admonition: "first, do no harm." This list is a very good idea: it presents the best available scientific information as to harmful smoking constituents and their levels to interested parties who may be in a position to use it effectively for research or product development. It is potentially dangerous for the FDA to overreach, to go beyond the letter of its responsibilities, and to try to make this information carry communications burdens that it is not well-suited to carry. We should not expect most consumers to understand the scientific aspects of this information. They don't need to in order to learn that all cigarettes contain very harmful ingredients and constituents----well beyond what is presently referred to as "tar." The real problem would be in expecting too much---or finding that research did not indicate a high level of comprehends of details--- and then concluding, in error, that some means of making the information simpler and more consumer-friendly was needed or would be helpful. Going down that road is fraught with peril, a lesson we learned well

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in trying to quantify and standardize information regarding the delivery of tar and nicotine (without sufficient insight into what cigarette manufacturers and consumers would do with this information).

Another unintended consequence of taking added steps (based on the research) to create some type of summary or reduced-form version of the detailed scientific information, would be any added "license" it might appear to give tobacco companies to use that information to make claims that appear to be forbidden under Section 911. The restrictions in section 911 represent an important safeguard against misuse of the constituent lists. FDA should make it very clear in any publication of this information that the restrictions of section 911 apply to any characterization or selective presentation of the information presented.

Sincerely,

Joel B. Cohen

Professor Joel B. Cohen
(By RY with authorization)

ADDENDUM: EXPERIENCE OF PROFESSOR JOEL B. COHEN RELEVANT TO THE SUBJECT MATTER ADDRESSED IN THIS COMMENT.

Personal Background as a Basis for Comments

The opinions expressed in this comment are based, first, on my scholarly research on how consumers use information to develop beliefs and attitudes that subsequently influence their behavior. Second, I have previously applied this background to two relevant tobacco issues: (1) how smokers are likely to respond to cigarette warning information, and (2) how consumers did

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respond to information about the tar and nicotine "content" of cigarettes as reflected in their publicized tar and nicotine ratings. In the first instance, I was asked by the Federal Trade Commission to evaluate the effectiveness of the warning messages then in place and consider several proposals for changing them. My 1980 report to the Federal Trade Commission (with Professor Thomas Srull), "Information Processing Issues Involved in the Communication and Retrieval of Cigarette Warning Information," was then included in the FTC's annual report to Congress, and I appeared before the United States Senate Commerce Committee to explain our findings. Our report endorsed the present rotational warning system.

I was again invited to appear before a congressional committee to provide my perspectives on the broader issue of "How Cigarette Advertising Affects Consumer Behavior" [in Tobacco Issues: Part I, pp. 187-199, U.S. Government Printing Office, 1989.] That testimony paid particular attention to steps that might be taken to reduce cigarette advertising's effects on children. In a similar context I served as a consultant and expert witness for the Federal Trade Commission in its investigation of R. J. Reynolds' "Joe Camel" advertising and promotional practices.

On behalf of the National Cancer Institute, I carried out a national probability study of smokers' understanding of advertised tar numbers, which I presented to the President's Cancer Panel and which appeared as Chapter 9 in NCI Monograph 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes**.** An expanded version became the *American Journal of Public Health* lead article, "Smokers' knowledge and understanding of FTC tar numbers: Health policy implications, published in 1996. This article is referred to in several chapters of the National Cancer Institute's Smoking and Tobacco Control Monograph *13:* Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine, for which I also served as peer reviewer.

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I am a past president of the Association for Consumer Research, the primary international scholarly association for the study of consumer behavior, and a member of the American Psychological Association and the American Marketing Association. I was the editor of the *Journal of Public Policy and Marketing* from 2002 to 2006 and received the Distinguished Service Award in 2007 from the *Journal of Consumer Research* (the flagship journal dealing with consumer behavior) for my lifetime contributions as an author, peer reviewer, and member of the editorial board. I have served on the editorial boards, as guest associate editor and as a reviewer, as well for a number of psychology and marketing journals (e.g. Journal of Marketing, Journal of Marketing Research, Journal of Consumer Psychology, Marketing Science, Addictive Behaviors, Social Forces), and I am regularly asked to assess the quality of manuscripts submitted for national conference presentations in marketing and consumer behavior/psychology.

My publications include a number of invited chapters including those in the Annual Review of Psychology, The Handbook of Consumer Behavior, The Handbook of Consumer Psychology, Affect and Social Behavior, Do Emotions Help or Hurt Decision Making? and Social Marketing: Theoretical and Practical Perspectives. My research on psychological processes in attitude formation and judgment, cognitive dissonance, affect, personality, and interpersonal influences appear in a number of leading journals including the *Journal of Consumer Research, Journal of Marketing Research, Journal of Experimental Social Psychology, Journal of Applied Psychology, Personality and Social Psychology Bulletin,* as well as a number of edited volumes. My work on attitude formation and the relationship between attitudes and behavior was presented with the 2009 best paper award by the *Journal of Consumer Research.*

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I have had active involvement in several public policy arenas including consumer protection, deceptive and misleading advertising, and the examination of cigarette industry marketing and advertising practices. I have served as a consultant on advertising, marketing and research design to the Federal Trade Commission on numerous occasions since 1972, participating in more than twelve regulatory actions and serving as the FTC's expert in its investigation of RJR's "Joe Camel" campaign. In the course of that work and the other professional activities listed above, I have reviewed hundreds of marketing and advertising plans and studies. I have also served as a consultant to the National Academy of Sciences Panel on the Impact of Drug Use and Misuse and advised the National Institute on Alcohol Abuse and Alcoholism on mass media approaches to alcohol abuse prevention. My articles on these public policy issues have appeared in the *American Journal of Public Health, Journal of Public Policy and Marketing* and a number of edited volumes.

I also served as the principal witness on cigarette marketing and advertising and consumer behavior for the plaintiff in the *Cipollone* case and, on several occasions, assisted the Canadian government in evaluating and developing evidence pertaining to advertising effects, as well as the advertising and promotion practices of the Canadian cigarette industry, and consumers' perceptions and beliefs concerning "Light" and "mild" cigarettes. I have testified in the *Miles/Price* and *Craft/Larsen "Lights"* cases and have provided deposition testimony in a number of similar cases. I also served as a peer reviewer for a number of government-sponsored reports on smoking starting with the 1989 Surgeon General's Report. Finally, I have been a consultant to the National Association of Attorneys General in their continuing scrutiny of advertising claims that may imply health advantages. My work on public policy issues led to my receipt of the 2011 Pollay Prize from the University of British Columbia for "Intellectual Excellence in Research on Marketing in the Public Interest."