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VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0987, 79 Fed. Reg. 41696 ("Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Testing as Used by the Food and Drug Administration Center for Tobacco Products") & Docket No. FDA-2014-N-0005, 79 Fed. Reg. 44779 ("Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications")

Dear Sir or Madam:

RAI Services Company ("RAIS"),[1] on its own behalf and on behalf of its affiliated tobacco companies, submits these comments to the public dockets established by the U.S. Food and Drug Administration ("FDA" or the "Agency") regarding proposed information collections relating to tobacco products. *See Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Testing as Used by the Food and Drug Administration Center for Tobacco Products*, 79 Fed. Reg. 41696 (July 17, 2014) (hereinafter "*Quantitative Testing Notice*"); *Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications*, 79 Fed. Reg. 44779 (Aug. 1, 2014) (hereinafter "*Qualitative Data Notice*").

[1] RAIS is a wholly owned subsidiary of Reynolds American Inc. that bears primary responsibility for coordinating implementation of the Family Smoking Prevention and Tobacco Control Act for RAI's FDA-regulated and to-be-regulated tobacco operating companies, namely R.J. Reynolds Tobacco Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., and R.J. Reynolds Vapor Company.

In an effort to educate and inform the public, FDA is proposing to collect information as part of formative research and pretesting of possible messages relating to tobacco products. RAIS submits that it is essential for FDA to perform this research. In particular, FDA has solicited comments on four topics: (1) whether its proposed collections of information are necessary for the proper performance of its functions, including whether the information will have "practical utility"; (2) the accuracy of FDA's estimates of the burdens of the proposed collections of information; (3) ways to "enhance the quality, utility, and clarity of the information to be collected"; and (4) ways to minimize the burdens of collecting this information. *Quantitative Testing Notice*, 79 Fed. Reg. at 41696/3; *Qualitative Data Notice*, 79 Fed. Reg. at 44779/3. RAIS submits these comments to address the Agency's first and third questions, *see infra* at § I (addressing first question); *infra* at § II (addressing third question).

First, RAIS believes that FDA's proposed collections of information, if done properly, are, in fact, necessary to the proper performance of its functions. As FDA has repeatedly acknowledged, its actions relating to tobacco products—including everything the Agency *says* about the risks and characteristics of such products—must be accurate, objective, and based on sound science. However, FDA's communications can satisfy these criteria only if the Agency carefully conducts the types of formative research and pretesting necessary to ensure that its messages effectively disseminate accurate health information. Consequently, the collection and analysis of accurate information is essential to the proper performance of FDA's functions.

Second, RAIS likewise agrees that there are numerous things that FDA can and must do to ensure that its proposed collections of information are performed properly; these actions, if undertaken properly, would enhance the quality, utility, and clarity of the information to be collected. Most importantly, FDA's formative research and pretesting must be used to create messages that accurately and fully inform the public about the risks—including the relative risks—of various tobacco products. Such messages should be targeted at dispelling the public's misperceptions about the risks of tobacco product categories—which also means that FDA should first collect information about the public's baseline knowledge and beliefs, so that it has a complete picture of the informational deficits that its communications must address. RAIS also discusses a handful of other improvements and urges FDA to provide additional information about the data it seeks to collect in order to allow RAIS and other stakeholders to provide more meaningful comments.

RAIS stands ready to work with FDA to ensure that its communications regarding tobacco products are accurate, clear, science-based, and aimed at fully informing the public of the risks—including the relative risks—of different categories of tobacco products. RAIS looks forward to working collaboratively with FDA to further these common goals.

COMMENTS

I. FDA'S PROPOSED COLLECTIONS OF INFORMATION ARE NECESSARY FOR THE PROPER PERFORMANCE OF THE AGENCY'S FUNCTIONS.

FDA has solicited comments about whether the Agency's proposed collections of information are necessary for the proper performance of its functions, including whether the information will have "practical utility." *Quantitative Testing Notice*, 79 Fed. Reg. at 41696/3; *Qualitative Data Notice*, 79 Fed. Reg. at 44779/3. As explained below, RAIS believes that FDA's proposed collections of information, if done properly, are, in fact, necessary to the proper performance of its functions. In particular, it is common ground that FDA's actions and communications must be objective and science-based. *See infra* at § I.A. FDA can accomplish this goal, however, only if it conducts the types of formative research and pretesting necessary to ensure that its messages effectively disseminate accurate health information. *See infra* at § I.B.

A. FDA's Actions and Communications Must Be Objective and Science-Based.

As an initial matter, RAIS fully agrees that FDA's regulation of tobacco products must be based on an objective, rigorous evaluation of scientific evidence. As Margaret A. Hamburg, the Commissioner of Food and Drugs, has declared, "FDA's experts need to be equipped to make science-based decisions resulting in sound regulatory policy." *FDA Modernizing Regulatory Science*, FDA Consumer Health Information (Aug. 2011) (last visited Sept. 9, 2014), *available at* http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM268209.pdf (attached as Exh. A). FDA's Center for Tobacco Products ("CTP") has likewise acknowledged its responsibility to "rel[y] on the most current science to make regulatory decisions on tobacco products." *Informing Tobacco Regulation Through Research*, FDA (last visited Sept. 9, 2014), *available at* http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/abouthecenterfortobaccoproducts/ucm383161.htm (attached as Exh. B). In short, FDA's regulation of tobacco products should be "evidence-based." *See* Letter from Specialists in Nicotine Science & Public Health Policy to Dr. Margaret Chan, Director General, World Health Organization 2 (May 26, 2014), *available at* http://nicotinepolicy.net/documents/letters/MargaretChan.pdf (attached as Exh. C) (arguing that the regulation of tobacco products should be "evidence-based").

Importantly, FDA's responsibility to be objective and science-based is not limited to its substantive regulation of tobacco products. Rather, this responsibility extends to the Agency's educational and public-information programs. In fact, FDA has expressly declared that it "has a long-standing commitment to being science-based and science-led, a commitment that also includes risk communication activities." *FDA's Strategic Plan for Risk Communication*, at 10 (Fall 2009) (attached as Exh. D-1, along with Appendix II (2012 Update) to *FDA's Strategic Plan for Risk Communication* (attached as Exh. D-2)). The Agency has further explained that it "fully supports using scientific methods to design and assess communications that will ensure maximum effectiveness." *Id.* RAIS, therefore, fully agrees that FDA's communications should be accurate, objective, and based on sound science.

B. The Agency Must Conduct Formative Research and Pretesting to Ensure That Its Communications Are Objective and Science-Based.

Inasmuch as FDA's educational and public-information programs must be objective and science-based, it is imperative that the Agency conduct formative research and pretesting. Doing so will allow FDA to refine its messages to maximize their effectiveness in disseminating accurate health information.

Regulators and academics alike have expressly declared that formative research and pretesting of communications are critically important. For example, FDA has stated that "effective health and risk communication involves conducting formative and evaluative research." *FDA's Strategic Plan for Risk Communication*, *supra*, at 17. Likewise, the National Cancer Institute has explained that "[d]eveloping and pretesting messages and materials are important because they allow you to learn early in the program which messages will be most effective with the intended audiences." *Making Health Communication Programs Work: A Planner's Guide* at 54, U.S. Department of Health and Human Services – National Cancer Institute (2008), *available at* http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook/page6 (attached as Exh. E). Academics also recognize that "[o]nce a written health education material has been designed[,] it is *essential* that it is pretested with a sample target audience." Tammy Hoffmann & Linda Worrall, *Designing Effective Written Health Education Materials: Considerations for Health Professionals*, 26 Disability & Rehab. 1166, 1170 (2004) (emphasis added) (attached as Exh. F); *see also* Margot Zimmerman & Lena Steckel, *Formative Research: Pretesting, Revising, and More Pretesting*, Dev. Commc'n Rep. 9, 12 (1985) ("Pretesting is an *essential* formative technique that builds upon information gathered during the materials development process.") (emphasis added) (attached as Exh. G).

Accordingly, with respect to FDA's first question about whether its proposed collections of information are necessary for the proper performance of its functions, RAIS submits that such collections are, in fact, essential, provided that they are done properly. Moreover, as discussed in the next section of these comments, there are numerous steps FDA should take to maximize the usefulness of the information that it collects. *See infra* at § II.

II. THERE ARE A NUMBER OF WAYS IN WHICH FDA CAN—AND SHOULD—ENHANCE THE QUALITY, UTILITY, AND CLARITY OF THE INFORMATION THAT IT COLLECTS.

The third question raised by FDA in the *Federal Register* notices is whether there are ways to "enhance the quality, utility, and clarity of the information to be collected." *See Quantitative Testing Notice*, 79 Fed. Reg. at 41696/3; *Qualitative Data Notice*, 79 Fed. Reg. at 44779/3. As discussed in detail below, RAIS submits that the Agency can—and should—take certain steps to enhance the quality, utility, and clarity of the information gathered during the Agency's formative research and pretesting. Most importantly, FDA's research and pretesting should be aimed at providing truthful, non-misleading information that corrects misperceptions about tobacco products. *See infra* at § II.A. In addition, FDA's formative research and pretesting should be guided by sound research principles that help enhance the usefulness of the information that is collected. *See infra* at § II.B. Finally, the Agency should provide further

information about its planned collections of information, thus facilitating a more robust opportunity for public comment concerning the Agency's planned research. *See infra* at § II.C.

A. FDA Should Design and Implement Its Formative Research and Pretesting in a Way That Helps Correct the Public's Misperceptions About Tobacco Products.

Through its formative research and pretesting, FDA should endeavor to develop communications that correct the public's misperceptions about tobacco products. In particular, FDA's principal objective should be to provide accurate, non-misleading information to the public about the risks—including the relative risks—of various tobacco product categories. *See infra* at § II.A.1. To do so, however, FDA must collect information about the public's baseline knowledge and beliefs, so that the Agency has a complete picture of the informational deficits that its communications should address. *See infra* at § II.A.2. The Agency should also use its formative research and pretesting to ensure that its proposed communications are fully comprehended by the public. *See infra* at § II.A.3. In sum, FDA must establish the correct objective for its communications; understand the misperceptions and informational deficits it is trying to solve; and then ensure that its messages are comprehended by the public.

1. The Overriding Objective of FDA's Formative Research and Pretesting Should Be to Craft Communications That Accurately Inform the Public About the Risks—Including the Relative Risks—of Various Tobacco Product Categories.

As discussed in detail below, the key goal of FDA's formative research and pretesting in the tobacco context should be to create messages that *accurately and fully* inform the public about the risks—including the relative risks—of various tobacco product categories. The objective should not be to misinform or attempt to shock the public into a particular course of action. It should, instead, be aimed at providing the public with truthful, non-misleading information so that adults can make fully informed choices.

It is undisputed that different types of tobacco products present different levels of risk. Public health researchers often compare the relative risks of tobacco product categories through a construct called a "continuum of risk," with the combustible cigarette category on one end and the noncombustible tobacco product categories such as smokeless tobacco products, snuffs, and electronic cigarettes on the other. *See* Mitchell Zeller, Dorothy Hatsukami, & the Strategic Dialogue on Tobacco Harm Reduction Group, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 Tob. Control 324, 325 (2009) (hereinafter "Zeller 2009") (attached as Exh. H). Indeed, in FDA's proposed rule that would deem e-cigarettes and numerous other products to be subject to Subchapter IX of the Federal Food, Drug, and Cosmetic Act, the Agency recently—and correctly—recognized that there is a "continuum of nicotine-delivering products that pose differing levels of risk to the individual." *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23142, 23147/3 (Apr. 25, 2014) (hereinafter "*Proposed Deeming Rule*") (attached as Exh. I); *id.* ("there are distinctions in the hazards presented by various nicotine-delivering

products"). Moreover, Mitch Zeller, who serves as CTP's Director, has repeatedly acknowledged the continuum of risk. Mr. Zeller has declared, for example, that "[a]nyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery." Mitchell Zeller, *Reflections on the 'Endgame' for Tobacco Control*, Tob. Control 22:i40-i41, at i40 (2013) (attached as Exh. J); *see also, e.g.*, Zeller 2009, *supra*, at 325 ("There is a very pronounced continuum of risk depending upon how toxicants and nicotine . . . are delivered. Cigarette smoking is undoubtedly a more hazardous nicotine delivery system than various forms of noncombustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products."); Mitchell Zeller, *The FDA Center for Tobacco Products: 20 Years Later: Returning to FDA to Regulate Tobacco*, FDA Basics Webinar, at 12, 13 (Dec. 11, 2013), *available at* http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM378104.pdf (attached as Exh. K) (declaring that "[c]ertain products pose more individual risk than others" and referring to the "[o]ngoing debate about how to regulate products based upon where they fit on a 'continuum of risk' given their toxicities and how they are used").[2]

In light of the well-established continuum of risk, FDA must strive to ensure that consumers are accurately informed about the risks—including the relative risks—of different categories of tobacco products. Just as FDA has been vigilant about informing consumers that all tobacco products pose health risks, it also should be vigilant in informing the public that some tobacco products present fewer and lower health risks than others. In other words, FDA should inform the public that a continuum of risk exists. Such truthful information is critical to ensure that the public is fully informed about tobacco products.[3]

FDA's communications about tobacco products should not only embrace the existence of a continuum of risk; they also should inform the public about where various tobacco product categories fall on that continuum. "Indeed, within the public health and tobacco control

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[2] *See also, e.g.*, D.J. Nutt *et al.*, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 Eur. Addict. Res. 218, 224 (2014) (attached as Exh. L) (discussing "a continuum of harm from nicotine-containing products with cigarettes at one end and [nicotine replacement therapy] products at the other end"); May 26, 2014 Letter from Specialists in Nicotine Science, *supra*, at 2 (contending that the regulation of tobacco products "should be evidence-based and proportionate to risk, and give due weight to the significant reductions in risk that are achieved when a smoker switches to a low risk nicotine product"); RAIS Comments on *Proposed Deeming Rule* at 32-78 (Aug. 8, 2014), Docket No. FDA-2014-N-0189 (hereinafter "Deeming Comments") (attached as Exh. M) (discussing the continuum of risk); RAIS Summary of Scientific Literature Regarding E-Cigarettes (attached as Exh. N).

[3] FDA's vigilance for truthful communication should also extend to the messages broadcast to consumers by sister federal government agencies such as the Centers for Disease Control, as well as state government institutions. Misleading and/or inaccurate information from these government institutions will undermine FDA's attempts to remedy the public's misperceptions and confusion about the relative risks of different tobacco products.

communities, it has been argued that smokers have a human right to receive accurate information about such relative risks." Citizen Petition, FDA Docket No. FDA-2011-P-0573, at 4 (July 28, 2011) (attached as Exh. O-1); *see also* App'x A to Citizen Petition (attached as Exh. O-2); App'x B to Citizen Petition (attached as Exh. O-3). FDA's communications should clarify—not obfuscate—which categories of tobacco products present less or more risk than others. Such an approach will help counteract the misperceptions and misinformation that presently exist and will encourage more switching from more risky to less risky tobacco products by those who will not quit their use of nicotine-delivering products altogether. *See Proposed Deeming Rule*, 79 Fed. Reg. at 23158/1.

It is therefore noteworthy that FDA's proposed deeming rule expresses a desire to correct the public's misperceptions about the risks of tobacco products. *See Proposed Deeming Rule*, 79 Fed. Reg. at 23153/2, 23164/1-2, 23165/2, 23166/2; *see also* Pam Harrison, *FDA Seeks to Regulate e-Cigs, All Other Tobacco Products* (Apr. 25, 2014), *available at* http://www.medscape.com/vivewarticle/824137_print (attached as Exh. P) (quoting Director Zeller's statement that, "[w]hen finalized, the deeming rule will result in significant public health benefits, including . . . helping correct consumer misperception"). FDA also has embraced the notion that "risk communication activities" should "enable people to make informed judgments about use of FDA-regulated products." *FDA's Strategic Plan for Risk Communication*, *supra*, at 8. RAIS fully agrees with these sentiments. But for reality to match these sentiments, FDA must conduct formative research and pretesting that will enable it to craft communications that accurately describe the risks of tobacco products—not only in absolute terms, but also in relative terms. No amount of surveys or focus groups will have significant value unless they are performed with the objective of creating communications that accurately inform consumers about where various tobacco products fall on the continuum of risk.

For the reasons outlined above, FDA should pretest various messages and then determine which ones will most accurately and fully inform consumers about (1) the fact that there is a continuum of risk and (2) where particular tobacco product categories fall on that continuum. In creating such messages, FDA should not merely strive for messages that are literally true, as many literally true messages are, in fact, misleading. Instead, FDA should use non-misleading messages that improve the public's understanding of the pertinent risks. For example, FDA should avoid messages such as the statement that smokeless tobacco products are "not a safe alternative to cigarettes," which is one of the mandatory labeling statements for smokeless tobacco products. 15 U.S.C. §§ 4402(a)(1), (b)(3)(A); *see, e.g.*, Citizen Petition, *supra*, at 1-50; Deeming Comments, *supra*, at 72-75. As RAIS explained in a Citizen Petition, this warning statement is highly misleading because it inaccurately implies that smokeless tobacco products do not present less risk than cigarettes. That is, the challenged warning is a statement about the safety of both cigarettes and smokeless tobacco products, but it omits the critical information that smokeless tobacco products present a materially lower health risk than do cigarettes. Because the warning clearly implies that cigarettes are unsafe, a statement that smokeless tobacco products are "not a safe alternative to cigarettes" is technically true, but highly misleading. Simply put, the material omission invites consumers to infer incorrectly that cigarettes and smokeless tobacco products are equally unsafe when, in fact, smokeless tobacco products present significantly less risk of harm than do cigarettes. *See, e.g.*, Citizen Petition, *supra*, at 1-29; *id.* at 3 (noting the "scientific consensus" that, although smokeless tobacco products "do present health

risks," they "present substantially lower health risks than do cigarettes"); Deeming Comments, *supra*, at 72-75.[4]

In its comments relating to FDA's proposed deeming rule, RAIS urged FDA to establish and publish a chart that clearly reflects the risks—including the relative risks—of various tobacco products. *See* Deeming Comments, *supra*, at 77-78. Communicating with the public in this way would encourage existing tobacco users to switch from more risky to less risky tobacco products. *Id.* For instance, after the Independent Scientific Committee on Drugs convened an expert panel to consider the question of where various tobacco products fall on the continuum of risk, the following chart was published to convey the panel's conclusions:

[4] Because the challenged warning statement is highly misleading, the Citizen Petition urged FDA to initiate a rulemaking to adjust the text of the warning, so that it would read: "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes." Citizen Petition, *supra*, at 1; *see also* First Supplement to Citizen Petition, FDA Docket No. FDA-2011-P-0573 (Aug. 21, 2012) (hereinafter "First Supplement") (attached as Exh. Q-1); App'x A to First Supplement (attached as Exh. Q-2); Second Supplement to Citizen Petition, FDA Docket No. FDA-2011-P-0573 (Mar. 28, 2013) (hereinafter "Second Supplement") (attached as Exh. R-1); *see also* Attachments 1, 2, & 3 to Second Supplement (attached as Exhs. R-2, R-3, & R-4). The Second Supplement continued to advocate the Citizen Petition's initial proposal for modifying the challenged warning, but it also proposed the following alternative formulation: "WARNING: No tobacco product is safe; however, exclusive use of smokeless tobacco products presents substantially less risk to health than cigarettes." Second Supplement, *supra*, at 3. The Citizen Petition, First Supplement, and Second Supplement, as well as their corresponding appendices and attachments, are incorporated into these comments as if fully stated herein.

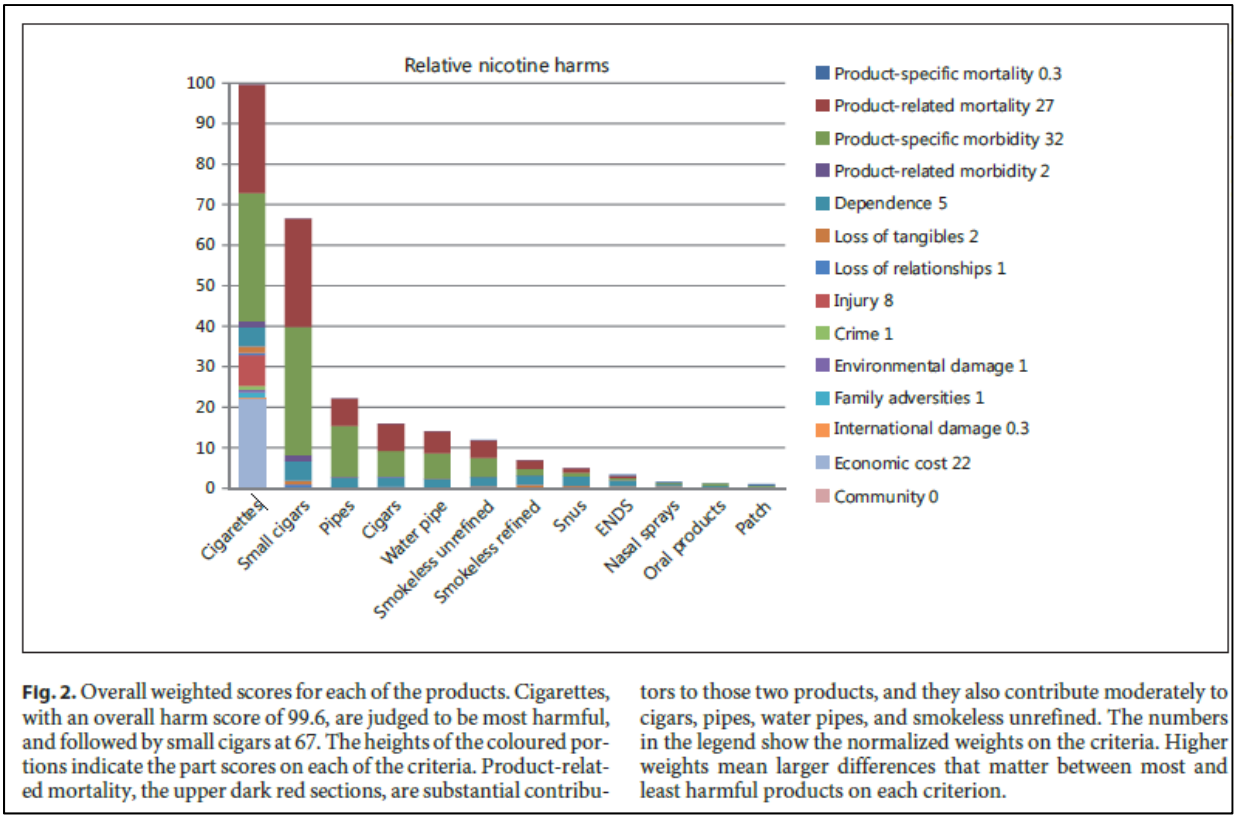


Fig. 2. Overall weighted scores for each of the products. Cigarettes, with an overall harm score of 99.6, are judged to be most harmful, and followed by small cigars at 67. The heights of the coloured portions indicate the part scores on each of the criteria. Product-related mortality, the upper dark red sections, are substantial contributors to those two products, and they also contribute moderately to cigars, pipes, water pipes, and smokeless unrefined. The numbers in the legend show the normalized weights on the criteria. Higher weights mean larger differences that matter between most and least harmful products on each criterion.

Nutt, *supra*, at 222. FDA should test whether such a chart would accurately inform the public about the risks—including the relative risks—of tobacco products. Communicating this information should be unobjectionable to FDA, given that, as discussed above, the Agency and its Director routinely refer to the continuum of risk that is reflected in the chart.

In short, the overriding objective of FDA's formative research and pretesting in this context should be to accurately and fully inform the public about the risks—including the relative risks—of various tobacco products.

2. FDA Should Collect Data About Baseline Knowledge and Beliefs.

In order to ensure that its messages accurately and fully inform the public about the risks—including the relative risks—of various tobacco products, FDA should first collect information about the public's baseline knowledge and beliefs, so that the Agency has a complete picture of the informational deficits that its communications should address. Thus, in performing its formative research and pretesting, FDA should gather data from survey respondents and interviewees regarding baseline knowledge, beliefs, and attitudes pertaining to tobacco and health. *See* Statement of W. Kip Viscusi, at 2, 13 (Apr. 21, 2010) (hereinafter "Viscusi Stmt."), submitted as an attachment to the RAIS Comments (Apr. 22, 2010), Docket Nos. FDA-2010-N-0079 & FDA-2010-N-0084 (attached as Exh. S). In particular, FDA should collect information about baseline knowledge in order to identify the tobacco products for which the public currently has an inaccurate or skewed view of the relative risks. For example, as RAIS has emphasized in its Citizen Petition that challenges one of the warning statements for

smokeless tobacco products, the vast majority of the public erroneously believes that smokeless tobacco products are as harmful as, or more harmful than, cigarettes. *See, e.g.*, Citizen Petition, *supra*, at 1-29. The Citizen Petition cited more than a dozen scientific articles and primary sources that demonstrate the widespread public misunderstanding regarding the relative risks associated with the use of cigarettes and smokeless tobacco products. *See id.* at 20-27. Moreover, additional scientific literature published since the submission of the Citizen Petition provides even more evidence of this misunderstanding. *See* First Supplement, *supra*, at 4-6.

In addition, the Agency needs baseline data in order to assess whether the tested communications, in fact, increase awareness and knowledge. *See* Viscusi Stmt. at 13. The dimensions on which the baseline risk measures are defined should make possible a meaningful comparison with risk beliefs that exist after the proposed communications are tested. *See id.* In short, baseline data are necessary in order to effectively evaluate the possible influence of various messages on knowledge, beliefs, and attitudes regarding tobacco and health. *See id.* at 2; *Qualitative Data Notice*, 79 Fed. Reg. at 44779/3 ("FDA must first understand people's knowledge and perceptions about tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies.").

In sum, FDA should collect data about baseline knowledge and beliefs, which will help the Agency identify misperceptions that the public may have about the risks—including the relative risks—of tobacco product categories. The collection of such baseline data will then enable the Agency to identify and create messages that correct such misperceptions.

3. FDA Should Use Formative Research and Pretesting to Ensure That the Public Understands the Intended Messages.

Finally, FDA's formative research and pretesting should ensure that members of the public who are exposed to the Agency's communications correctly perceive and understand the messages that the Agency is attempting to convey. FDA should pretest its proposed messages and materials "with representatives of the target population to determine if the intended message is being conveyed and if it is clear and acceptable to them." Zimmerman & Steckel, *supra*, at 9. As FDA has recognized, "[i]t is critical that individuals receive information that is adequate to ensure that they make informed choices." *FDA's Strategic Plan for Risk Communication*, *supra*, at 9. If individuals do not accurately grasp the intended message, however, it is clear that the message cannot aid them in making informed choices.

In order for pretesting to demonstrate whether the target audience understands the intended message, the pretesting must be sufficiently robust to achieve its intended purpose. Pretesting should not, for example, be limited to confirming that a computerized survey runs correctly. *See* Viscusi Stmt. at 13. Instead, survey respondents and interviewees should be prompted to explain what the wording of FDA's proposed messages means to them and whether there are any ambiguities in the wording. *See id.*[5] Such testing can help identify initial areas of

[5] In addition, FDA's formative research and pretesting should be designed in a way that allows the Agency to determine the extent to which the specific components of the message—*i.e.*, the

confusion that require changes to the messages that are being tested. *See FDA's Strategic Plan for Risk Communication*, *supra*, at 17 (explaining that "initial areas of confusion and misinterpretation" identified through pretesting "can highlight aspects of a message that require further work").

If pretesting reveals that confusion exists among members of the target audience—as is clearly the case with respect to the smokeless tobacco warning discussed above, *see supra* at §§ II.A.1, II.A.2—then FDA should revise its proposed messages or create entirely new messages. The Agency should then perform additional pretesting of the revised messages to confirm that the public correctly perceives and understands the points that FDA is trying to convey. Zimmerman & Steckel, *supra*, at 9 ("Revised materials should likewise be tested until they communicate the information as intended."). When revised messages are not pretested, it is difficult, if not impossible, to determine whether the revisions clarified the ambiguity or solved the problem they were attempting to address. *See* Theresa J. DeMaio *et al.*, U.S. Bureau of the Census, *Improving Survey Quality Through Pretesting* at 6 (last visited Aug. 12, 2014), *available at* https://www.census.gov/srd/papers/pdf/sm98-03.pdf (attached as Exh. T) (noting that when "question revisions resulting from question pretesting do not get retested prior to inclusion in the production survey," it "is rarely known whether the expected benefit from the revision is realized").

In sum, for the reasons articulated above, FDA should utilize formative research and pretesting to ensure that the public understands the messages that the Agency is attempting to convey. Additionally, when initial research and pretesting reveal that a message needs to be revised, the modified message should be subjected to additional pretesting.

B. FDA's Formative Research and Pretesting Should Be Guided by Sound Research Principles That Help Enhance the Usefulness of the Information That Is Collected.

In addition to the critical points discussed above—namely, that FDA should seek to accurately inform the public about the risks and relative risks of tobacco products, understand the public's misperceptions about these risks and relative risks, and ensure that the public understands the Agency's messages—it is also important for FDA to observe sound research principles when performing its research and pretesting. For example, FDA should conduct well-designed studies that can be generalized to the U.S. population and should provide sufficient information to the public about such studies so that other investigators can critically evaluate these studies and replicate the findings. Additionally, the Agency should consider factors that have the potential to influence tobacco use behaviors, such as smoking initiation and cessation,

(continued…)

text, the formatting of the text, or the medium in which the message is conveyed—contribute to any potential increase in information or change in risk beliefs among respondents. *See* Viscusi Stmt. at 14.

so that it can control for confounding variables to the maximum extent possible, *see infra* at § II.B.1, and should test across subjects in order to avoid demand effects, information overload, and question-order bias, *see infra* at § II.B.2. Conducting research that comports with such foundational research principles will help ensure the usefulness of the information that FDA collects.

1. The Agency Should Consider Factors That Have the Potential to Influence Tobacco Use Behaviors.

FDA should consider data from survey respondents and interviewees about factors that have the potential to influence tobacco use behaviors, such as smoking initiation and cessation. Viscusi Stmt. at 20. The relevant literature indicates that a number of factors can potentially influence decisions to start or stop smoking. *Id.* Such factors include price, access, motivation, self-efficacy, and social influences such as use among friends or family members. *Id.* If the Agency intends to assess whether particular communications prevent or discourage initiation among never-smokers or renewed smoking among former smokers, it may be important to consider such material factors among the respondents. *Id.* Such an approach would help FDA to evaluate the possible impact of the messages, while properly controlling for such confounding variables to the maximum extent possible. *Id.* at 2, 20.

2. FDA Should Test Across Subjects in Order to Avoid Demand Effects, Information Overload, and Question-Order Bias.

FDA's formative research should test across subjects, as opposed to within subjects, so that the Agency can assess any experimental effects. *See* Viscusi Stmt. at 14. For instance, if the Agency is testing two different messages relating to a particular topic, different respondents should view the different warnings in order to avoid demand effects resulting from the survey. *See id.* Failure to do so will lead to an overestimate of the effect of bolder warnings. *See id.* That is, if the study is performed within subjects, bolder warnings will tend to prompt a higher reported risk assessment than would be reported in relation to less bold warnings in the same survey. *See id.*

Testing across subjects also could help prevent information overload and question-order bias. There is a danger of information overload if consumers are asked to review too many different communications. Viscusi Smt. at 15. And testing across subjects also may reduce the risk of question-order bias, which stems from the fact that once a respondent has been given risk information in a prior survey or interview question, the respondent cannot take herself back to her pre-survey (or pre-interview) state of knowledge. *Id.*

C. The Agency Should Provide Additional Information About Its Proposed Formative Research and Pretesting.

Finally, the *Federal Register* notices at issue here provide only a bare-bones notification that FDA plans to conduct formative research and pretesting. For instance, the Agency has not provided detailed information about the content of the proposed surveys and interviews. Nor has

the Agency provided a concrete description of the methodology it will utilize when administering surveys, performing interviews, or facilitating focus groups.

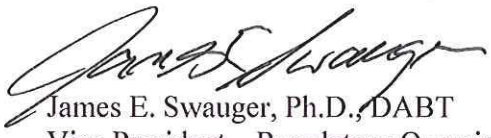
It is impossible for RAIS to provide comments regarding aspects of FDA's proposal that are not adequately described in the *Federal Register* notices. As a result, the Agency should provide additional information about the data it seeks to collect, the persons from whom it will seek this information, and the methodology it will use when collecting this data. Moreover, after FDA provides such further information, the public should have an additional opportunity to comment on FDA's proposed information collections.

* * *

RAIS appreciates the opportunity to comment on issues relating to FDA's proposed collections of information. The company looks forward to working with FDA to ensure that the Agency's communications about tobacco products are accurate, clear, science-based, and consistent with the continuum of risk.

Thank you for your consideration of these important concerns.

Respectfully submitted,



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