Juul Labs®

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Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2018-N-0180; Comment on Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications; OMB Control Number 0910-0810 — Extension

To whom it may concern:

Juul Labs, Inc. (JLI or the Company)[1] appreciates the opportunity to provide comment to the Food and Drug Administration (FDA or the Agency) on its Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications (Notice).[2]

I. INTRODUCTION

In the Notice, FDA states that it proposes to "collect information related to foundational research informing message development or the formative pretesting of tobacco communication messages and other materials directed at consumers" to, among other things, develop "health messages relating to the control and prevention of disease."[3]

FDA not only serves as the gatekeeper of new tobacco products that may have a positive public-health benefit but also can play a critical role in communicating their relative health risks compared to other, more harmful products like combustible cigarettes.[4] Accurate, reliable, and evidence-based communications remain essential to

[1] JLI is the manufacturer of the JUUL System, a closed, cartridge-based electronic nicotine delivery system (ENDS) that utilizes proprietary heating technology to aerosolize and deliver nicotine without combustion. The JUUL System is composed of the JUUL Device and JUULpods. JUULpods are pre-filled with a nicotine-containing e-liquid formulation, which varies by tobacco or menthol flavor and nicotine concentration. The JUUL System is marketed as an alternative for adult smokers to transition and completely switch them from combustible cigarettes.

[2] 86 Fed. Reg. 51897 (Sept. 17, 2021).

[3] *Id.*

[4] Recognizing the importance of accurate, reliable, and objective federal agency communications, Congress passed the Information Quality Act (IQA) in 2000, directing the Office of Management and Budget (OMB) to issue guidelines "that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by" such agencies. Pub. L. 106–554, §1(a)(3) [title V, §515] (Dec. 21, 2000), codified at 44 U.S.C. § 3516 note; 67 Fed. Reg. 8452 (Feb.

provide adult current users of tobacco products relevant health-risk information to further the Agency's Comprehensive Plan for Tobacco and Nicotine Regulation (Comprehensive Plan) and shift the trajectory of tobacco-related death and disease in the United States. Such is particularly relevant and necessary given the significant and worsening misperceptions among current users on both the role of nicotine and relative risk of noncombustible products as alternatives to combustible cigarettes.

And as the saying goes, perhaps "there's no time like the present." The Agency is completing its rigorous premarket review of currently marketed, deemed new tobacco products and transitioning the marketplace to one that is fully regulated and science-based. As it determines certain products are appropriate for the protection of public health, FDA has the opportunity to accurately and clearly communicate the relative health risks of these novel, potentially less harmful products post-authorization. In doing so, the Agency can tailor these communications to their intended audience (adult current users) while mitigating against unintended ones (nonusers, particularly youth).

Central to this messaging and communications approach should be both FDA's regulatory mission to protect and promote public health and the Comprehensive Plan. A hallmark in tobacco-harm-reduction policy, the Comprehensive Plan refocuses the public-health debate on the role of nicotine and that it, while addictive, is "delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes."[5] As has been quoted often: "Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year."[6] Thus, a science-based, regulatory agenda was set in motion to reduce cigarette-related death and disease and, for those unable or unwilling to quit nicotine, to provide "potentially less harmful tobacco products [that] could reduce risk while delivering satisfying levels of nicotine . . . ."[7]

Over four years into the Comprehensive Plan, a key element of realizing the positive public-health impact of moving currently addicted adult smokers down the continuum of risk for nicotine delivery is communicating the continuum of risk to that target audience. This begins with correcting the stark misperceptions on nicotine and the relative risk

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22, 2002). Under IQA guidelines issued by OMB and the Department of Health and Human Services (HHS), information disseminated by agencies, among other things, should be "accurate, reliable, clear, complete, unbiased and useful." OMB Guidelines; U.S. Dep't of Health and Hum. Servs., HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (Oct. 1, 2002), https://bit.ly/2W747ic.

The Notice itself recognizes that the Center for Tobacco Products (CTP) will conduct such research "and develop health messages relating to the control and prevention of disease." 86 Fed. Reg. at 51897.

[5] FDA News Release, "FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death" (July 27, 2017), available at https://bit.ly/3jcCGhT.

[6] S. Gottlieb, M.D., & M. Zeller, J.D., A Nicotine-Focused Framework for Public Health, New England Journal of Medicine (2017).

[7] *Id.*

between combustible cigarettes and noncombustible alternatives. While manufacturers have an opportunity to (and should) develop evidence-based consumer communications through modified-risk orders, public-health authorities like FDA and other trusted stakeholders can take a swift and more comprehensive approach when substantiated by the best available science.

Moreover, the proposed research and messaging development in the Notice is consistent with FDA's stated research priorities, which include research on "methods and messages for communicating complex scientific concepts to the general public, including risk and harms of tobacco use taking into account unintended consequences."[8] To that end, the Agency has committed to provide adult current users with adequate information to help them transition down the continuum of risk from combustible products to less harmful and potentially less harmful alternatives.[9] FDA also has recognized that significant misperceptions exist in the public's mind about nicotine, particularly the role of nicotine in tobacco-related disease, and the risk differential between noncombustible and combustible products.[10]

We believe the information that the Agency proposes to collect can support the research and development of tobacco-related messaging and communications to provide adult smokers accurate, non-misleading information relating to the continuum of risk. This, in part, can help stem and correct the increasingly entrenched misperceptions among adult smokers on nicotine and the relative risk of noncombustible products, support the Comprehensive Plan, and advance tobacco harm reduction.

II. THE IMPORTANCE OF CORRECTING MISPERCEPTIONS ON THE ROLE OF NICOTINE AND RELATIVE RISK BETWEEN NONCOMBUSTIBLE AND COMBUSTIBLE TOBACCO PRODUCTS

The current state of public (mis)understanding about the harms of nicotine and relative risk of noncombustible compared to combustible products highlights the need for research and messaging development to support accurate, non-misleading information for adult current users, particularly those of combustible cigarettes. This information, in turn, can help move adult smokers down the continuum of risk and support broader regulatory and public-health objectives based on the data and science and evidence.

On the role of nicotine, a substantial proportion of U.S. adults incorrectly perceive that nicotine is a significant contributor to the harms of tobacco use and causes major smoking-related diseases, including cancer, chronic obstructive pulmonary disease (COPD), and cardiovascular disease. According to a recent analysis of Wave 4 of the National Institute of Health (NIH) and FDA's Population Assessment of Tobacco and Health (PATH)

[8] FDA, Center for Tobacco Products, Research Priorities, https://bit.ly/3BTfyw6.

[9] *See* K. Crosby, "What Is the Mindset of Today's Cigarette Smokers?," presentation at The E-cigarette Summit USA 2021 (May 25, 2021).

[10] *See* M. Holman, "FDA Perspective: Opportunities for Harm Reduction," presentation at the 74th Tobacco Science Research Conference (Aug. 4, 2021).

Study, 68.3% of respondents answered "definitely yes" or "probably yes" in response to the statement "nicotine in cigarettes causes most of the cancer caused by smoking."[11]

The Agency's own analysis of the Health Information National Trends Survey (HINTS) revealed that 49% of respondents agreed or strongly agreed with the statement "nicotine is the substance that causes most of the cancer caused by smoking" and an additional 24% of respondents were unsure.[12] FDA further stratified its analysis by smoking status and reported that among adult smokers planning to quit, 48% agreed or strongly agreed that nicotine causes most of the cancer caused by smoking, 17% were unsure, and only 35% disagreed or strongly disagreed. Nicotine misperceptions among recent "smoking quitters" were more imbalanced: 64% of this group agreed or strongly agreed that nicotine causes most of the cancer caused by smoking, 7% were unsure, and only 28% disagreed or strongly disagreed.[13]

These misperceptions are not limited to the public writ large but also are observed among healthcare professionals. In one study, over 80% of physicians "strongly agreed" that "nicotine directly contributes to" cancer, COPD, and cardiovascular disease.[14]

In a follow-up study, the same group conducted a survey among physicians to understand the impact of question wording on estimates of nicotine risk.[15] Specifically, these researchers randomly fielded two versions of a survey item on nicotine and disease implications. Version 1 was "Please indicate the extent to which you agree or disagree that nicotine directly contributes to the development of the following health problems by selecting your choice"; while version 2 was more specific, reading "Please indicate the extent to which you agree or disagree that nicotine <u>on its own</u> directly contributes to the development of the following health problems by selecting your choice."[16]

Large majorities of respondents to both versions strongly agreed that nicotine directly contributes to the development of cancer, COPD, and cardiovascular disease. However, version 2 of the question, which included the phrase "nicotine on its own," elicited less strong agreement compared to the responses to version 1. For example, 85%

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[11] R. Delinger-Apte, et al., Risk Perceptions of Low Nicotine Cigarettes and Alternative Nicotine Products Across Priority Smoking Populations, International Journal of Environmental Research and Public Health 18, 5311 (2021).

[12] E. O'Brien, et al., U.S. Adults' Addiction and Harm Beliefs About Nicotine and Low Nicotine Cigarettes, Preventive Medicine 96, 94 (2017).

[13] *Id.*

[14] M. Steinberg, et al., Nicotine Risk Misperception Among US Physicians, Journal of General Internal Medicine (2020).

[15] M. Bover Manderski, et al., Persistent Misperceptions About Nicotine Among US Physicians: Results from a Randomized Survey Experiment, International Journal of Environmental Research and Public Health 18(14):7713 (2021).

[16] *Id.*

of respondents to version 1 strongly agreed that nicotine directly contributes to cancer compared to 69.6% of respondents to version 2. The authors concluded that "even after accounting for question version, the proportion of surveyed physicians who believe that nicotine directly contributes to these health outcomes is alarmingly high."[17]

As critically, the public also harbors significant misperceptions about the relative risk between combustible tobacco products and noncombustible alternatives. For example, smokeless tobacco products have been observed to present less risk compared to combustible cigarettes.[18] Yet only approximately 10% of U.S. adults correctly endorse that such products are less harmful than cigarettes.[19] In one study that evaluated risk perceptions of snus products, which have received a modified-risk order,[20] 55% of respondents reported snus to be as harmful as cigarettes with an additional 20% reporting snus to be more harmful.[21]

While data on the potential long-term health risks associated with electronic nicotine delivery systems (ENDS) are not yet available, multiple lines of evidence support that ENDS products are expected to carry far lower individual health risk than combustible cigarettes.[22] Thus, public-health authorities have recognized the potential for ENDS to reduce the significant and established harms of cigarette smoking among adult current users who switch to these products.[23]

A real and glaring hurdle to the harm-reduction potential of ENDS products is the misperception of relative risk between these noncombustible alternatives and their counterpart — combustible cigarettes. For example, based on Wave 3 (2015–16) of the PATH Study, 72.7% of U.S. adults perceive ENDS products to be as harmful or more harmful

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[17] *Id.*

[18] *See* M. Fisher, et al., Smokeless Tobacco Mortality Risks: An Analysis of Two Contemporary Nationally Representative Longitudinal Mortality Studies, Harm Reduction Journal 16:27 (2019); E. Salazar, et al., Modeling Mortality Risk Effects of Cigarettes and Smokeless Tobacco: Results from the National Health Interview Survey Linked Mortality File Data, BMC Public Health 21:1773 (2021).

[19] S. Feirman, et al., Monitoring Harm Perceptions of Smokeless Tobacco Products Among U.S. Adults: Health Information National Trends Survey 2012, 2014, 2015, Addictive Behaviors (2017).

[20] FDA News Release, "FDA Grants First-Ever Modified Risk Orders to Eight Smokeless Tobacco Products (Oct. 22, 2019), available at https://bit.ly/3pbvyWR.

[21] O. Wackowski, et al., Smokers' Perceptions of Risks and Harm from Snus Relative to Cigarettes: A Latent Profile Analysis Study, Addictive Behaviors (2019).

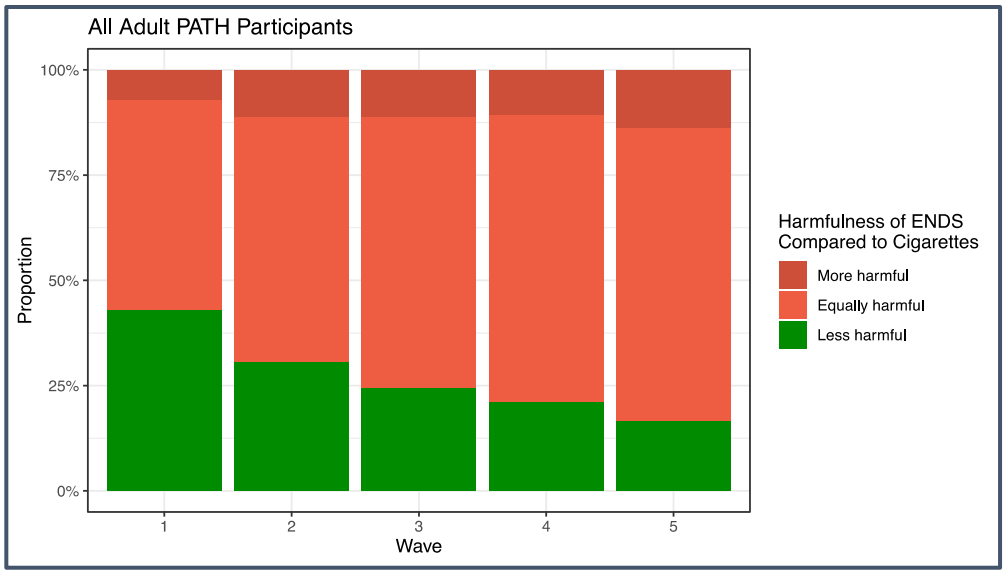
[22] *See, e.g.*, National Academies of Sciences, Engineering, and Medicine, Public Health Consequences of E-cigarettes (2018).

[23] *See, e.g.*, Centers for Disease Control and Prevention, Electronic Cigarettes, https://bit.ly/3vk4tBX; S. Gottlieb, M.D., & M. Zeller, J.D., A Nicotine-Focused Framework for Public Health, New England Journal of Medicine (2017).

than cigarettes.[24] Analysis of the 2017 HINTS survey yielded similar results: 65.5% of U.S. adults perceived ENDS products to be as harmful or more harmful than cigarettes.[25]

These misperceptions on relative risk also have degraded over time. Multiple surveys show a steady increase in the proportion of respondents believing ENDS products to be as harmful or more harmful than cigarettes.[26] Based on JLI's analysis of the PATH Study, 42.9% of adults perceived ENDS products to be less harmful than cigarettes in Wave 1 (2012–2013), declining to 16.7% in Wave 5 (2018–2019). The proportion of adults perceiving ENDS products to be equally as harmful as cigarettes underwent a corresponding increase from 49.9% in Wave 1 to 69.5% in Wave 5. The proportion of adults perceiving ENDS products to be more harmful than cigarettes doubled from 7.2% in Wave 1 to 13.9% in Wave 5.

Figure 1: Risk Perceptions of ENDS Products Relative to Combustible Cigarettes; PATH Study Waves 1–5, All Adults



[24] L. Malt, et al., Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data, Harm Reduction Journal 17:65 (2020).

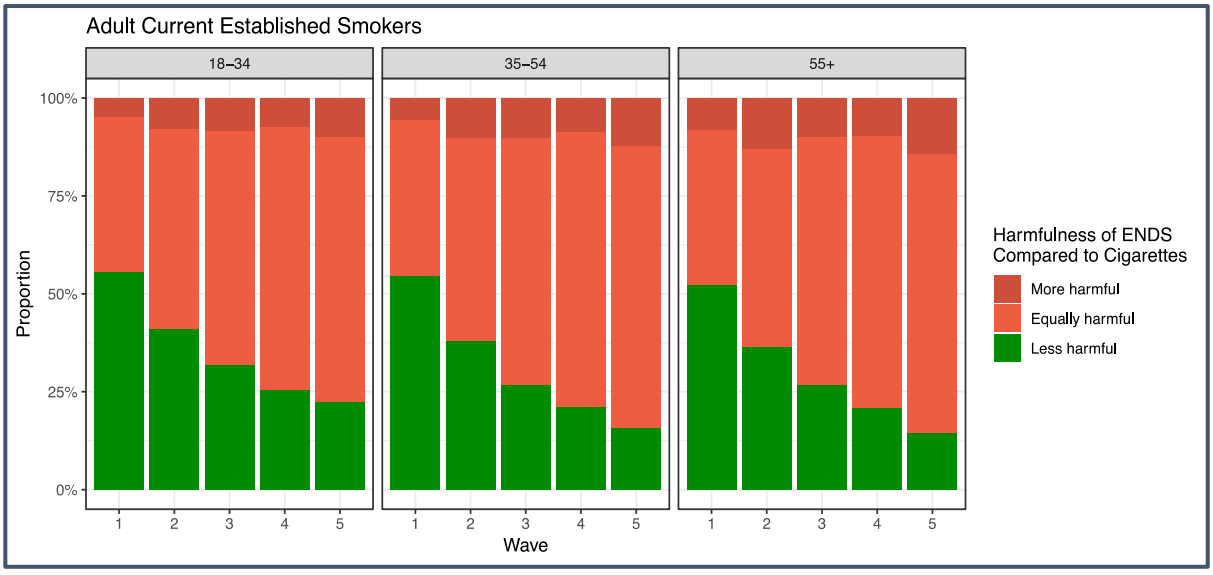
[25] J. Huang, et al., Changing Perceptions of Harm of E-cigarette vs Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, JAMA Network 2(3):e191047 (2019).

[26] *See* A. Nyman, et al., Perceived Comparative Harm of Cigarettes and Electronic Nicotine Delivery Systems, JAMA Network 2(11):e1915680 (2019); A. Persoskie, et al., Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among US Adult Cigarette and E-cigarette Dual Users, Addiction 114, 2197 (2019); L. Malt, et al., Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data, Harm Reduction Journal 17:65 (2020); J. Huang, et al., Changing Perceptions of Harm of E-cigarette vs Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, JAMA Network 2(3):e191047 (2019).

Worse yet, these degrading misperceptions occur among adult smokers, the very group most likely to act on and potentially benefit from accurate perceptions of the relative risk of ENDS products compared to cigarettes.[27] In Wave 1 of the PATH Study, the majority of current established smokers (54.4%) perceived ENDS products to be less harmful than cigarettes, 39.6% perceived ENDS products to be as harmful as cigarettes, and 6.0% perceived ENDS products to be more harmful than cigarettes. By Wave 5, only 17.4% of current established smokers perceived ENDS to less harmful than cigarettes, 70% perceived ENDS products to be as harmful as cigarettes, and 12.3% perceived ENDS products to be more harmful than cigarettes.

Figure 2 below age-stratifies risk perceptions among adult current smokers and shows that risk perceptions have degraded most precipitously among older (35+) smokers. Notably, research shows that adults over the age of 35 are less likely to make a smoking quit attempt and less likely to successfully quit smoking compared to younger adults.[28]

Figure 2: Risk Perceptions of ENDS Products Relative to Combustible Cigarettes; PATH Study, Waves 1–5, Adult Current Established Smokers Stratified by Age



These misperceptions of nicotine and relative risk are significant barriers to realizing FDA's Comprehensive Plan and advancing tobacco harm reduction. By one example, the Agency proposes to increase access to and the use of medicinal nicotine

[27] *See* L. Malt, et al., Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data, Harm Reduction Journal 17:65 (2020); J. Huang, et al., Changing Perceptions of Harm of E-cigarette vs Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, JAMA Network 2(3):e191047 (2019).

[28] *See* K. Messer, et al, Smoking Cessation Rates in the United States: A Comparison of Young Adult and Older Smokers, American Journal of Public Health 98(2):317 (2008).

products for tobacco cessation. Research, however, shows that adult smokers who misperceive medicinal nicotine products to be as harmful as combustible cigarettes are less likely to use these products to support smoking cessation.[29]

The Comprehensive Plan also recognizes the role of scientifically-substantiated, less harmful noncombustible products to reduce the harms of combustible use and seeks to "ensure that it is possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources."[30] Here too misperceptions of the relative risk of noncombustible alternatives to combustible products are barriers. FDA's own analysis of adult smokers and dual users of cigarettes and ENDS products in the PATH Study concludes:

> [T]hose who perceived e-cigarettes as less harmful than cigarettes were more likely to switch to exclusive e-cigarette use, more likely to remain dual users and less likely to switch to exclusive smoking 1 year later. Our findings highlight the concern that perceptions of e-cigarettes as equally or more harmful than cigarettes could potentially deter complete switching to e-cigarettes among some US adult smokers.[31]

But these misperceptions can be addressed and reversed, and the proposed research in the Notice is timely to leverage an increasingly regulated, science-based marketplace for tobacco products. We are at a key inflection point for new, potentially less harmful products, including ENDS, and their harm-reduction potential for adult smokers. At the time of this submission, FDA is completing its rigorous, science-based review of premarket tobacco product applications (PMTAs) for ENDS and other deemed new tobacco products that have been on the market since jurisdiction was asserted. This process — one that is steeped in science and evidence and conducted by career scientists and technical experts — will validate those products that are determined to be appropriate for the protection of public health. That is, as marketing granted orders are issued, the Agency will have independently determined a product is likely to have a net positive effect on the health of the population as a whole.

Once this process is complete, all legally marketed, new tobacco products in the United States will have undergone scientific review and obtained marketing authorization. FDA then will be well positioned to "inform and educate the public, tobacco retailers, and

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[29] *See* S. Shiffman, et al., Perceived Safety and Efficacy of Nicotine Replacement Therapies Among US Smokers and Ex-smokers: Relationship with Use and Compliance, Addiction 103(8):1371 (2008); S. Ferguson, et al., Providing Accurate Safety Information May Increase a Smoker's Willingness to Use Nicotine Replacement Therapy as Part of a Quit Attempt, Addictive Behaviors 36(7):713 (2011).

[30] FDA, Transcript of FDA Media Briefing on Pivotal Public Health Step to Explore Dramatically Reducing Smoking Rates by Lowering Nicotine in Combustible Cigarettes to Minimally or Non-Addictive Levels (Mar. 15, 2018), available at https://bit.ly/3vjsE3z.

[31] A. Persoskie, et al., Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among US Adult Cigarette and E-cigarette Dual Users, Addiction 114, 2197 (2019).

health professionals about the health risks of tobacco use, how to quit using tobacco products, and FDA's role in regulating tobacco," armed with a complete, scientific understanding of new products comprising the market and the extensive regulatory authorities provided to the Agency.

III. FDA'S VOICE CAN PLAY A CRITICAL ROLE TO CORRECT THE MISPERCEPTIONS THAT UNDERMINE THE COMPREHENSIVE PLAN AND TOBACCO HARM REDUCTION

In its 2001 report *The Future of the Public's Health in the 21st Century*, the Institute of Medicine concluded that "[a]ll partners within the public health system should place special emphasis on communication as a critical core competency of public health practice."[32] Given its role in public health and thorough understanding of the regulatory science on tobacco and nicotine products, FDA is uniquely situated to communicate to the public and segments within the population on the role of nicotine and relative risk among products.

First, the public trusts FDA to provide accurate information. One study that included two samples of nationally representative adults and adolescents evaluated public trust in FDA as a provider of information.[33] Among adults who were aware of FDA, 62.5% responded "yes" to the question "In your opinion, does the (CDC or FDA) give trustworthy information to the public?" compared to only 42.9% who expressed trust in the federal government generally.[34]

Second, FDA has unparalleled visibility into the tobacco-product marketplace because of, among other tools, the review of product applications, ingredient disclosure and reporting, submission of health information, facility registration and product listing, inspections of manufacturing sites, and various information collections. Through its review of product submissions for traditional tobacco products (e.g., combustible cigarettes, smokeless tobacco), the Agency has been provided exact design and performance characteristics, detailed ingredient reports, and extensive testing data for levels of harmful and potentially harmful constituents across product types. Today, FDA is gaining even more information about novel tobacco products (e.g., ENDS, oral nicotine-containing products) through the PMTA process, including data on the perceptions and use behaviors associated with these types of products. Meanwhile, the Agency continues to add to its corpus of science and information through the Tobacco Regulatory Science Program in

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[32] Institute of Medicine, Committee on Assuring the Health of the Public in the 21st Century, The Future of the Public's Health in the 21st Century (2002).

[33] S. Kowitt, et al., Awareness and Trust of the FDA and CDC: Results from a National Sample of US Adults and Adolescents, PLoS One 16;12(5):e0177546 (2017).

[34] *Id.*

partnership with NIH,[35] as well as extramural research sponsored by the Tobacco Centers of Regulatory Science.[36]

And third, FDA has dedicated staff tasked with "developing and evaluating the communication of complex scientific and regulatory information" about tobacco products.[37] Through 2017, CTP has funded 113 research projects under the domain of "communication."[38]

As the leading public-health authority and expert in tobacco regulatory science, FDA can appropriately communicate accurate, non-misleading information about the role of nicotine and the risk differential between noncombustible and combustible tobacco products. With the proposed research in the Notice, FDA can strike the appropriate balance to provide the public messaging to discourage tobacco use and promote cessation while correcting, and not reinforcing, existing misperceptions that undermine the Comprehensive Plan and public health.

IV. FDA SHOULD CONSIDER CERTAIN PRINCIPLES WHEN DEVELOPING MESSAGING AND COMMUNICATIONS RELATING TO TOBACCO PRODUCTS TO SUPPORT PUBLIC-HEALTH OBJECTIVES

With the above in mind and as FDA conducts "foundational research informing message development or the formative pretesting of tobacco communication messages and other materials directed at consumers," we offer the following principles for its consideration:[39]

First, individuals are best able to make decisions consistent with their goals when they have the benefit of clear, correct, and comprehensive information. Applied to tobacco products, current users will benefit from accurate, non-misleading information which could have a positive effect on tobacco-use behaviors. The proposed research would aid FDA in providing clear and complete, evidence-based communications and messaging to prevent initiation and promote cessation of tobacco products while encouraging adults, who otherwise would not or cannot quit nicotine consumption, to move down the continuum of risk and reduce the harms of combustible use.

Second, messaging and communications should provide science-based information about the risks of tobacco products and discourage initiation among nonusers, especially

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[35] *See* NIH, Tobacco Regulatory Research Priorities, https://bit.ly/2Z1zi2B.

[36] *See* FDA, Tobacco Centers of Regulatory Science (TCORS), https://bit.ly/3DOyywr.

[37] FDA, Center for Tobacco Products Office of Science, Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights, Fiscal Years 2010–2017, available at https://bit.ly/3BS6cRw.

[38] *Id.*

[39] 86 Fed. Reg. at 51897.

youth, without compounding misperceptions on nicotine and the relative risk of noncombustible products. The public-health benefits of preventing initiation and promoting tobacco cessation are self-evident. Yet lingering misperceptions about nicotine and noncombustible alternatives also impact public health.

Adult smokers who misperceive the risks associated with nicotine are less likely to avail themselves of FDA-approved medicinal nicotine products. And adult smokers who misperceive the relative risk of noncombustible compared to combustible products are less likely to transition and completely switch to potentially less harmful alternatives. Realization of the Comprehensive Plan requires not only that the public be informed about the health effects of tobacco use, but also that relevant population segments understand the role of nicotine in disease causation and the significant differences in risk among tobacco and nicotine products.

Third, the impact of messaging and communications should be tested in both intended and unintended audiences. FDA's proposed research is intended "[t]o ensure that these educational and public information programs have the highest potential to be received, understood, and accepted by those for whom they are intended."[40] But public-health communications, especially from a trusted source such as FDA, has the potential to impact intended and unintended audiences. FDA should test the impacts of proposed educational and public information programs among audiences to mitigate against "dangerous unintended outcomes caused by audiences interpreting messages in a way that was not intended by the drafters."[41]

For example, in its draft guidance on *Modified Risk Tobacco Product Applications*, FDA recommends that manufacturers conduct extensive testing of proposed modified-risk claims among both intended and unintended audiences.[42] Specifically, the draft guidance states that:

> All MRTPAs must contain evidence to show that the advertising and labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.[43]

FDA recognizes that relevant health information about tobacco products, such as modified-risk claims, has the potential to impact the perceptions and behaviors of current users and nonusers and thus requires data demonstrating that proposed messaging is

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[40] *Id.*

[41] *Id.* at 51898.

[42] *See* FDA, Draft Guidance for Industry: Modified Risk Tobacco Product Applications (Mar. 2012).

[43] *Id.* at 20.

appropriately received and understood by the public in general and not just the intended audience. Moreover, the Agency recognizes that product-specific, modified-risk messaging also implicates perceptions and behaviors for all tobacco products; not just the proposed modified-risk product.[44] As FDA conducts the proposed research in the Notice, it should consider the impact of potential public-health messaging and communications on target and non-target audiences, particularly as messaging seeks to clarify the role of nicotine and relative risk among tobacco products.

V. CONCLUSION

JLI supports FDA's proposed research to "collect information related to foundational research informing message development or the formative pretesting of tobacco communication messages and other materials directed at consumers" to support "health messages relating to the control and prevention of disease."[45]

The need for science-based, tobacco-related communications and messaging is clear: Millions of adult current users of tobacco products misperceive the risks associated with nicotine and do not understand the risk differential between the most harmful combustible products and potentially less harmful noncombustible alternatives.

The public-health consequences of these misperceptions are equally stark. Adult smokers who might successfully quit using FDA-approved medicinal nicotine products instead continue to smoke. Likewise, adult smokers who might switch from combustible cigarettes to potentially lower risk noncombustible products instead continue to smoke.

Balance in communications will remain key. On one hand, FDA should continue to focus its messaging to prevent tobacco initiation and encourage tobacco cessation across the population. On the other, particularly for adult current users, the development and dissemination of accurate, non-misleading information on the role of nicotine and relative risk among products is essential to further the Comprehensive Plan and reduce tobacco-related death and disease.

Respectfully submitted,

[44] *See Id.*

[45] 86 Fed. Reg. at 51897.