October 15, 2019

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

Re: Comments on Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, Docket No. FDA-2019-N-3065.

The undersigned public health and medical organizations submit these comments in response to the request for comments on FDA's proposed rule to establish new required health warnings for cigarette packages and advertisements, "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements," 84 Fed. Reg. 42754 (August 16, 2019) (proposed rule).

I. Introduction

It has been over ten years since the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act or Act) required FDA to issue a final rule mandating color graphic health warnings on cigarette packages and ads. In enacting that landmark legislation, Congress determined that the current Surgeon General warnings on the sides of cigarette packages were largely ignored and utterly ineffective in communicating the health hazards of cigarettes to the public. Those warnings remain just as ineffective today. Over 120 countries have adopted graphic health warnings; 81 in the ten years since enactment of the Tobacco Control Act. The evidence is overwhelming that such warnings substantially increase public understanding of the

dangers of smoking.[1] Yet, in the U.S., cigarette packages and advertising today remain devoid of effective health warnings. Given the length of time that the Congressional mandate of graphic health warnings has remained unfulfilled, and the strong support for the proposed warnings in the administrative record, FDA must ensure that a final rule is issued by the March 15, 2020 deadline established by order of the United States District Court for the District of Massachusetts in *Am. Acad. of Pediatrics v. FDA*, No. 1:16-cv-11985-IT, Dkt. No. 56 (March 5, 2019).[2]

There is no question that the graphic warnings in the proposed rule would effectively promote greater public understanding of the negative health consequences of cigarette smoking. The administrative record supporting the proposed rule establishes (1) that the current Surgeon General's warnings on cigarette packs are wholly inadequate because they are not noticed and fail to address many of the health harms of smoking of which the public has little knowledge; (2) research from across the globe demonstrates that large, pictorial health warnings enhance the effectiveness of textual warnings in increasing public understanding of the health harms of smoking; (3) the FDA's own research supporting the development of the proposed textual and graphic elements in the proposed rule strongly supports the conclusion that the proposed warnings will lead to greater public understanding of the health harms of smoking; (4) the proposed rule and supporting justification are responsive to the First Amendment concerns that led the U.S. Court of Appeals, in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012) to strike down the final rule issued by FDA in June, 2011 (the 2011 rule) and remand the matter to the agency; and (5) the various textual and graphic elements in the proposed rule should be considered severable and workable on their own and, should portions of the rule be invalidated by the courts, the implementation of other portions would nevertheless promote greater public understanding of the health harms of smoking.

II. The Dimensions of the Health Harms of Smoking Underscore the Importance of Greater Public Understanding of Those Harms

Tobacco use is the leading cause of preventable death in the United States, killing more than 480,000 Americans each year—more than the total number killed by AIDS, alcohol, motor vehicles, homicide, illegal drugs and suicide combined.[3] Despite tremendous progress in reducing smoking, there are still approximately 34.3 million adult smokers in the United States today, about half of whom will die prematurely as a result of their addiction.[4] Each day, more than 300 children under the age of 18 become regular, daily smokers and almost one-third will

---

[1] *See* WHO Report on the Global Tobacco Epidemic, Geneva: World Health Organization; 2019.

[2] *See also Am. Acad. of Pediatrics, Inc. et al. v. FDA*, 330 F.Supp.3d 657 (2018) (finding FDA had "unlawfully withheld" and "unreasonably delayed" issuance of a final rule mandating graphic health warnings).

[3] U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General* (2014 SG Report), 2014, http://www.surgeongeneral.gov/library/reports/50-years-of-progress/.

[4] Centers for Disease Control and Prevention (CDC), "Tobacco Product Use Among Adults — United States, 2017," *MMWR* 67(44):1221-1232, November 9, 2018. https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6744a2-H.pdf..; HHS, *The Health Consequences of Smoking. A Report of the Surgeon General* (2004 SG Report), 2004, http://www.cdc.gov/tobacco/data_statistics/sgr/2001/index.htm

eventually die from smoking.[5] The 2014 Report of the Surgeon General projected that, if current trends continue, 5.6 million of today's youth will die prematurely from a smoking-related illness.[6]

Cigarette smoke contains over 7,000 chemicals, at least 69 of which are known carcinogens.[7] Smoking impacts nearly every organ of the body; more than 87% of lung cancer deaths, 61% of all pulmonary disease deaths, and 32% of all deaths from coronary heart disease are attributable to smoking and exposure to secondhand smoke.[8] In addition to this staggering toll of premature mortality, millions of Americans suffer from debilitating medical conditions throughout their lives due to smoking. As of 2014, more than 16 million Americans were living with a disease caused by smoking, with 60% of them suffering from chronic obstructive pulmonary disease (COPD).[9]

In 1964, the Surgeon General first documented the harmful effects of smoking in *Smoking and Health: Report of the Advisory Committee of the Surgeon General of the Public Health Servic*e, which summarized the state of the science regarding tobacco use at that time.[10] Since the first Surgeon General's report on smoking and health was published over 50 years ago, more than 20 million Americans have died because of smoking.[11] During this time, new diseases have been linked to smoking and the evidence base on the health consequences of smoking has grown substantially. Yet health warnings on cigarette packs have not changed for nearly 35 years—a missed opportunity to communicate the latest science to the public. Given the substantial health toll of tobacco use, it is difficult to imagine a more compelling governmental interest than to ensure that the public understands the health consequences of smoking. Health warnings on cigarettes are one of the most efficient and effective ways of doing so.

III. The Current Cigarette Warnings Are Wholly Inadequate

A. The Current Cigarette Warnings Are Unnoticed by Smokers

As is persuasively summarized in the proposed rule, the current health warnings on cigarette packs are wholly inadequate because they have been unchanged for nearly 35 years, are small and do not contain a color image.[12] As the FDA notes, the current warnings do not

---

[5] Derived from HHS, *"Results from the 2017 National Survey on Drug Use and Health: Detailed Tables*," https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.pdf); HHS *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General,* Fact Sheet, A13.

[6] HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General* (2014), at 1 (Executive Summary) (2014 SG Report). https://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf.

[7] *See* 2004 SG Report, *supra*, at 3.

[8] *See* 2014 SG Report, *supra*, at 5.

[9] *Id.*

[10] Available at http://profiles.nlm.nih.gov/NN/B/C/X/B/.

[11] *See* 2014 SG Report, *supra*, at 5.

[12] Proposed Rule, 84 Fed. Reg. at 42759-61.

effectively inform the public or promote greater understanding of the negative health effects because they do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking. In the 35 years since the implementation of these warnings, their effect on smokers has drastically weakened, and the current warnings now have virtually no impact in informing the public.[13]

As the FDA describes, the ability of a message to attract and maintain attention is critical to enhance message processing and consequently, learning and understanding.[14] Research indicates that the frequency with which smokers notice, read and think about health warnings lessens over time as smokers become desensitized to the warnings.[15] Further, studies show that the salience of health warnings decreases with repeated exposure and diminishes over time.[16] The Surgeon General concluded in 1994 that empirical studies of "the visibility of cigarette warnings in advertising ... consistently indicate that the Surgeon General's warnings are given little attention or consideration by viewers." [17] The same warnings deemed ineffective by the Surgeon General in 1994 are still in effect 25 years later. These conclusions are further supported by the prestigious Institute of Medicine, which in 1994 found that, "The current warnings are inadequate even when measured against an informed choice standard, but they are woefully deficient when evaluated in terms of proper public health criteria."[18] In 2007, a comprehensive report issued by the Institute of Medicine reiterated this finding, concluding that the current Surgeon General warnings had become "unnoticed and stale" and "failed to convey relevant information in an effective way."[19] Recent research continues to support the conclusion that the current warnings are ineffective. For example, FDA describes research from Wave 4 (2016-2017) of the Population Assessment of Tobacco and Health Study, which found that nearly three-quarters (73.5%) of the U.S. population "never" or "rarely" noticed health warnings on cigarette packs.[20]

---

[13] *Id*. at 42760,
[14] *Id.*
[15] Health Canada. Health Warning Testing: Final Report. Prepared by Environics Research Group, 1999. See also, Informa Market Research Co. Ltd. Focus group research on new health warnings on tobacco packages. 1999; Hammond, D., et al., "Measures to evaluate the effectiveness of tobacco product labeling policies. In: IARC Handbook II: Evaluating the Effectiveness of Population Based Tobacco Control. International Agency for Research on Cancer, 2007.
[16] Institute of Medicine, Ending the Tobacco Epidemic, A Blueprint for the Nation (2007). Ference R, Hammond G, Fong D, Warning Labels, C-3.
[17] HHS, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (1994) https://www.cdc.gov/mmwr/PDF/rr/rr4304.pdf.
[18] Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children*, National Academy of Sciences, 1994.
[19] Institute of Medicine, Ending the Tobacco Epidemic: A Blueprint for the Nation, 2007.
[20] FDA, Center for Tobacco Products. "Memorandum of Summary of Data from Wave 4 of the Population Assessment of Tobacco and Health (PATH) Study." 2019.

B. The Public's Knowledge of the Health Harms of Smoking is Incomplete

Despite the numerous public reports on the risks of smoking, studies show that a large number of smokers have inadequate knowledge of the health effects of smoking.[21] While many smokers are aware that smoking causes lung cancer, knowledge of other smoking-caused illnesses is significantly lower.[22] Further, while some smokers generally know that tobacco use is harmful, they underestimate the severity and magnitude of the health risks and tend to perceive other smokers to be at greater risk for disease than themselves.[23]

While health warnings on cigarette packs have remain unchanged for nearly 35 years, the science base has grown substantially regarding the number of diseases caused by smoking. Even in just the eight years since FDA first issued a final rule on graphic warnings, research has linked additional diseases to smoking. As noted in the proposed rule, the 2014 Surgeon General's Report added eleven diseases causally linked to smoking to the list of 40 other health consequences of smoking and exposure to secondhand smoke that had been previously determined.[24] Public education about the health risks of smoking has largely focused on a small subset of the health consequences of smoking, resulting in low awareness for many of the health consequences of smoking.[25] By focusing on some of the lesser-known health effects, the FDA's proposed warnings will increase the public's knowledge and understanding of the health consequences of smoking.

IV. Research Overwhelmingly Supports the Conclusion that Large, Pictorial Health Warnings Enhance the Effectiveness of Textual Warnings in Increasing Public Understanding of the Health Harms of Smoking

The requirement of large, pictorial warnings is based on the best available science and real-world experience regarding graphic warnings, including best practices from other countries and the recommendations of the World Health Organization (WHO), Institute of Medicine of the National Academy of Sciences, the U.S. Surgeon General and other leading health experts. Health warnings on cigarette packs effectively inform smokers about the health hazards of smoking and are one of the most effective ways to reach smokers because they pair the warning directly with smoking behavior—a pack-a-day smoker could be exposed to the warnings more than 7,000 times per year.[26]

---

[21] Rutten, LJF, et al., "Smoking knowledge and behavior in the United States: Sociodemographic, smoking status, and geographic patterns," *Nicotine & Tobacco Research,* 10(10): 1559-1570, 2008; Proposed Rule, 84 Fed. Reg. At 42760.
[22] Proposed Rule, 84 Fed. Reg. at 42761.
[23] Weinstein, ND, et al., "Smokers' unrealistic optimism about their risk," *Tobacco Control,* 14: 55-59, 2005.
[24] Proposed Rule, 84 Fed. Reg. at 42766.
[25] *Id*.
[26] Hammond, D, et al., "Impact of the graphic Canadian warning labels on adult smoking behavior," *Tobacco Control* 12(4): 391-395, December 2003.

The scientific evidence conclusively shows that graphic health warnings are more effective than text-only warnings at increasing knowledge and public understanding of the health effects of smoking. FDA persuasively summarizes how graphic health warnings increase attention, noticeability, recall, information processing and understanding of warnings.[27] As noted in the proposed rule, "Visual depictions of smoking-related disease in pictorial cigarette warnings help address gaps in public understanding of the negative health consequences of smoking by providing new information beyond what is in the text of the warnings through reinforcing and helping to depict and explain the health effect described in the text."[28] The WHO has concluded that "health warnings on tobacco packages increase smoker's awareness of their risk. Use of pictures with graphic depictions of disease and other negative images has greater impact than words alone."[29] Real world experience from countries that have implemented graphic health warnings on cigarette packs supports these conclusions. Smokers in countries where a warning depicts a particular health hazard of smoking were much more likely to know about that hazard, and smokers who reported noticing warnings were 1.5 to 3.0 times more likely to believe in each health hazard.[30] A study of smokers in Australia, Canada and Mexico found that smokers from countries where graphic warnings contained information about *specific* tobacco-related diseases had higher knowledge of those diseases than smokers in countries that did not have information about those diseases in their graphic warnings.[31]

Pictures especially increase the accessibility of health warnings to people with low levels of literacy.[32] In the U.S., knowledge of the health risks of smoking is even lower among people with lower income and fewer years of education because of lower health literacy and limited access to information about the hazards of smoking.[33] These populations also have higher smoking rates. Among adults 25 and older, 23.1 percent who do not graduate from high school smoke and 36.8 percent with a GED smoke, compared to just 7.1 percent of those with a college education and 4.1 percent of those with a graduate degree. Over 21 percent of adults with a

---

[27] Proposed Rule, 84 Fed. Reg. at 42762-5

[28] *Id.* at 42763.

[29] World Health Organization, report on the global Tobacco epidemic, 2008, at 34-35.

[30] Hammond, D, et al., "Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey," *Tobacco Control* 15(Suppl 3):iii19-iii25, 2006.

[31] Swayampakala, K, et al., "Pictorial health warning label content and smokers' understanding of smoking-related risks—a cross-country comparison," *Health Education Research,* 30(1): 35-45, 2014.

[32] Hammond, D. Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11, February 2009. See also, CRÉATEC + Market Studies. *Effectiveness of Health Warning Messages on Cigarette Packages in Informing Less-literate Smokers, Final Report*. Prepared for Communications Canada, Dec 2003; Millar WJ, Reaching smokers with lower educational attainment. *Health Rep* 1996; 8: 11-9; Siahpush M, et al., "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: Results from the 2002 International Tobacco Control Policy Evaluation Survey," *Tob Control* 15(Suppl III): iii65–iii70, 2006.

[33] See e.g., Siahpush, M, et al., "Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITCS) Four Country Survey," *Tobacco Control,*15 (Suppl III): ii65-ii70, 2006. Rutten, LJF, et al., "Smoking knowledge and behavior in the United States: Sociodemographic, smoking status, and geographic patterns," *Nicotine & Tobacco Research,* 10(10): 1559-1570, 2008.

household income less than $35,000 smoke, compared to 11.8 percent of adults with a household income between $75,000 and $100,000, and 7.6 percent of those with a household income of $100,000 or more.[34] According to research from the International Tobacco Control (ITC) project, "Large, graphic warnings on cigarette packages are an effective means of increasing health knowledge among smokers [and] health warnings may also help to reduce the disparities in health knowledge by providing low-income smokers with regular access to health information."[35] The effectiveness of graphic warnings across the globe reflects their ability to effectively communicate information to diverse populations.

Research also shows that size plays a key role in the effectiveness of graphic warnings—larger graphic health warnings are more effective. Warnings must be large enough to be easily noticed and read, and should be as large as possible.[36] A major multi-country study that compared health warnings in four high-income countries (Australia, Canada, the United Kingdom, and the United States), found that larger, more comprehensive health warnings were more likely to be noticed and rated as effective by smokers.[37] The size of the warning required by the proposed regulation is consistent with the international standard—the WHO Framework Convention on Tobacco Control (FCTC) recommends that the warning size be at least 50% of the pack size. Based on a review of the evidence, the Article 11 Guidelines for the WHO FCTC concluded that,

> "Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text only health warnings, larger warnings with pictures are more likely to be noticed, better communicate health risks… Larger picture warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people."[38]

---

[34] CDC, "Tobacco Product Use Among Adults—United States, 2017," MMWR 67(44): 1225-1232, November 9, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6744a2-H.pdf. See also, Drope J, Liber AC, Cahn Z, Stoklosa M, Kennedy R, Douglas CE, Henson R, Drope J. Who's still smoking? Disparities in adult cigarette smoking prevalence in the United States. CA Cancer J Clin. 2018 Mar;68(2):106-115.https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21444

[35] Hammond, D, et al., "Text and graphic warnings on cigarette packages: Findings from the international tobacco control four country study," *American Journal of Preventive Medicine* 32(3):202-9, 2007.

[36] Hammond, D, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, February 2009, http://www.tobaccolabels.ca/toolkit.

[37] Hammond D et al. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: Findings from the International Tobacco Control (ITC) Four Country Survey. Tob Control. 2006; 15 (Suppl III): iii19–iii25. Hammond D et al. Text and Graphic Warnings on Cigarette Packages: Findings from the International Tobacco Control Four Country Study. Amer J Prev Med. 2007; 32(3):210-217.

[38] World Health Organization Framework Convention on Tobacco Control (WHO FCTC), *Guidelines for implementation of Article 11: Packaging and labelling of tobacco products*, https://www.who.int/fctc/treaty_instruments/adopted/Guidelines_Article_11_English.pdf?ua=1.

Thus, the existing research overwhelmingly supports the conclusion that large, pictorial health warnings enhance the effectiveness of textual warnings in increasing public understanding of the health harms of smoking.

V. FDA's Research Protocol for the Development of the Proposed Textual and Graphic Elements Supports the Conclusion that the Proposed Warnings Will Lead to Greater Public Understanding of the Health Harms of Smoking

The FDA undertook a rigorous, multistep process to develop revised textual and graphic warnings that will have the greatest impact on increasing knowledge and public understanding of the health consequences of smoking. FDA based its selection of health consequences on those that the Surgeon General has determined are causally related to smoking. The Surgeon General's categorization of the strength of causal inference is based on rigorous standards informed by the work of the Institute of Medicine and the International Agency for Research on Cancer.[39]

The FDA's revision of the textual warnings relied on research generated from a large sample including adolescent smokers, adolescents at risk for smoking, and adult smokers, ensuring that the warnings chosen would increase knowledge and understanding among these critical populations. As described in the proposed rule, FDA assessed whether the revised textual warnings provided new information to participants and whether participants reported learning something from the warning statements, as compared with the textual warnings in the Tobacco Control Act.[40] As noted in the proposed rule, "communications science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehensive and learning."[41] The higher rating of many of these new textual warnings as providing new information and greater self-learning indicates that FDA's approach of focusing on the lesser known health effects of smoking will effectively increase public awareness of the health consequences of smoking.

FDA's approach to developing associated graphics to correspond with the revised textual warnings for the second phase of the research protocol was rigorous and based on best practices. The FDA used an iterative, research-based approach, relying on interviews, focus groups and experimental testing to refine and select the photorealistic illustrations in the proposed warnings. FDA's online experimental study with nearly 10,000 adolescent and adult smokers and nonsmokers was an appropriate and efficient method for determining which graphic warnings are most effective. These types of panels are regularly used in consumer market research and are especially appropriate when the primary goal is measuring relative effectiveness of the graphics. Importantly, the two follow-up sessions over the course of two weeks allowed FDA to assess recall and perceptions of the warning over time. The survey measures FDA used to assess understanding, knowledge and recall are validated and well-grounded in research.

---

[39] Proposed Rule, 84 Fed. Reg. at 42766.
[40] Proposed Rule, 84 Fed. Reg. at 42768.
[41] *Id*.

The 13 proposed warnings all showed statistically significant higher levels of providing new information and self-reported learning compared to the current Surgeon General's warnings on cigarette packs. As such, these proposed warnings will achieve the government's interest in increasing understanding of the health risks of cigarette smoking. FDA thus attained its research goals of identifying graphics that "(1) are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the statements on the same health conditions."[42]

We urge FDA to incorporate all thirteen of the proposed warnings in the final rule. Research shows that health warnings need to be rotated regularly with new text and images to avoid overexposure.[43] A larger pool of graphic warnings with regular rotation will help prevent the warnings from becoming stale in a short time. We also encourage FDA to establish a process to periodically review and revamp the warnings to ensure that they remain fresh, effective and strong.

VI. The Proposed Rule Would Not Violate the First Amendment

Since the Supreme Court's decision in *Zauderer v. Office of Disc. Counsel*, 471 U.S. 626 (1985), mandatory disclosures of "purely factual and uncontroversial" information about products and services have been subject to less exacting First Amendment judicial scrutiny than prohibitions of speech. This distinction is grounded in the *Zauderer* Court's observation that "the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides."[44] While restrictions on commercial speech decrease the flow of information to consumers, requiring advertisers to disclose additional facts increases the information available to them. As the *Zauderer* Court concluded, the "constitutionally protected interest in *not* providing any particular factual information" in advertising "is minimal."[45] In evaluating the constitutionality of disclosure requirements, it is therefore appropriate to apply a less stringent test than that applied in evaluating the constitutionality of restrictions on speech. Thus, in *Zauderer*, the Supreme Court rejected the application to such mandatory factual disclosures of the "intermediate scrutiny" test applied to restrictions on commercial speech in *Central Hudson Gas & Elec. Corp. v. Public Serv. Commission of N.Y.*, 447 U.S. 557 (1980).

The disclosures required by the proposed rule also effectively convey undeniably valuable factual information to consumers. Because the warnings satisfy the standards set out in *Zauderer*, they do not violate the First Amendment. Moreover, the disclosures would be

---

[42] *Id*. at 42770
[43] Hammond, D, *Tobacco Labelling & Packaging Toolkit, A Guide to FCTC Article 11*, February 2009.
[44] 471 U.S. at 651.
[45] *Id*. (emphasis in original).

consistent with the First Amendment even under the more demanding standards of *Central Hudson*.

A. The Constitutional Framework of *Zauderer* and *Central Hudson*

Zauderer addressed the validity of an Ohio rule of professional conduct that required attorneys who advertise contingency-fee services to disclose in their advertisements that a losing client might still be responsible for certain litigation fees and costs. The lawyer-plaintiff Zauderer had advertised that he would represent clients on certain kinds of cases for a contingent fee, and stated that "no legal fees" would be owed if the client achieved no recovery. However, because his ad did not disclose that clients may still be liable for litigation costs if they were unsuccessful, he was disciplined by the state Supreme Court and required to disclose the potential that clients might still be subject to payment of costs.[46] Zauderer challenged the rule under which he was disciplined, arguing that it was a restriction of his commercial speech rights that should be subject to the "intermediate scrutiny" test of *Central Hudson*. In *Central Hudson*, the Supreme Court struck down a state regulation banning promotional advertising by a utility, holding that restrictions on non-misleading commercial speech about lawful activity can be upheld under the First Amendment only if they directly advance a substantial government interest and are not more extensive than necessary to serve that interest.[47]

In rejecting the application of the *Central Hudson* test to the mandatory disclosure of the terms of an attorney's provision of legal services, the Court in *Zauderer* invoked the distinction between requiring the disclosure of a fact and requiring the expression of a personal or political opinion. Contrasting the disclosure mandated by the Ohio rule with "compulsions to speak" struck down in non-commercial contexts, the Court noted that the State, in imposing disclosure requirements on Zauderer "has not attempted to 'prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to express by word or act their faith therein.'"[48] Rather, the Ohio disclosure requirement simply required lawyers to include in their advertising "purely factual and uncontroversial information" about the terms under which their services would be rendered.[49] Because the disclosure requirement was "reasonably related to the State's interest in preventing deception of consumers, and was not so "unjustified or unduly burdensome" as to "chill protected commercial speech," the Court held it did not offend the First Amendment.[50]

B. The Warnings in the Proposed Rule Are Constitutional Under the *Zauderer* Standard

In *R.J. Reynolds Tobacco C. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), the majority opinion of the U.S. Court of Appeals for the D.C. Circuit held that the graphic health warnings mandated by the final rule issued by FDA in the 2011 rule violated the First Amendment. The

---

[46] *Id*. at 626.
[47] 447 U.S. 557 (1980).
[48] 471 U.S. at 651 (internal citations omitted).
[49] *Id*.
[50] *Id*.

Court determined that the *Zauderer* test did not apply to the 2011 rule and struck down the warnings under the *Central Hudson* test.[51] In formulating the proposed rule, FDA has carefully considered the First Amendment concerns raised by the *Reynolds* majority and has been responsive to those concerns. Given relevant legal developments since the *Reynolds* decision, and legally significant differences between the 2011 rule and the current proposed rule, the *Zauderer* test is applicable to the proposed rule and the rule satisfies the elements of that test.

As an initial matter, it is important to recognize that the scope of the *Reynolds* decision was limited to the particular graphic health warnings mandated by the 2011 rule, based on the administrative record generated by FDA in support of those specific warnings. The *Reynolds* court did not suggest that graphic health warnings of any kind are inconsistent with the Constitution or that the *Zauderer* standard could not be applied to a different set of graphic warnings, supported by a different administrative record. Indeed, several months before *Reynolds* was decided, the U.S. Court of Appeals for the Sixth Circuit upheld, against a facial challenge, the statutory provision requiring FDA to issue a rule mandating textual and graphic health warnings for cigarettes. In *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509 (6th Cir. 2012), the Court held that the *Zauderer* framework should govern a facial challenge to the statute. The Court determined that the factual accuracy of the textual warnings in the statute was undisputed and that the statutory mandate of graphics to accompany those warnings would be facially unconstitutional only if "a graphic warning cannot convey the negative health consequences of smoking accurately, a position tantamount to concluding that pictures can never be factually accurate, only written statements can be."[52] The Court rejected this position because "[w]e can envision many graphic warnings that would constitute factual disclosures under *Zauderer*."[53] In *Reynolds*, the D.C. Circuit held *Zauderer* inapplicable only to the particular graphic warnings at issue.[54]

The *Reynolds* majority found Zauderer inapplicable to the 2011 warnings for two reasons: (1) the warnings were not designed to correct false or misleading claims made by the advertiser; and (2) the warnings were not "purely factual and uncontroversial."[55]

The *Reynolds* Court first found *Zauderer* applicable only to disclosure requirements that are "reasonably related to the State's interest in preventing deception of consumers."[56] Thus, the Court found *Zauderer* inapplicable to the graphic health warnings for cigarettes because "FDA has not shown that the graphic warnings were designed to correct any false or misleading claims made by cigarette manufacturers in the past," nor that "absent disclosure, consumers would likely be deceived by the Companies' packaging in the future."[57]

---

[51] The dissenting opinion of Judge Rogers found that the Court should have applied Zauderer, rather than Central Hudson and found the 2011 warnings largely consistent with the First Amendment.
[52] 674 F.3d at 559.
[53] *Id.*
[54] 696 F.3d at 1214.
[55] *Id.* at 1216.
[56] *Id.* at 1227.
[57] *Id.* at 1216.

However, the holding in *Reynolds* that *Zauderer* is limited to cases in which the government invokes its interest in correcting deception was expressly overruled by the D.C. Circuit's subsequent ruling in *American Meat Institute v. U.S. Dept. of Agriculture*, 760 F.3d 18 (D.C. Cir. 2014) (AMI). The Court in *AMI* found that *Zauderer* extends beyond correction of deception and applies "more broadly to factual and uncontroversial disclosures required to serve other government interests."[58] Applying *Zauderer*, the *AMI* Court upheld mandatory country-of-origin labeling of meat products, citing government's long-standing interest in enabling consumers to choose American-made products, including for "individual health concerns."[59] In the proposed rule, FDA asserts a substantial interest in "promoting greater public understanding of the negative health consequences of cigarette smoking."[60] As the Sixth Circuit wrote in *Discount Tobacco*, "[t]here can be no doubt that the government has a significant interest in . . . warning the general public about the harms associated with the use of tobacco products."[61] Thus, under current law, the application of *Zauderer* would not be precluded simply because the warnings are not addressed to correcting actual misrepresentations by the advertiser.

In *Reynolds*, the D.C. Circuit also found that the graphic warnings required by the 2011 rule were not the kind of "purely factual and uncontroversial" information to which the *Zauderer* standard applies.[62] Although the Court recognized that "the government can certainly require that consumers be fully informed about the dangers of hazardous products," the Court regarded the specific warnings in the 2011 rule as an effort by the government "to compel a product's manufacturer to convey the state's subjective – and perhaps even ideological – view that consumers should reject the other legal, but disfavored, product . . . ."[63]

In characterizing the warnings in the 2011 rule as "ideological" and not factual, the Court noted several features of the warnings: (1) that FDA tacitly admitted the warnings were primarily intended to evoke an emotional response; indeed, the agency had tested the warnings for their effect in causing viewers to feel "depressed," "discouraged," or "afraid"; (2) that some of the graphics could be misinterpreted to convey messages quite different than the textual warnings they accompanied, such as the image of a man smoking through a tracheotomy hole paired with a warning about addiction; (3) that many of the images did not convey any warning information at all, such as a man wearing a T-shirt with the words "I quit"; and (4) that each of

---

[58] 760 F.3d at 21.
[59] *Id*. at 23.
[60] Proposed Rule, 84 Fed. Reg. at 42755.
[61] 674 F.3d at 519. In holding *Zauderer* not limited to warnings to cure consumer deception, courts have indicated that the asserted governmental interest in compelling disclosures must be "substantial," CTIA-*The Wireless Association v. City of Berkeley*, 928 F.3d 832, 844 (9th Cir. 2019) (CTIA) and more than the satisfaction of mere "consumer curiosity." *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104, 115, n.6 (2nd Cir. 2001) (Sorrell). Surely the government's interest in effectively communicating the health risks of a product that kills almost 500,000 Americans annually is at least as important as a city's interest in communicating the health risks of carrying cell phones in certain ways (*CTIA*), or a state's interest in requiring manufacturers of certain products to disclose that they contain mercury and should be disposed of as hazardous waste (*Sorrell*), or the federal government's interest in requiring meat products to disclose the country in which the animal was born, raised and slaughtered (*AMI*).
[62] 696 F.3d at 1216.
[63] *Id*. at 1212.

the warnings carried the hotline phone number 1-800-QUIT-NOW" with no explanation of the services offered by the hotline. The combination of these features led the Court to conclude that the warnings were not "pure attempts to convey information to consumers," but were rather attempts to "browbeat consumers into quitting."[64]

The graphic warnings in the proposed rule, in contrast, do not cross the line between information and ideology. They communicate messages that convey factual information alone; they express no opinions as to whether smokers should no longer smoke or whether non-smokers should start. They contain no message to "quit smoking" comparable to the 1-800-QUIT-NOW message included on each of the 2011 warnings and every one of the proposed graphics directly relates to the health risk described in its paired textual warning. Each of the photorealistic graphics depicts the health harm described or the effect of that harm on the smoker; none could be misinterpreted as conveying a message unrelated to the textual warning. Moreover, the textual messages are factually accurate, each being supported by a broad consensus of scientific research and a Report of the U.S. Surgeon General.[65]

Nothing in the administrative record supporting the proposed rule suggests that the graphics were intended to evoke an emotional response to smoking instead of illustrating the factual statements made in the text. FDA's review of the extensive scientific literature on graphic health warnings for cigarettes assessed only their impact on increasing consumer understanding of the negative health consequences of smoking by making textual warnings more noticeable, increasing the learning of new information about those consequences and heightening recall of those consequences. FDA concluded from its review that "[i]t is well established in the scientific literature that vivid features (e.g. images) increase noticeability of and attention to textual health risk information (e.g. cigarette health risk information) and increase comprehension, understanding, and recall of health messages."[66] At no point does FDA address research bearing on whether graphic health warnings evoke emotional responses unconnected to information comprehension, understanding and recall or whether they have an impact on the desire to quit or start smoking. This approach is in sharp contrast to the record made to support the 2011 rule, in which FDA described its choice of images in this way: "We have chosen a balanced set of images, *including those that may arouse fear and those that may generate other emotional responses in certain individuals* in order to reach a diverse population of smokers and nonsmokers . . . ."[67]

In addition, the qualitative and quantitative studies performed by FDA were designed to measure whether various possible graphics or text/graphic pairings led to greater consumer understanding of the risks of smoking; at no point did FDA assess whether the tested graphics caused particular emotional responses or had an impact on the participants' desire to quit or initiate smoking. Thus, in FDA's final research study, an on-line survey of 9,760 participants,

---

[64] *Id*. at 1216-17.
[65] *See* supra note 3,5.
[66] 84 Fed. Reg. at 42770.
[67] 76 Fed. Reg. at 36635 (emphasis supplied).

participants in both the control group (shown one of the four current Surgeon General's cigarette warnings) and in the treatment group (shown one of 16 of the new text-image paired warnings), were asked a series of questions assessing outcomes such as whether the warning was new information, whether they learned something from the warning, whether the warnings made them think about the health risks of smoking, whether the warning was perceived to be informative, whether the warning was recalled, etc. FDA included in the proposed rule only the warnings that demonstrated statistically significant improvements over the current Surgeon General's warnings in new information and in self-reported learning, because those were the two outcomes "predictive for the task of identifying which of the cigarette health warnings increase understanding of the negative health consequences of cigarette smoking."[68] The study did not assess the participants' emotional responses to the warnings, nor whether they affected the participants desire to initiate or quit smoking.

Thus, the proposed rule, and the administrative record that supports it, do not support a characterization of the rule as expressing an ideological viewpoint or, indeed, an opinion of any kind.[69] Indeed, some of the graphics chosen by FDA match the examples given by the Sixth Circuit in *Discount Tobacco* of factual disclosures as understood by the Supreme Court in *Zauderer*, including "a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition," or "a picture of drawing of a person suffering from a smoking-related medical condition . . . ."[70] As the Sixth Circuit also noted, although *Zauderer* did not address graphic health warnings, the *Zauderer* opinion itself "eviscerates the argument that a picture or drawing cannot be accurate or factual."[71] In striking down a state rule banning all illustrations in attorney advertising, the *Zauderer* Court wrote that "the use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly. Accordingly, commercial illustrations are entitled to the First Amendment protections afforded verbal commercial speech."[72] For analogous reasons, the graphic health warnings in the proposed rule do not violate the First Amendment because they also function to enhance communication of factual information and, as the *Zauderer* Court determined, companies have

---

[68] 84 Fed. Reg. at 42769.

[69] The non-ideological content of the health warnings in the proposed rule distinguishes them from the mandatory disclosure struck down by the D.C. Circuit in *National Association of Manufacturers v. SEC*, 800 F.3d 518 (2015) (*NAM*). At issue in *NAM* was an SEC rule requiring companies that used certain minerals originating in the Democratic Republic of the Congo to disclose whether they were "conflict free," referring to the war and humanitarian crisis in that country. The Court found *Zauderer* inapplicable to the SEC rule, in part because the companies were required to make the disclosure not in connection with voluntary advertising (as in *Zauderer* and as in the proposed rule), but rather in SEC filings and on their websites. In addition, the Court found that the label "not conflict free" was "hardly factual and non-ideological," but rather "conveys moral responsibility for the Congo war," suggesting that the products "are ethically tainted". Id. at 529 (quoting Court's previous opinion at 748 F.3d at 371.) The "not conflict free" disclosure bears no resemblance to the health warnings in the proposed rule, which simply communicate uncontroversial facts about the dangers of smoking, while expressing no moral judgments about the product or advising consumers not to use the product.

[70] 674 F.3d at 559.

[71] *Id*. at 560.

[72] 471 U.S. at 647.

little cognizable First Amendment interest in limiting the factual information available about their products.

There is little doubt that FDA, through its review of the extensive scientific literature on graphic health warnings for cigarettes, and through the studies it conducted to support the selection of the specific graphic warnings in the proposed rule, has established that the proposed warnings are reasonably related to the government interest in promoting greater public understanding of the health risks of smoking.

Moreover, the proposed warnings do not unduly burden protected speech. The size of the textual/graphic warnings in the proposed rule is mandated by statute to be the top 50 percent of the front and rear panels, and 20 percent of the area at the top of an advertisement. In upholding the statutory mandate of the warnings against First Amendment attack, the Sixth Circuit found that "ample evidence support[s] the size requirements for the new warnings" and "that the remaining portions of their packaging" are sufficient for the companies "to place their brand names, logos or other information."[73] This is not a case, like the sugar-sweetened beverage warning struck down in *American Beverage Association v. City and County of San Francisco*, 916 F.3d 749 (9th Cir. 2019) in which the record contained evidence that a warning one-half the size of the challenged warning would be just as effective. Rather, FDA found that "[t]he scientific literature strongly supports that larger warnings, such as those proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings."[74]

The constitutionality of mandatory disclosures also was recently addressed by the U.S. Supreme Court in *Natl. Inst. of Family and Life Advocates (NIFLA) v. Becerra*, 138 S.Ct. 2361 (2018). The Court struck down a California statute directed at "crisis pregnancy centers" which offer a range of free pregnancy options but clearly aim to discourage women from seeking abortions. Among other mandatory notices, the statute required licensed clinics to post a state-required notice about the availability of California's programs providing low-cost access to family planning services, including abortion. In finding *Zauderer* inapplicable, the Court noted that the required notice was not limited to factual and uncontroversial information related to the services that the clinics provided, but rather required those clinics to disclose information about the availability of abortion services elsewhere.[75] These notices are surely not analogous to the graphic health warnings in the proposed rule, which relate specifically to factual and uncontroversial health harms from use of the products on which the warnings appear. Moreover, as the Ninth Circuit observed in *CTIA*, the compelled statement in *NIFLA* "took sides in a heated political controversy."[76] The same cannot be said for the warnings in the proposed rule. Indeed, the Court in *NIFLA* itself distinguished the mandatory notices at issue in that case from health

[73] *Id.* at 530-31.
[74] 84 Fed. Reg. at 42779.
[75] 138 S.Ct. at 2372.
[76] 928 F.3d at 845.

and safety warnings, stating: "We do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products."[77]

Therefore, the *Zauderer* standard governs the First Amendment analysis of the proposed rule and, under that standard, the proposed rule is consistent with the First Amendment: the proposed warnings are factual and uncontroversial disclosures that are reasonably related to the substantial government interest in increasing understanding of the negative health effects of smoking and they do not unduly burden protected speech.

C. The Warnings in the Proposed Rule Are Constitutional Under the *Central Hudson* Standard

Even under the more stringent *Central Hudson* standard for the First Amendment assessment of restrictions on speech, the proposed rule would not violate the Constitution. Under that standard, the proposed warnings must (1) directly advance a substantial governmental interest and (2) must be no more extensive than necessary to serve that interest. In *Reynolds*, the D.C. Circuit, having found the *Zauderer* test inapplicable to the warnings mandated by the 2011 rule, then applied the *Central Hudson* test and found the rule unconstitutional under that standard.[78] As discussed above, the proposed rule would mandate different warnings supported by a different administrative record. It would be constitutional even under the *Central Hudson* standard.

According to the *Reynolds* court, the 2011 rule was unconstitutional under *Central Hudson* because "[t]he only explicitly asserted interest in either the Proposed or Final rule is an interest in reducing smoking rates," and "FDA has not provided a shred of evidence . . . showing that the graphic warnings will "directly advance" its interest in reducing the number of Americans who smoke."[79] In reaching this conclusion, the court engaged in an extensive discussion of FDA's failure to offer any evidence that graphic warnings on cigarettes have directly caused a material decrease in smoking rates in any of countries where they are required. The court also relied on FDA's Regulatory Impact Analysis which, according to the court, conceded "the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates."[80]

The *Reynolds* opinion noted FDA's assertion of an interest in "effectively communicating health information," but also found that "as FDA concedes, this purported 'interest' describes only the *means* by which FDA is attempting to reduce smoking rates."[81] According to the court, an asserted interest in "effective" communication "is too vague to stand on its own" because FDA had offered no "barometer" for assessing the effectiveness of the graphic warnings other

---

[77] NIFLA, 138 S.Ct. at 2376.
[78] 696 F.3d at 1222.
[79] *Id*. at 1218-9.
[80] *Id*. at 1219-20.
[81] *Id*. at 1221(emphasis in original).

than whether "they encourage current smokers to quit and dissuade would-be smokers from taking up the habit."[82]

In the proposed rule, on the other hand, FDA has clearly and consistently articulated its interest in "promoting greater public understanding of the negative health consequences of smoking"[83] and provided "barometers," in the form of extensive test data, to demonstrate that the warnings accomplish that purpose. FDA has presented that interest, not as as a means to advance the goal of reducing smoking rates, but rather as an entirely legitimate and substantial governmental interest of its own. The government has a substantial interest in ensuring that consumers have accurate factual information about the serious health effects of using products offered to them. Unlike the 2011 rule, the proposed rule has set out several "barometers" to measure the effectiveness of the proposed graphic warnings in promoting understanding of the health harms of smoking and has tested the proposed warnings against those metrics. Thus, as noted above, FDA's final quantitative study evaluated whether the proposed warnings showed statistically significant improvements in the key outcomes of "new information" and "self-reported learning" because those two metrics were, according to the scientific literature, predictive of whether the warnings would promote greater public understanding of the risks of cigarette smoking. There is nothing "vague" about this governmental objective, nor about how the FDA determined that the proposed warnings would directly advance that interest.

Because smoking is the leading cause of preventable death in the United States, and causes 16 million Americans to suffer from debilitating disease in any given year, the government's interest in informing the public about the health risks of smoking is not only "substantial," but vital. Extensive evidence in the administrative record demonstrates that there are significant gaps in the public's knowledge about the health harms of smoking, particularly the harms addressed by the warnings in the proposed rule. Given the indisputable health risks involved, ensuring that consumers have sufficient information to make a fully informed decision to initiate smoking,[84] or to continue smoking, is itself a substantial governmental interest, regardless of how that information ultimately affects their behavior. In evaluating the constitutionality of the statutory mandate for larger, graphic health warnings on cigarettes, the Sixth Circuit found that, even if it could not be shown that such warnings reduce tobacco use, this would be "irrelevant" to the constitutional issue: "What matters in our review of the required warnings is not how many consumers ultimately choose to buy tobacco products, but that the warnings effectively communicate the associated health risks so that consumers possess accurate, factual information when deciding whether to buy tobacco products."[85]

---

[82] *Id.*
[83] See e.g. 84 Fed. Reg. at 42755, 42778.
[84] The need for effective communication of health risks is particularly salient with respect to youth. Not only do 80-90% of smokers initiate smoking before the age of 18, but, as FDA found, the gaps in knowledge about the health risks of smoking are particularly significant for young people. 84 Fed. Reg. at 42761.
[85] *Discount Tobacco*, 674 F.3d at 567.

The administrative record here amply establishes that the proposed warnings will "directly advance" the government's interest in promoting greater public understanding of the health harms of smoking. FDA's qualitative and quantitative consumer research – on potential statements, potential images and potential pairings of statements and images – furnish valid scientific support for the effectiveness of the proposed warnings on public understanding. Moreover, as noted above, the record establishes that larger-size warnings affect consumer awareness much more than smaller warnings. Therefore, the warnings in the proposed rule are not larger than necessary to substantially advance the government's interest in effectively communicating the risks and they do not unduly burden protected speech.

Therefore, the warnings to be mandated by the proposed rule are entirely consistent with the First Amendment, even under the legal standards for restrictions on speech in *Central Hudson*. Under either *Zauderer* or *Central Hudson*, the constitutional deficiencies found by the *Reynolds* Court in the 2011 rule are not present in the warnings and supporting record in the proposed rule.

VII. FDA's Severability Proposal Is Justified and Consistent with Statutory Law

FDA indicates that in accordance with Section 5 of the Tobacco Control Act, the various requirements established by this proposed rule, when finalized, would be considered severable and the individual provisions of this rule would be considered workable on their own.[86]

We agree with the FDA that the individual provisions of the proposed rule are severable and should portions of the proposed rule be invalidated by the courts, the implementation of other portions is justified and consistent with statutory law and would nevertheless promote greater public understanding of the health harms of smoking.

In *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 684 (1987), the Supreme Court explained the severability standard as follows - "Unless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as law." *Alaska Airlines* outlined a two-part test in applying the severability standard. First, a court must determine "whether the statute will function in a *manner* consistent with the intent of Congress." *Id.* at 685. Second, even if the remaining provisions can operate as Congress intended them to, a court must determine if "the balance of the legislation is capable of functioning independently." *Id.* The *Alaska Airlines* Court noted that the inclusion of a severability clause eases the inquiry and "creates a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision…unless there is strong evidence that Congress intended otherwise." *Id.* at 686. Courts addressing the severability of administrative regulations have applied a severability standard similar to the one used in *Alaska Airlines*. *See K-Mart Corp. v. Cartier*, 486 U.S. 281 (1988) (finding that the invalid subsection of the regulation was severable because invalidating the subsection would "not impair the function of the statute as a whole" and because "there was no indication that the regulation

[86] 84 Fed. Reg. at 42785.

would not have been passed but for its inclusion."). Some courts have addressed severability of administrative regulations on the intent prong alone. *See North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008) ("Whether a regulation is severable depends on the issuing agency's intent).

Here, severability of the proposed rule is consistent with both Section 5 of the Tobacco Control Act and congressional intent. The severability clause in Section 5 creates a presumption in favor of severability and suggests that Congress did not intend the validity of FDA's proposed rule to be dependent on the constitutionally problematic provision. Section 5 states that "If any provision of this division, of the amendments made by this division, or of the regulations promulgated under this division (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this division, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible." It is clear that "the regulations promulgated under this division" applies to FDA's proposed rule. Thus, if courts invalidate any provision of the proposed rule, implementing the valid provisions of the rule would be consistent with the intent of Congress.

Further, under Section 5 of the Tobacco Control Act, FDA has the authority to implement the proposed rule "to the fullest extent possible." FDA's implementation of the proposed rule to the fullest extent possible may include, but is not limited to enforcing the proposed rule by implementing warning labels that include 1) revised textual warnings and images that were not struck down; 2) a combination of graphics and textual warnings or revised textual warnings only 3) revised textual warnings only if all the graphic warnings are struck down; or 4) original textual warnings proposed in section 201(a)(1) if all the proposed graphics and revised textual warnings are struck down. A warning label, whether composed of a proposed textual warning alone or whether composed of a textual warning accompanied with graphics is capable of functioning independently even if some or all of the graphic and textual warnings are invalidated. Each valid warning would be complete and capable of being executed independently of what is rejected.

Congress's intent in requiring new warnings was to replace the stale Surgeon General's warnings and to promote greater understanding of the negative health consequences of smoking. Thus, if a court invalidates some of the warnings, Congress would have intended for the valid warnings to be implemented instead of invalidating all the warnings and keeping the stale Surgeon General warnings as the only warnings on cigarette packages. This intent of Congress is reflected in Section 5 of the Tobacco Control Act, which states that the valid provision of any regulation proposed "shall continue to be enforced to the fullest extent possible."

Therefore, severability of the proposed rule would be consistent with Congress's intent to replace the stale 1984 Surgeon's General's warnings and would be consistent with the authority given to FDA to promote greater understanding of the negative health consequences of smoking.

Respectfully submitted,

Action on Smoking & Health
Allergy & Asthma Network
American Academy of Family Physicians
American Academy of Oral and Maxillofacial Pathology
American Academy of Pediatrics
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Physicians
American College of Preventive Medicine
American Dental Association
American Heart Association
American Lung Association
American Medical Association
American Public Health Association
American School Health Association
American Society of Clinical Oncology
Association of Schools and Programs of Public Health
Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Counter Tools
Eta Sigma Gamma – National Health Education Honorary
LUNGevity Foundation
March of Dimes
National Association of County & City Health Officials
National Association of Pediatric Nurse Practitioners
National Association of Social Workers
National Coalition for Cancer Survivorship
National Hispanic Medical Association
National Multiple Sclerosis Society
National Network of Public Health Institutes
Oncology Nursing Society
Prevent Cancer Foundation
Public Health Solutions
Society for Public Health Education
Students Against Destructive Decisions
The Society of Thoracic Surgeons
Truth Initiative
WomenHeart: The National Coalition for Women with Heart Disease