

FDA’s proposed required textual warning label statements and accompanying color images will promote greater public understanding of the negative health consequences of smoking and should be implemented with some improvements

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Thirty-five years after the four currently used text-only warning statements were required on cigarette packages and in cigarette advertisements, nine years after Congress directed FDA to require new cigarette health warnings that would include textual statements and accompanying color images depicting the negative health consequences of smoking, eight years after FDA issued its first final rule which specified nine images to accompany nine textual warning statements, and seven years after a federal court vacated the rule and asked FDA to redesign the warnings, FDA has proposed a final rule¹ (“Proposed Rule”) to establish 12 textual warning statements and 13 accompanying color images. As required by the law, the new cigarette health warnings would occupy the top 50% of the area on the front and rear panels of cigarette packages and at least 20% of the area at the top of cigarette advertisements. Additionally, the rule requires random display and distribution of the required warnings on cigarette packages, quarterly rotations of the warnings in cigarette advertisements.

FDA developed the new cigarette health warnings included in this proposed rule through a science-based, iterative process including extensive qualitative and quantitative consumer research. They are intended to promote greater public understanding of the negative health consequences of cigarette smoking.

FDA proposed² that every cigarette package must include one of the following 12 required textual warning statements, along with one of 13 corresponding color images³:

(1) WARNING: Tobacco smoke can harm your children.

¹ Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, Proposed Rule, 84 FR 42754 (August 16, 2019). Available at: <https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements>

² Proposed final rule, 21 CFR 1141.10. 84 FR 42754 at 42797.

³ Graphic images available here: <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings>

- (2) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- (3) WARNING: Smoking causes age- related macular degeneration, which can lead to blindness.
- (4) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- (5) WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- (6) WARNING: Smoking causes cataracts, which can lead to blindness.
- (7) WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- (8) WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- (9) WARNING: Smoking causes head and neck cancer.
- (10) WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- (11) WARNING: Smoking during pregnancy stunts fetal growth.
- (12) WARNING: Smoking causes COPD, a lung disease that can be fatal.

1. FDA’s proposed health warnings satisfy the D.C. Circuit Court’s requirements

The Federal Cigarette Labeling and Advertising Act (FCLAA)⁴ requires cigarette packages and advertising to include one of four textual warnings. These warnings have not changed since 1984 and are currently used on cigarette packs and advertisements. Section 201 of the Tobacco Control Act⁵ (enacted in June 2009) amends FCLAA to require that one of nine new health warning statements appear on cigarette packages and advertisements, and directs FDA to issue regulation to require color images to accompany each textual statement “depicting the negative health consequences of smoking.” Section 201 also permits FDA to adjust the type size, text, and format of the warnings so that both the color images and the accompanying textual warning statements are clear, conspicuous, and legible and appear within the specified area. Section 202(b) permits FDA to adjust the format, type size, color images, and text of any of the label requirements if these changes would promote greater public understanding of the risks associated with the use of tobacco products. In June 2011, FDA issued a final rule⁶ that specified nine images to accompany the nine textual warnings statements set out in Tobacco Control Act Section 201. The final rule was challenged in federal court, and in August 2012, the U.S. Court of Appeals of the District of Columbia struck down the color images that accompanied the nine

⁴ Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1333.

⁵ Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 21 U.S.C. 387 et seq. (June 22, 2009).

⁶ Required Warnings for Cigarette Packages and Advertisements; Final Rule. 76 FR 36628 (June 22, 2011).

textual warning statements.⁷ The court found⁸ that the color images were designed “to evoke an emotional response” with “inflammatory images and the provocatively-named hotline,” that some of the images “could be misinterpreted by consumers,” and that some of the images did “not convey any warning information at all... (For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words ‘I QUIT’ do not offer any information about the health effects of smoking.)”

As detailed in the preamble to the Proposed Rule, FDA has conducted qualitative and quantitative research since 2013 to address the D.C. Circuit Court’s concerns, develop a careful research plan and rulemaking process, and to ultimately create a new cigarette health warnings rule. ***FDA provided extensive scientific evidence demonstrating that the proposed cigarette health warnings are factual and accurate, advance the substantial government interest in promoting greater public understanding of the negative health consequences of smoking, and are not unduly burdensome.***

The proposed rule is well-conceived and well-supported by FDA’s research. The FDA demonstrates that the proposed text warnings will be understood by the general public, and that they provide information about smoking health effects that are not appreciated or under-appreciated by the public. FDA further demonstrated that the accompanying color images convey information that is both accurate and factual, are unambiguous, and are unlikely to be misinterpreted or misunderstood by consumers. FDA further demonstrated that the new text warnings, paired with the accompanying images, included new information that promotes greater public understanding of the negative health consequences of smoking. The timeline for implementation (5 months after publication of the final rule for cigarette companies to submit their plans to the FDA and 15 months after publication of the final rule to begin implementing the rule) are reasonable, especially, given the very long delay in the time that the FDA took to issue this rule.

2. The proposed health warnings are well-justified because they accurately, factually and effectively promote greater public understanding of the negative health consequences of smoking

As FDA detailed in the preamble to the Proposed Rule and supported with substantial scientific evidence, the current cigarette warnings have not changed in nearly 35 years, are text-only, and are small; therefore, they are woefully inadequate to effectively convey relevant information about the negative health consequences of cigarette smoking. They do not attract attention, are not remembered, and do not prompt thoughts about the risks of smoking. In contrast, health warnings that are not stale, are noticeable, and increase knowledge more effectively promote public understanding of the harms of smoking. Importantly, ***pictorial cigarette warnings increase attention to warning messages, which leads to increased understanding of the negative health consequences of smoking, increase the likelihood that***

⁷ *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep’t of Agric.*, 760 F.3d 18, 22–23 (D.C. Cir. 2014) (en banc).

⁸ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d at 1216 (D.C. Cir. 2012)

consumers will read, recall, and understand the warnings, and can address gaps in public understanding about the consequences.

FDA developed and implemented an extensive science-based, iterative research process for developing new cigarette health warnings that would effectively address the shortcomings of the current warnings and gaps in public understanding, and that would convey factual and accurate information about the negative health consequences of smoking. FDA's describes its science-based approach and supports its conclusions and proposed warnings with more than 200 scientific studies. FDA's testing focused on "new information" and "self-reported learning" (See, for example, Proposed Rule p. 42769 and p.42772), which further demonstrates that the proposed warnings rather were designed to provide new, factual, and accurate information that were most likely to advance FDA's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

3. The proposed color images are appropriate because they convey accurate, factual, and uncontroversial information that help promote greater public understanding of the negative health consequences of smoking

FDA's proposed color images satisfy the D.C. Circuit Court's requirements. As FDA detailed in the preamble to the Proposed Rule and supported with significant scientific evidence, the proposed color images convey information that is both accurate and factual, are unambiguous, and are unlikely to be misinterpreted or misunderstood by consumers. FDA further demonstrated that these color images, when paired with the accompanying textual warnings, included new information that promotes greater public understanding of the negative health consequences of smoking.

The tobacco industry, as they did previously, might object to the use of the proposed images (or, for that matter, any images) because they "evoke an emotional response." However, this objection should not be grounds for preventing the implementation of these warnings. It has been argued⁹ and demonstrated empirically that any information about the actual negative health effects of smoking evokes emotion.¹⁰ However, this does not make the information or images any less factual. A law review article on tobacco warnings and the First Amendment concluded, "Just because the images may be discomfoting or even disturbing to look at does not make them factually inaccurate."¹¹ Likewise, the 6th Circuit Court of Appeals found that, "Facts can disconcert, displease, provoke and emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions."¹² ***The selected text and images in the proposed warnings convey accurate, factual, and uncontroversial information.***

⁹ Tushnet R. More than a Feeling: Emotion and the First Amendment. *Harvard Law Review* 2014;127.

¹⁰ Popova L, Owusu D, Jenson D, *et al.* Factual text and emotional pictures: overcoming a false dichotomy of cigarette warning labels. *Tobacco Control* 2018;27:250-253.

¹¹ Nathan Cortez, Do Graphic Tobacco Warnings Violate the First Amendment, 64 HASTINGS L.J. 1467, 1470 (2013).

¹² *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 569 (6th Cir. 2012)

Indeed, in the brief submitted by the cigarette companies in their appeal to the DC Circuit Court, the companies themselves stated that they “never disputed that graphics may sometimes convey purely factual and uncontroversial information,” and that graphic warnings can be effectively designed to provide information – “including as to risks of dependence or death.”¹³

The FDA has paid special attention to the importance of the concordance between the text and images on attention to and recall of the message, supported by recent health communication research (e.g., Lochbuehler et al., 2018¹⁴). ***The FDA has rigorously tested the images, ensuring that the resulting graphic warning labels meet the standards recommended by research.***

Moreover, there is very good evidence that the implementation of graphic warning labels on cigarette packs will reduce smoking among youth and young adults.

A 2019 systematic review of 28 experimental studies that examined the impact of tobacco-pack graphic warnings on youth and young adults concluded that such warnings are effective at increasing attention, eliciting stronger cognitive and affective reactions, and increasing intentions not to use tobacco products.¹⁵

This includes test studies among American adolescents that suggest that cigarette graphic warning labels will be successful in reducing youth smoking in the United States. Among middle school students, viewing graphic warning label cigarette packs stimulated greater negative affect (i.e., feeling afraid, disturbed, guilty, or scared) and greater risk beliefs about smoking.¹⁶ In a study of adolescents experimenting with smoking, graphic warnings evoked fear, reduced cravings, and increased quitting contemplation.¹⁷ In a brain imaging study, graphic warning labels reduced cravings among adolescent smokers to an even greater extent that measured among adults.¹⁸

¹³ *R.J. Reynolds Tobacco Co. v. FDA*, Brief for Appellees, p. 24, 30 (January 23, 2012).

Available at <https://www.chamberlitigation.com/cases/rj-reynolds-tobacco-company-et-al-v-fda-et-al>

¹⁴ Lochbuehler K, Mercincavage M, Tang KZ, et al. Effect of message congruency on attention and recall in pictorial health warning labels. *Tobacco Control* 2018;27:266-271.

¹⁵ Francis DB, Mason N, Ross JC, Noar SM. Impact of tobacco-pack pictorial warnings on youth and young adults: A systematic review of experimental studies. *Tob Induc Dis*. 2019 May 15;17:41. doi: 10.18332/tid/108614. eCollection 2019. Review.

¹⁶ Skurka C, Byrne S, Davydova J, Kemp D, Safi AG, Avery RJ, Dorf MC, Mathios AD, Niederdeppe J. Testing competing explanations for graphic warning label effects among adult smokers and non-smoking youth. *Soc Sci Med*. 2018 Aug;211:294-303. doi: 10.1016/j.socscimed.2018.06.035. Epub 2018 Jun 25.

¹⁷ Andrews JC, Netemeyer RG, Burton S, Kees J. Effects of plain package branding and graphic health warnings on adolescent smokers in the USA, Spain and France. *Tob Control*. 2016 Dec;25(e2):e120-e126. doi: 10.1136/tobaccocontrol-2015-052583. Epub 2016 Apr 18.

¹⁸ Do KT, Galván A. FDA cigarette warning labels lower craving and elicit frontoinsula activation in adolescent smokers. *Soc Cogn Affect Neurosci*. 2015 Nov;10(11):1484-96. doi: 10.1093/scan/nsv038. Epub 2015 Apr 17.

Studies from countries where cigarette graphic warning labels are already present support graphic warning label effectiveness among youth. In national student surveys before and after the introduction of graphic warning labels in Australia, following warning label introduction, there was widespread awareness and recognition of the labels among adolescents, increased thinking about quitting among adolescents who had already smoked cigarettes, and decreased intentions to smoke cigarettes among youth who had talked about the warning labels.¹⁹ Focus group study of youth in New Zealand, graphic warning labels were linked to greater perceptions of cigarette harms and less social appeal of smoking.²⁰

Even as cigarette smoking has declined in the United States, both among youth and adults, there has been an increase in the use of non-cigarette tobacco products.^{21,22,23} Use of cigars and smokeless tobacco pose multiple significant health risks to Americans, including higher mortality risk overall.^{24,25}

Good evidence suggests that graphic warning labels on non-cigarette products would be similarly effective as graphic warning labels for cigarettes. In a study of rural American male smokeless (oral) tobacco users, graphic warnings garnered more attention and greater recall of health messages than did text-only warnings.²⁶ In a web-based U.S. study, graphic warning

¹⁹ White V, Webster B, Wakefield M. Do graphic health warning labels have an impact on adolescents' smoking-related beliefs and behaviours? *Addiction*. 2008 Sep;103(9):1562-71. doi: 10.1111/j.1360-0443.2008.02294.x.

²⁰ McCool J, Webb L, Cameron LD, Hoek J. Graphic warning labels on plain cigarette packs: will they make a difference to adolescents? *Soc Sci Med*. 2012 Apr;74(8):1269-73. doi: 10.1016/j.socscimed.2011.12.043. Epub 2012 Feb 17.

²¹ Corey CG, King BA, Coleman BN, Delnevo CD, Husten CG, Ambrose BK, Apelberg BJ; Centers for Disease Control and Prevention. Little filtered cigar, cigarillo, and premium cigar smoking among adults--United States, 2012-2013. *MMWR Morb Mortal Wkly Rep*. 2014 Aug 1;63(30):650-4.

²² Johnson AL, Collins LK, Villanti AC, Pearson JL, Niaura RS. Patterns of Nicotine and Tobacco Product Use in Youth and Young Adults in the United States, 2011-2015. *Nicotine Tob Res*. 2018 Aug 14;20(suppl_1):S48-S54. doi: 10.1093/ntr/nty018.

²³ Gentzke AS, Creamer M, Cullen KA, Ambrose BK, Willis G, Jamal A, King BA. Vital Signs: Tobacco Product Use Among Middle and High School Students - United States, 2011-2018. *MMWR Morb Mortal Wkly Rep*. 2019 Feb 15;68(6):157-164. doi: 10.15585/mmwr.mm6806e1.

²⁴ Inoue-Choi M, Shiels MS, McNeel TS, Graubard BI, Hatsukami D, Freedman ND. Contemporary Associations of Exclusive Cigarette, Cigar, Pipe, and Smokeless Tobacco Use With Overall and Cause-Specific Mortality in the United States. *JNCI Cancer Spectr*. 2019 Sep;3(3):pkz036. doi: 10.1093/jncics/pkz036. Epub 2019 May 17.

²⁵ Rostron BL, Corey CG, Gindi RM. Cigar smoking prevalence and morbidity among US adults, 2000-2015. *Prev Med Rep*. 2019 Feb 11;14:100821. doi: 10.1016/j.pmedr.2019.100821. eCollection 2019 Jun.

²⁶ Klein EG, Quisenberry AJ, Shoben AB, Cooper S, Ferketich AK, Berman M, Peters E, Wewers ME. Health Warning Labels for Smokeless Tobacco: The Impact of Graphic Images on

labels on smokeless tobacco packs were associated with more consideration of health risks, perceived as more attention-grabbing, and less likely to want to be seen using by peers when compared to a text-only warning.²⁷ In India and Bangladesh, graphic warning labels for smokeless tobacco were similarly associated with greater perceived effectiveness versus text-only or symbol-only warnings.²⁸

The implementation of graphic warning labels on cigarette packages and advertisements is a sensible policy that will save lives. However, failing to implement similar graphic warning labels on deadly non-cigarette tobacco products, such as cigars and smokeless tobacco, is a missed opportunity to protect the health of Americans.

FDA should implement graphic warning labels all tobacco products rather than just cigarettes, including, but not limited to, smokeless (oral) tobacco, little cigars, premium cigars, hookah, e-cigarettes, and heated tobacco products (e.g., IQOS).

4. FDA should include in the final rule a provision that requires implementing the textual warning statements in the event that a court were to invalidate the images

The FDA proposed that if any part of the proposed rule (e.g., certain images, or even all images) were invalidated by a court, the rest of the rule would go into effect. For example, even if all images were struck down in court, the rule would require displaying only the new text warnings. This provision is reasonable and will work well as an interim measure. In our own research, we found that both large (covering 50% of the pack) pictorial and large textual warnings performed better in correcting smokers' misperceptions about their longevity than the current text-only warnings.²⁹ ***This proposal appropriately applies the severability provision in Section 5 of the Tobacco Control Act and should be included in the final rule.***

Tobacco companies' internal research on improving the prominence of pack elements suggests that health warning labels using black lettering on a contrasting yellow background would most effectively seize and hold consumers' attention and signal the danger of cigarettes

Attention, Recall, and Craving. *Nicotine Tob Res.* 2017 Oct 1;19(10):1172-1177. doi: 10.1093/ntr/ntx021.

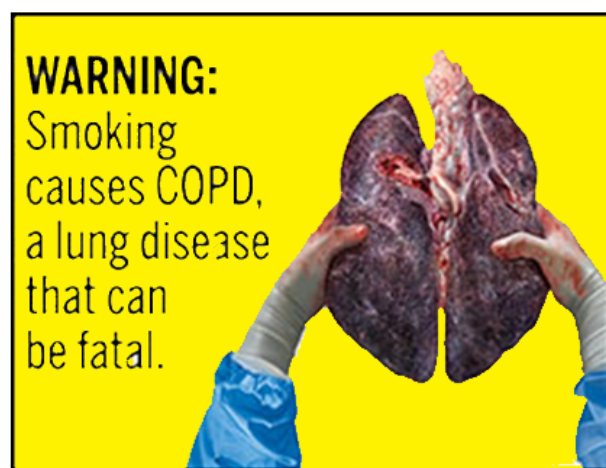
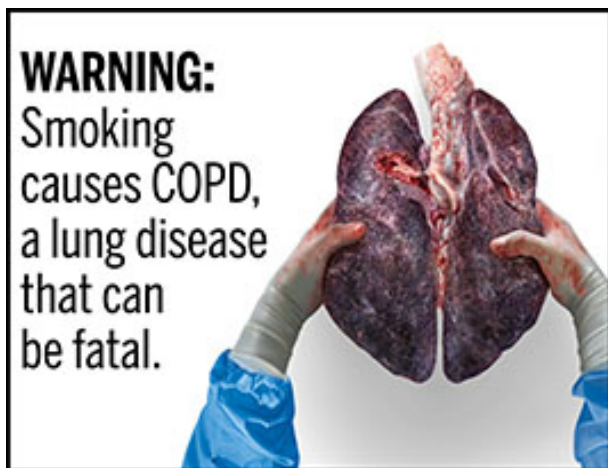
²⁷ Adkison SE, Bansal-Travers M, Smith DM, O'Connor RJ, Hyland AJ. Impact of smokeless tobacco packaging on perceptions and beliefs among youth, young adults, and adults in the U.S: findings from an internet-based cross-sectional survey. *Harm Reduct J.* 2014 Jan 17;11:2. doi: 10.1186/1477-7517-11-2.

²⁸ Mutti S, Reid JL, Gupta PC, Pednekar MS, Dhumal G, Nargis N, Hussain AG, Hammond D. Perceived effectiveness of text and pictorial health warnings for smokeless tobacco packages in Navi Mumbai, India, and Dhaka, Bangladesh: findings from an experimental study. *Tob Control.* 2016 Jul;25(4):437-43. doi: 10.1136/tobaccocontrol-2015-052315. Epub 2015 Jul 22.

²⁹ Popova L, Thrul J, Glantz SA. Effects of Large Cigarette Warning Labels on Smokers' Expected Longevity. *American Journal of Health Behavior* 2018;42(2):85-92.

*and other tobacco products.*³⁰ Experts on how colors are used in communication, such as Carlton Wagner (whose research was relied upon by the tobacco companies when they designed their packs), have found that yellow is the most noticeable color, and thus yellow is used on packages to shout out messages like “new and improved” or “free offer!” The combination of black on yellow is “found in nature (and used by humans) ... to notify or warn you that you should notice something for your own good: “stinging bees are yellow and black; so are many road signs.”³¹ For this reason, Wagner advised package designers to “take a lesson from nature, and use [yellow] as an indicator to call quick attention to something.”³²

Whether or not the textual warnings are accompanied by color graphics, by simply changing the background of the text warnings to the same yellow used on highway warning signs (like a school zone warning sign; see comparison below), the FDA would go far to increase their visibility and strengthen their effectiveness. Significantly, the color itself would clearly transmit the fact that it was a “warning.” FDA should require a bright yellow background on all warning labels.



5. FDA appropriately designed the warnings and graphic images for low literacy people and non-English speakers

While the national smoking rate has been continuously decreasing thanks to various tobacco control measures, some subgroups show high smoking rates: for example, in California, 22.8% of Vietnamese males and 27.3% of Korean males are current smokers,³³ up to two times

³⁰ Lempert LK, Glantz SA, Implications of Tobacco Industry Research on Packaging Colors for Designing Health Warning Labels, *Nicotine & Tobacco Research*, Volume 18, Issue 9, September 2016, Pages 1910–1914, <https://doi.org/10.1093/ntr/ntw127>

³¹ <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=qnmj0074>

³² <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=rnmj0074>

³³ California Health Interview Survey. UCLA Center for Health Policy Research. 2017; <http://healthpolicy.ucla.edu/Pages/AskCHIS.aspx>.

the national and state average. Moreover, while the nation overall is witnessing a steady and significant decrease in smoking rates, smoking rates among these Asian American subgroups has remained high.³⁴

Compared to the current text-only warning labels, graphic warning labels provide the possibility that they will be understood by those who have low literacy or limited English proficiency. This is important given the fact that among some immigrant populations, low English proficiency is associated with greater smoking prevalence (e.g., older Asian males³⁵, who show greater smoking prevalence than the US in general). As a result, ***the proposed warning labels will contribute to not only enhancing the public understanding of the negative health consequences of the smoking, but also to mitigating the tobacco-related health disparities, especially among Asian males and other groups with low English proficiency.***

6. FDA’s proposed health warnings do not violate the First Amendment

In March 2012, the U.S. Court of Appeals for the Sixth Circuit upheld the Tobacco Control Act’s requirement for graphic warnings, finding that the law did not violate the First Amendment. The Sixth Circuit found that the graphic warnings “are reasonably related to the government’s interest in preventing consumer deception and are therefore constitutional.”³⁶ In a separate case, the U.S. Court of Appeals for the D.C. Circuit found that the *specific images* proposed by the FDA did not address the law’s underlying requirement.³⁷ FDA demonstrated in the Proposed Rule that the specific new images it proposed would pass muster under the D.C. Circuit’s findings.

The Supreme Court has interpreted First Amendment protections for commercial speech less stringently than for political speech, and has determined that the government may compel commercial disclosures if there is a “rational basis” for those disclosures. This means that the FDA may require warning labels on cigarette packages and in cigarette advertising so long as the requirement is justified by a reasonable government interest and does not unduly burden protected speech.³⁸ As the FDA demonstrates in great detail in the preamble to the Proposed

³⁴ Asian Pacific Partners for Empowerment, Advocacy & Leadership. Tobacco Use in Asian American Communities. 2013.

³⁵ Tang, H., Shimizu, R. and Chen, M. S. (2005), English language proficiency and smoking prevalence among California's Asian Americans. *Cancer*, 104: 2982-2988. doi:10.1002/cncr.21523; Ning An, Susan D. Cochran, Vickie M. Mays, William J. McCarthy, Influence of American Acculturation on Cigarette Smoking Behaviors Among Asian American Subpopulations in California, *Nicotine & Tobacco Research*, Volume 10, Issue 4, April 2008, Pages 579–587, <https://doi.org/10.1080/14622200801979126>

³⁶ *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509 (6th Cir. 2012).

³⁷ *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep’t of Agric.*, 760 F.3d 18, 22–23 (D.C. Cir. 2014) (en banc).

³⁸ *Zauderer v. Office of Disciplinary Counsel; Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018).

Rule, the proposed warnings are justified by the government’s interest in promoting greater public understanding of the negative health consequences of cigarette smoking, and are not unduly burdensome because tobacco manufacturers can convey other information it chooses in the remaining space available on cigarette packages and advertisements. In upholding the Tobacco Control Act’s health warning requirements, the Sixth Circuit concluded that “there 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.”³⁹

Under the “substantial interest” test for commercial speech, the FDA can regulate speech if the regulation advances a “substantial government interest” and the regulation is no more extensive than necessary.⁴⁰ ***Even under this more rigorous test, the FDA provided significant evidence in the Proposed Rule that the government’s interest in informing the public and correcting misperceptions about the risks of cigarette smoking is substantial and the Proposed Rule requiring graphic images accompanying text warnings is not more extensive than necessary.***

The proposed warnings are not unduly burdensome. The proposed warnings will occupy 50% of the front and back surface of the cigarette pack. This is much smaller compared to the warnings in other countries. For example, plain packaging in Australia and other countries where the brand’s logos are not allowed to be used and the pictorial warning covers 80% of the pack. In Canada, health warnings were required to cover 50% of the front and back of cigarette packages from 2001 to 2011, and beginning in 2012, the size was increased to cover 75% of the front and back of packages.⁴¹ The size is appropriate – GWLs covering smaller area of the pack (such as 30%) would be less effective, as past research showed.⁴² The Sixth Circuit found that the warning requirement for cigarettes is not unduly burdensome because a manufacturer has the ability to convey other information of its choosing in the remaining space available.⁴³

7. In addition to the 12 proposed text warnings and 13 accompanying graphic images, the FDA should add a warning about the effects of secondhand smoke on cardiovascular disease

The FDA proposes a warning that secondhand smoke can harm children (“Tobacco smoke can harm your children”) and damages lungs (“Tobacco smoke causes fatal lung disease

³⁹ *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 519 (6th Cir. 2012).

⁴⁰ *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557 (1980)

⁴¹ Campaign for Tobacco-Free Kids, *Global Issues: Warning Labels*. Updated August 15, 2019. Available at <https://www.tobaccofreekids.org/what-we-do/global/warning-labels>

⁴² Skurka C, Kemp D, Davydova J, Thrasher JF, Byrne S, Safi AG, Avery RJ, Dorf MC, Mathios AD, Scolere L, Niederdeppe J. Effects of 30% and 50% cigarette pack graphic warning labels on visual attention, negative affect, quit intentions, and smoking susceptibility among disadvantaged populations in the United States. *Nicotine and Tobacco Research*. 2017 Nov 4;20(7):859-66. Skurka C, Kalaji M, Dorf MC, Kemp D, Safi AG, Byrne S, Mathios AD, Avery RJ, Niederdeppe J. Independent or synergistic? Effects of varying size and using pictorial images in tobacco health warning labels. *Drug and alcohol dependence*. 2019 May 1;198:87-94.

⁴³ *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d at 530-31.

in nonsmokers”). These are important and appropriate warnings, but, of the estimated 2,457,000 deaths attributed to secondhand between 1965 and 2014 by the Surgeon General⁴⁴ 2,194,000 (89%) were due to coronary heart disease compared to 263,000 for lung cancer. As discussed in the proposed rule, relatively few people appreciate the link between active smoking and heart disease; it is likely that even fewer appreciate the link between secondhand smoke and heart disease, despite the fact that secondhand smoke has been identified by the Surgeon General and others as a *cause* of myocardial infarction.⁴⁵

Therefore, FDA should add the following warning, paralleling the proposed heart disease warning (“WARNING: Smoking can cause heart disease and strokes by clogging arteries.”):

WARNING: Secondhand smoke can cause heart disease and strokes by clogging arteries.

The same graphic image currently paired with the active smoking message could be used. If the FDA does not want to add an additional message, the currently proposed warning for heart disease should be replaced with the message proposed above because the term “smoke” can apply to both active and passive smoking.

8. In addition to the 12 proposed text warnings and 13 accompanying graphic images, the FDA should add a warning about active and passive smoking and breast cancer

In 2005 the California Environmental Protection Agency, as part of evaluating secondhand smoke as a “toxic air contaminant” under California law, determined that secondhand smoke was a *cause* of breast cancer in younger, primarily premenopausal women.⁴⁶ Cal EPA concluded after an extensive peer review process that “the weight of the evidence (including toxicology of tobacco smoke constituents, epidemiological studies, and breast biology) *is* consistent with a causal association between [secondhand smoke] exposure and breast cancer in younger, primarily premenopausal women.”⁴⁶

⁴⁴ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, p. 676. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available at https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm

⁴⁵ U.S. Department of Health and Human Services, Office on Smoking and Health. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Atlanta, GA. 2006. Available at <https://www.ncbi.nlm.nih.gov/books/NBK44324/>

⁴⁶ California Environmental Protection Agency, Proposed Identification of Environmental Tobacco Smoke as A Toxic Air Contaminant, p. 7-119. Available at <https://oehha.ca.gov/media/downloads/crnrr/app3partb2005.pdf> California Office of Environmental Health Hazard Assessment, Health Effects of Exposure to Environmental Tobacco Smoke: Final Report. Sept. 1, 2005. Available at <https://oehha.ca.gov/air/report/health-effects-exposure-environmental-tobacco-smoke-final-report>.

The 2006 Surgeon General report⁴⁷ identified essentially the same epidemiological risks, but only considered the evidence “suggestive but not sufficient to infer a causal relationship,” largely because the Surgeon General did not consider the toxicological evidence^{47, 48} together with the epidemiological evidence, which CalEPA did. Since then, the evidence for both passive and active smoking has continued to accumulate,⁴⁹ ***By 2014 there were 12 peer reviewed large cohort studies that consistently demonstrate a dose-response relationship with smoking before first birth and increased breast cancer risk.***

The fact that the Surgeon General has not revisited the breast cancer issue in the 13 years since the 2006 Surgeon General report should not prevent FDA from warning women that smoking increases the risk of breast cancer.

Therefore, FDA should add the following text warning, together with an appropriate graphic image:

WARNING: Smoking can cause breast cancer, especially in younger women.

If the FDA is not willing to rely on the CalEPA and subsequent evidence, the FDA could use more tentative language consistent with the 13-year-old 2006 Surgeon General report and still educate women about the risks of passive and active smoking:

WARNING: Smoking may cause breast cancer, especially in younger women.

9. FDA’s use of a break-even analysis in the regulatory impact assessment (RIA) is appropriate; the per pack benefit of the proposed graphic warnings will easily exceed one-cent (1¢) per pack

While the FDA correctly states that it is difficult to quantitatively estimate the economic benefits, Max and colleagues⁵⁰ found that the cost of smoking in California in 2009 was \$18.06 per pack including \$9.83 per pack for healthcare costs alone (\$19.22 and \$10.46 in 2019 dollars). This estimate makes it clear that ***the benefits of graphic warnings that reduce smoking prevalence exceed the break-even level of \$0.01 per pack by a factor of by at least 1000-2000 .***

⁴⁷ U.S. Department of Health and Human Services, Office on Smoking and Health. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Atlanta, GA. 2006. Available at <https://www.ncbi.nlm.nih.gov/books/NBK44324/>

⁴⁸ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available at https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm

⁴⁹ Glantz SA, Johnson KC. The surgeon general report on smoking and health 50 years later: breast cancer and the cost of increasing caution. *Cancer Epidemiol Biomarkers Prev.* 2014 Jan;23(1):37-46. doi: 10.1158/1055-9965.EPI-13-1081

⁵⁰ Max W, Sung H-Y, Shi Y, Stark B. The cost of smoking in California. *Nicotine Tob Res.* 2016;18(5):1222-1229.

Additionally, states and localities will benefit from the proposed warnings through reduced medical costs for treating smoking-caused illnesses.

The RIA notes that “In the event there is a decline in cigarette smoking, sectors affiliated with tobacco and tobacco products could lose sales revenues, and governments could lose tax revenues.” As noted above, however, the medical costs associated with every pack of cigarettes far exceed the tax revenues collected by states through cigarette taxes. In California, for example, the total cost of smoking per pack of \$18.06 in 2009 far exceeded the excise tax revenues per pack that year of \$0.87 per pack.⁵⁰ California voters increased the excise tax to \$2.87 per pack as of April 1, 2017, but this is still far less than the healthcare cost per pack of \$9.83 and the total cost per pack of \$18.06 which also includes lost productivity from illness and premature mortality. Also, as the RIA notes, people who reduce or stop smoking (or never start) will still spend the money they would have spent on cigarettes, so this money will still remain in the economy.

While the RIA shows that the proposed rule will unquestionably have substantial net positive economic effects, the fact that Congress mandated graphic warning labels makes the RIA moot.

As the FDA’s sensitivity analysis shows, changes in the number of warnings or speed of implementation will have little effect on costs to industry, so the issues of agency discretion will have little impact on the overall cost. Even so, this is not a rule that was developed at the discretion of the agency, so much of the RIA justification for the need for the rule is irrelevant because Congress ordered the FDA to issue a rule mandating graphic warning labels, and a federal court ordered FDA to issue a final rule requiring graphic warnings by March 2020.⁵¹

10. The implementation schedule proposed by FDA is reasonable and should be maintained

The timeline for implementation (5 months after publication of the final rule for cigarette companies to submit their plans to the FDA and 15 months after publication of the final rule to begin implementing the rule) is reasonable, especially, given the very long delay in the time that the FDA took to issue this rule.

Nevertheless, based on experience in the US and throughout the world, the cigarette companies are likely to argue that the proposed implementation schedule is unreasonably fast. The FDA should reject this argument for the following reasons:

- The cigarette companies have been on notice that graphic warnings were coming for at least 10 years, since Congress mandated them in the 2009 Family Smoking Prevention and Tobacco Control Act.

⁵¹ *American Academy of Pediatrics et al. v. United States Food and Drug Administration*, Memorandum and Order Granting Injunctive Relief, March 5, 2019. Civil Action No. 1:16-cv-11985-IT

- The cigarette companies (or their international counterparts) have implemented graphic warning labels in at least 120 countries,⁵² beginning with Canada in 2001, so they know how to do it.
- The public has been deprived of the benefits of graphic warning labels for almost a decade due to the FDA's slow response in proposing this rule; further delay will mean more youth starting to smoke and fewer smokers quitting.

Conclusion

The FDA's proposed final rule for 12 new textual health warnings and 13 new accompanying color graphics for cigarette packs and advertising should be implemented for the following reasons:

- The proposed health warnings and color images were developed using a rigorous science-based, iterative process including extensive qualitative and quantitative consumer research.
- The proposed health warnings will effectively promote greater public understanding of the negative health consequences of cigarette smoking.
- Implementation of graphic warning labels on cigarette packs will likely reduce smoking among youth and young adults.
- The proposed health warnings are accurate, factual, unambiguous, and uncontroversial.
- The proposed health warnings are not unduly burdensome.
- The proposed health warnings do not violate the First Amendment.
- FDA appropriately designed the warnings and images for low literacy people and non-English speakers.
- The proposed rule will have substantial net positive economic benefits.
- The implementation schedule proposed by FDA is reasonable.
- The rule is long overdue, and further delay will mean more youth will start smoking and fewer smokers will quit.

Further, FDA should require the following additional warnings, along with accompanying color images:

- **WARNING: Secondhand smoke can cause heart disease and strokes by clogging arteries.**
- **WARNING: Smoking can cause breast cancer, especially in younger women.**

Finally, FDA should begin the process of requiring color images on all tobacco products, including little cigars and smokeless (oral) tobacco.

⁵² Campaign for Tobacco-Free Kids, Global Issues: Warning Labels. Updated August 15, 2019. Available at <https://www.tobaccofreekids.org/what-we-do/global/warning-labels>