



October 15, 2019

Commissioner Norman Sharpless M.D.
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Required Warnings for Cigarette Packages and Advertisements

Docket No. FDA-2019-N-3065

Dear Commissioner Sharpless:

The Public Health Law Center and our partners are pleased to submit these comments to the U.S. Food and Drug Administration (FDA) regarding the establishment of graphic warning labels (GWL) for cigarette packages and advertisements. The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies.¹ For twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. This comment is joined by Micah Berman, JD, from Ohio State University, Elizabeth Klein, PhD, from Ohio State University, and Ellen Peters, PhD, from the University of Oregon. These three researchers join the comment and its contents as individuals and not on behalf of their affiliated organizations.

This comment will focus on the evidence base that supports requiring GWL on tobacco product packaging and advertisements. This evidence base includes

¹ The Public Health Law Center's commercial tobacco control program operates as part of a national network of nonprofit legal centers working to protect the public from the devastating health consequences of tobacco use. The Center's affiliated legal organizations include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at the University of Michigan, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

information on how this policy increases information retention, changes attitudes, and ultimately changes behavior. While the FDA's proposed rule emphasizes that the purpose behind the establishment of GWL is to educate users about the health outcomes of lesser-known tobacco-caused diseases, research demonstrates that these new warning labels will, at the same time, increase tobacco cessation and likely decrease initiation in the U.S. and thereby secure tremendous public health benefits. This comment will outline some of those benefits in addition to those related to increasing knowledge of the health consequences of smoking.

The proposed rule shows that the FDA has examined the implementation of GWL carefully and has considered ways in which the labels can be utilized to maximize the public health benefits. Even so, there are a few small changes that the FDA could implement that would provide even greater protection to public health. This comment will identify such changes.

Finally, this comment will outline the significant changes to the legal landscape that have occurred since the FDA's last attempt to implement GWL for cigarette packages and advertisements. Given the litigious nature of cigarette manufacturers and the fact that government regulation of speech increases the specter of litigation, it is particularly important that the FDA provide adequate justification of its action in the final rule and that the government rigorously defend the inevitable legal challenge.

I. The Growing Evidence Base

The FDA has explained that the governmental interest supporting the current proposed rule is "promoting greater public understanding of the negative health consequences of cigarette smoking." The FDA provides a plethora of evidence to support its assertion that the proposed graphic warnings are informative to the viewer, and this information alone should be sufficient for the GWL to withstand a First Amendment challenge. Nonetheless, it is possible that a court would still consider evidence submitted regarding the benefits of graphic warnings beyond those that are purely informational. Because of this and because the evidence base is so strong regarding the overall benefit of graphic warnings to public health, this comment focuses on summarizing and documenting the evidence base as it has grown since the previous proposed rule and legal challenges.

In the legal challenge to the previously proposed GWL, the court struck down the final rule partially because the court found a lack of "direct" evidence supporting the FDA's assertion that GWL would impact smoking cessation.² While in our view the

² Another primary reason for striking down the previously proposed rule was related to misconstruing the available evidence on the emotional aspect of GWL, finding that evoking emotion was contrary to providing factual information and an attempt to "brow-beat" consumers into changing their smoking habits. However, research demonstrates that emotions and affect are an

court misconstrued the available evidence,³ more evidence has emerged since that legal challenge and is summarized here. The body of available evidence on GWL and smoking rates can be thought of as a causal chain – the GWL provide information that sets off a chain reaction that results in the intention to quit, which leads to more attempts at quitting, and, finally, increased cessation at a population level.

Much of the current evidence base describing how GWL increase information is well-summarized in a 2016 meta-analysis by Seth Noar and colleagues.⁴ Their research, which pools data from 37 studies across 16 countries through the year 2013, evaluates how GWL influenced 17 different cognitive and emotional variables in viewers.⁵ Of those 17 variables, 12 “exhibited statistically significant effects . . . favouring pictorial warnings.”⁶ Noar and colleagues concluded that, “[c]ompared with text warnings, pictorial warnings . . . more effectively increased intentions to not start smoking and to quit smoking.”⁷

important part of the cognitive pathways that lead to decision-making and behavior change. Far from being misinformative, emotion-evoking GWL enhance decision-making by enhancing risk perceptions, motivating quitting behaviors, and increasing scrutiny of risks. A decision-maker needs both deliberative thinking and affective thinking to process information. Psychological theory and supporting experimental evidence support that GWL are more likely to be remembered and are given greater consideration by the viewer. *See* Ellen Peters et al., *Emotion in the Law and the Lab: The Case of Graphic Cigarette Warnings*, 2 TOBACCO REG. SCI. 404-413 (2017). This bears true in an experimental setting as well, Lucy Popova et al. used an online survey of 1,838 US adults both cigarette users and non-users exposed to both GWL and text-only warnings. They found that participants did not believe that GWL were less factual than text-only warnings. Lucy Popova et al., *Factual Text and Emotional Pictures: Overcoming a False Dichotomy of cigarette Warning Labels*, 27 TOBACCO CONTROL 250-253 (2018).

³ *See, e.g.*, Micah L. Berman & Annice E. Kim, *Bridging the Gap Between Science and Law: The Example of Tobacco Regulatory Science*, 43 J. Law Med. & Ethics (Supp. 1) 95-98 (2015) (“In seeking evidence that the graphic health warnings ‘directly caused’ smoking rates to fall, the court failed to comprehend the difficulty of establishing causation in real-world settings, where the influence of graphic warnings cannot possibly be disentangled from the impact of other tobacco control policies and the general decline in tobacco use.”).

⁴ Seth M. Noar et al., *Pictorial Cigarette Pack Warnings: A Meta-Analysis of Experimental Studies*, 25 TOB. CONTROL 341, 346 (2016).

⁵ *Id.* at 345.

⁶ *Id.*

⁷ *Id.* at 346. Noar et al. looked at several measures that impact decision-making and behavior. Many aspects of GWL impact many mechanisms or pathways the viewer uses that ultimately change behavior. These include attention and recall, cognitive, emotional and physiological reactions – all of these combined impact intentions, which, in turn, impacts behavior. *Id.* Since Noar et al.’s analysis, other studies have emerged in support of their conclusions. Recent studies find that GWL were effective at increasing attention to and engagement with cigarette packs and elicit more quit attempts. Niederdeppe et al., *Using Graphic Warning Labels to Counter Effects of Social Cues and Brand Imagery in Cigarette Advertising*, 34 HEALTH EDUCATION RESEARCH 38 (2018); Brewer et al., *Understanding Why Pictorial Cigarette Pack Warnings Increase Quit Attempts*, 53 ANNALS OF BEHAVIORAL MED. 232 (2019). In another study, researchers found that “[GWL] were effective in impacting adolescent cigarette craving, evoked fear, pack feelings and thoughts of quitting.” Jonathan T. Macy et al., *Exposure to Graphic Warning Labels on Cigarette Packages: Effects on Implicit and*

A. Evidence of the impact of GWL on quit intentions.

There is a strong body of evidence that establishes the connection between the information provided by the GWL and a person's intention to quit smoking. In Noar et al.'s meta-analysis, all of the studies that measured quit intentions found a significant increase in study participants' intentions to quit when exposed to graphic warnings as compared to text-only warnings. More recent research confirms these findings by using experimental, real-world exposure methods to demonstrate that, over time, GWL increase risk perceptions, which, in turn, increases quit intentions.⁸ Also of note, at least two studies have compared pictorial warnings that are more arousing versus ones that are more bland, in both of those studies, more arousing images produced the greatest quit intentions, both by increasing risk perceptions and by increasing retention of information over time.⁹ In fact, in one study, the bland pictorial warnings actually diminished risk perceptions and quit intentions as compared to text-only warnings.¹⁰

B. The impact of GWL on quit attempts.

Explicit Attitudes Towards Smoking Among Young Adults, 31 PSYCH. & HEALTH 349 (2016). Yet another study showed that more emotional GWL "had greater effects and differed from [less emotional graphic labels] on two key indicators of effectiveness: recognition memory and reduction in the immediate urge to smoke." An-Li Wang et al., *Emotional Reaction Facilitates the Brain and Behavioral Impact of Graphic Cigarette Warning Labels in Smokers*, 24 TOB. CONTROL 225 (2015). In another study, researchers found that GWL made participants think more negatively about smoking, remember accompanying text warnings more, and pay more attention to cigarette packaging. Abigail T. Evans et al., *Graphic Warning Labels Elicit Affective and Thoughtful Responses from Smokers: Results of a Randomized Clinical Trial*, 10 PLoS ONE e0142879 (2015), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0142879>. Note that "[t]here were no significant differences between conditions in risk perceptions, quit intentions, or risk knowledge." Ultimately, GWL are effective because they impact so many factors that lead to behavior change. When this comment refers to information, the intention of that word is the summation of all these concepts.

⁸ Evans, A.T., Peters, E., Strasser, A.A., Emery, L.F., Sheerin, K., & Romer, D. (2015). Graphic warning labels elicit affective and thoughtful responses from smokers. *PLoS ONE*, 10(12): e0142879. doi:10.1371/journal.pone.0142879.

⁹ Evans, A.T., Peters, E., Shoben, A., Meilleur, L., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2017). Cigarette graphic warning labels are not created equal: They can increase or decrease smokers' quit intentions relative to text-only warnings. *Nicotine & Tobacco Research*, 19(10), 1155-1162. Peters, E., Shoots-Reinhard, B., Shoben, A., Evans, A.T., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2019). Pictorial warning labels and memory for cigarette health-risk information over time. *Annals of Behavioral Medicine*, 53, 358-371, <https://doi.org/10.1093/abm/kay050>

¹⁰ Evans, A.T., Peters, E., Shoben, A., Meilleur, L., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2017). Cigarette graphic warning labels are not created equal: They can increase or decrease smokers' quit intentions relative to text-only warnings. *Nicotine & Tobacco Research*, 19(10), 1155-1162.

GWL have been associated with increased quit attempts in several studies, both in the United States and abroad. In one experimental study that randomly assigned participants to text-only warnings or GWL on their cigarette packs for 4 weeks, Brewer et al. found that GWL engage the viewer by delivering information, which leads to increased quit attempts.¹¹ Those with GWL vs. those with text-only warnings had 1.29 greater odds of making a quit attempt and 1.53 greater odds of having quit smoking for at least 7 days prior to the end of the study.¹² In another study, researchers found that smokers in drug rehabilitation who received cigarette packs with GWL were more likely to join smoking cessation groups than those with text-only warning labels.¹³ Notably, Brewer et al. also reported that participants who had been given cigarette packs with GWL on them were more likely to skip a cigarette throughout the day.¹⁴ A systematic review, described in more detail below, also found that the use of GWL was significantly associated with increased quit attempts.¹⁵

C. The connection between GWL and successful quitting.

Naturally, not every smoker who sees a GWL thinks about quitting, or tries to quit, will successfully quit. However, researchers have found that thoughts or feelings about smoking, short-term smoking-related behaviors, and long-term smoking cessation success are linked: using data from the ITC Four-Country Survey, one team concluded, based on pathway modeling, that thoughts of smoking-related behavior were associated with quit attempts through at least three different cognitive and behavioral avenues.¹⁶ This model is substantiated by experimental research using

¹¹ Noel T. Brewer et al., *Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial*, 176 JAMA INTERN. MED. 905 (2016),

<http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2526671>.

¹² *Id.*

¹³ Joseph Guydish et al., *Do Cigarette Graphic Warnings Encourage Smokers to Attend a Smoking Cessation Programme: A Quasi-Experimental Study*, TOB. CONTROL (2016) (online) (doi:

10.1136/tobaccocontrol-2016-053207),

<http://tobaccocontrol.bmj.com/content/early/2016/12/02/tobaccocontrol-2016-053207>; Ophir et

al., *The Effects of Graphic Warning Labels' Vividness on Message Engagement and Intentions to Quit Smoking*, 46 COMM. RESEARCH 619 (2019).

¹⁴ Noel T. Brewer et al., *Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial*, 176 JAMA INTERN. MED. 905 (2016),

<http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2526671>. Note that

"[p]erceived likelihood of harm from smoking, positive smoking reinforcement attitudes, and negative smoking reinforcement attitudes did not differ by trial arm." *Id.* at 908. This study is described in more detail later on.

¹⁵ Seth M. Noar et al., *The Impact of Strengthening Cigarette Pack Warnings: Systematic Review of Longitudinal Observational Studies*, 164 SOC. SCI. & MED. 118 (2016),

<http://www.sciencedirect.com/science/article/pii/S0277953616302921>.

¹⁶ Hua-Hie Yong et al., *Mediation Pathways of the Impact of Cigarette Warning Labels on Quit Attempts*, 33 HEALTH PSYCH. 1410, 1419 (2014). It is possible that viewing a graphic warning label strengthens an individual's resolve to quit but is not strong enough on its own to lead to successful

pathway modeling relating thoughts and feelings about smoking evoked by GWL with an increase in quit intentions and risk perceptions.¹⁷

D. The impact of GWL on smoking rates.

The most direct evidence showing that GWL influence smoking initiation, cessation, and prevalence comes from other countries, including Canada. In 2012, few studies were available showing the direct impact of GWL on smoking prevalence. Since that time, studies have been published that support that association. In 2014, Canadian researchers relied on ten years of survey data in showing that GWL led to a statistically significant decrease in smoking prevalence in their country.¹⁸ These findings are supported by other studies linking Canadian¹⁹ and European²⁰ GWL to self-reported changes in smoking behavior.

Perhaps the most powerful evidence supporting an association between GWL and smoking prevalence is found in a 2016 systematic review by Seth Noar and colleagues. This review covers 32 longitudinal observational studies across 20 different countries, many of which evaluate the benefits of using GWL over text

quitting. One study from 2009 noted that thinking about quitting after seeing a health warning label was associated with a later quit attempt but not necessarily with successful quitting. See Ron Borland et al., *How Reactions to Cigarette Packet Health Warnings Influence Quitting: Findings from the ITC Four Country Survey*, 104 ADDICTION 669 (2009). If this is true, it does not mean that graphic warning labels are ineffective. Rather, it means that graphic warning labels part of a toolkit of policies that can be used to lower smoking rates.

¹⁷ Peters, E., Shoots-Reinhard, B., Shoben, A., Evans, A.T., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2019). Pictorial warning labels and memory for cigarette health-risk information over time. *Annals of Behavioral Medicine*, 53, 358–371, <https://doi.org/10.1093/abm/kay050>; Evans, A.T., Peters, E., Shoben, A., Meilleur, L., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2017). Cigarette graphic warning labels are not created equal: They can increase or decrease smokers' quit intentions relative to text-only warnings. *Nicotine & Tobacco Research*, 19(10), 1155-1162.; & Evans, A.T., Peters, E., Strasser, A.A., Emery, L.F., Sheerin, K., & Romer, D. (2015). Graphic warning labels elicit affective and thoughtful responses from smokers. *PLoS ONE*, 10(12): e0142879. doi:10.1371/journal.pone.0142879.

¹⁸ Sunday Azagba & Mesbah F. Sharaf, *The Effect of Graphic Cigarette Warning Labels on Smoking Behavior: Evidence from the Canadian Experience*, 15 NICOTINE & TOB. RES. 708 (2013).

¹⁹ See, e.g., David Hammond et al., *Graphic Canadian Cigarette Warning Labels and Adverse Outcomes: Evidence from Canadian Smokers*, 94 AM. J. PUB. HEALTH 1442, 1443 (2004) (finding that "19% of smokers reported that the [new graphic] warnings had made them smoke less, in contrast to only 1% who reported that they smoked more as a result of the labels"); David Hammond et al., *Impact of the Graphic Canadian Warning Labels on Adult Smoking Behavior*, 12 TOB. CONTROL 391, 391, 393 (2003) (finding that Canadian "smokers who read, discussed, and thought about the warnings at baseline were more likely to have quit, made a quit attempt, or have reduced their smoking at three month follow up.").

²⁰ I.T. Agaku et al., *Effectiveness of Text versus Pictorial Health Warning Labels and Predictors of Support for Plain Packaging of Tobacco Products within the European Union*, 21 EUR. ADDICTION RES. 47 (2015).

labels.²¹ Researchers found that implementing GWL over text labels had a statistically significant impact on participant smoking prevalence.²²

Direct evidence of an association between viewing GWL and quitting smoking is also available in experimental research. In one study in the United States with over 2000 participants, smokers were divided into two groups and either given conventional cigarette packs or cigarette packs with GWL.²³ Importantly, the researchers found that “having quit smoking for at least the 7 days immediately prior to their last visit was more common among smokers with pictorial than text-only warnings (5.7% vs 3.8%; OR, 1.53 [95% CI, 1.02–2.29]).”²⁴

Modeling studies also provide persuasive evidence of the potential impact of GWL on smoking prevalence. Several countries have used what is known as the *SimSmoke* model to estimate how various tobacco policy changes might impact smoking rates.²⁵ In the United States, *SimSmoke* researchers estimate that GWL “would reduce smoking prevalence by 5% (2.5%–9%) relative to the status quo over the short term and by 10% (4%–19%) over the long term.”²⁶ This finding is bolstered by a recent modeling analysis by Huang and colleagues, who assert that the FDA’s previous regulatory impact assessment modeling was flawed and that, under their more accurate model, the actual “estimated reduction in smoking rates in the USA is 33–53 times larger than the 0.088 percentage-point reduction estimated by FDA. . . . [or] a reduction of 5.3–8.6 million adult smokers in the USA in 2013.”²⁷

E. Impact on Targeted and Vulnerable Populations

Some population-level data suggest that GWL may have a significant impact on smoking in vulnerable populations. In one study of 18 countries with GWL, warnings had a statistically significant effect on smoking prevalence only among

²¹ Noar et al., *supra* note 15, at 121.

²² *Id.* at 125.

²³ Noel T. Brewer et al., *Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial*, 176 JAMA INTERN. MED. 905, 908 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5458743/>.

²⁴ *Id.* at 908.

²⁵ See, e.g., Gera E. Nagelhout et al., *The Effect of Tobacco Control Policies on Smoking Prevalence and Smoking-Attributable Deaths. Findings from the Netherlands SimSmoke Tobacco Control Policy Simulation Model*, 107 ADDICTION 407 (2011).

²⁶ David T. Levy et al., *Public Health benefits from Pictorial Health Warnings on US Cigarette Packs: a SimSmoke Simulation*, TOB. CONTROL (2016) (online).

²⁷ Jidong Huang et al., *Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis*, 23 TOB. CONTROL i7, i10 (2014).

adults who had not completed a secondary education.²⁸ In another study, researchers found that GWL may be effective at reaching smokers who were HIV-positive.²⁹ However, generally speaking, research demonstrates that GWL are an equitable approach because they have a tendency to have a positive impact on all viewers regardless of race, socio-economic status, or age.³⁰ Because smoking rates are higher among certain groups, those groups will experience a disproportionate benefit from GWL.

Additionally, graphic warnings on both packaging and advertising at the point-of-sale are likely to have an equitable impact on populations that disproportionately experience higher retailer density and more advertising: racial minorities and low SES communities. Because these communities also have disproportionately high smoking rates, the overall impact on reducing smoking rates will advance health equity.³¹

There is a clear linear path between adoption of GWL and the ultimate impact on cessation rates. GWL increase information and cause cognitive, emotional, and physiological reactions that lead to increased quit intentions, which, in turn, leads to quit attempts which increases cessation rates. The totality of information from GWL helps the viewer to make a rational decision and this ultimately impacts smoking prevalence at the population level.

II. The Proposed Rule

We appreciate that the FDA has adhered to the court-imposed deadlines for issuing a proposed rule while still proposing a strong and effective rule. The international

²⁸ Ce Shang et al., *The Association between Warning Label Requirements and Cigarette Smoking Prevalence by Education-Findings from the Global Adult Tobacco Survey (GATS)*, 14 INT'L J. RESEARCH PUB. HEALTH 98 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5295348/pdf/ijerph-14-00098.pdf>.

²⁹ Lauren Pacek et al., *Graphic Warning Labels Affect Hypothetical Cigarette Purchasing Behavior among Smokers Living with HIV*, INT'L J. OF ENVIRO. RESEARCH AND PUB. HEALTH, 1-13 (2019).

³⁰ This general consensus may depend on the type of warning. Predominately, these studies are conducted using loss-framed messages (focusing on the health consequences or "loss" of engaging in smoking), recent research may demonstrate that gain message GWL aimed at women of reproductive age may not be as universally effective. Elizabeth Klein et al., *Framing Pregnancy-Related Tobacco Cessation Messages for Women of Reproductive Age*, AM. J. OF PUB. HEALTH (forthcoming 2019).

³¹ One paper examining warnings in the food and beverage landscape concludes, "[c]onsistent with that possibility, one recent simulation study projected that implementing SSB [sugar sweetened beverage] warnings in the U.S. would yield the largest reductions in SSB consumption by racial/ethnic minorities and individuals with lower socioeconomic status, a result driven by higher baseline SSB consumption among these groups (rather than warnings having a stronger impact on behavior)." Grummon AH, Smith NR, Golden SD, Frerichs L, Taillie LS, Brewer NT. Health warnings on sugar-sweetened beverages: Simulation of impacts on diet and obesity among U.S. adults. Am J Prev Med. Forthcoming.

landscape of current health warnings on cigarette packages makes it apparent that the United States is woefully behind in warning users of the health harms of smoking cigarettes, and this rule is long overdue. Changing the current tired and stale warnings will certainly have a positive impact on public health. While any form of GWL would be a major improvement over the status quo, the FDA should also consider the improvements suggested below that have the potential to maximize the public health benefits of the final rule.

A. Choosing the subset of final warnings

Because communicating information about the harms caused by smoking is the FDA's primary interest, the agency has proposed 13 new GWL that address some of the common smoking-related health harms but also some of the less common health harms. As a whole, the images selected appear to evoke emotion in a way that would be adequately arousing. Research shows that arousal in GWL acts as information itself, a motivator, and an enhancer of information.³² Arousal is important for the long-term memory of the information the FDA wishes to convey.³³ However, individually, some of the images appear to have a lower level of arousal than others. Research shows that less arousing images will not support lasting knowledge of the associated health effects as well as more arousing images due to the overall effects of emotion on memory and its specific long-term effects through memory consolidation.³⁴ As the FDA decides to keep or abandon any particular warning in the final rule, with regard to the images with a lower level of arousal, the FDA should consider either improving the images or abandoning those warnings.

B. Different GWL on different panels

The proposed rule does not anticipate different warnings on each panel of any individual package. The FDA could follow the lead of some other countries like Canada, Australia, and China by requiring warnings in both of the two most predominately spoken languages, one warning in each language on each side.

³² James Thrasher et al., *Advancing Tobacco Product Warning Labels Research Methods and Theory: A Summary of a Grantee Meeting Held by the US National Cancer Institute* 00 NICOTINE AND TOB. RESEARCH, 1,3 (2018).

³³ Peters, E., Shoots-Reinhard, B., Shoben, A., Evans, A.T., Klein, E., *Tompkins, M.K., Romer, D., & Tusler, M. (2019). Pictorial warning labels and memory for cigarette health-risk information over time. *ANNALS OF BEHAVIORAL MED.*, 53, 358-371, <https://doi.org/10.1093/abm/kay050>.

³⁴ Ellen Peters et al., *Pictorial Warning Labels and Memory for Cigarette Health-risk Information over Time*, 4 *ANNALS OF BEHAVIORAL MED.* 358-371 (2019). See also L.J. Kleinsmith & S. Kaplan, *Paired-Associate Learning as a Function of Arousal and Interpolated Interval*, 65 *J. EXP. PSYCHOL.* 190-193 (1963); L. Cahill & J.L. MCGaugh, *Mechanisms of Emotional Arousal and Lasting Declarative Memory*, 7 *TRENDS IN NEUROSCIENCE* 294-299 (1998); Zhenhao Shi et al., *The Importance of Relevant Emotional Arousal in the Efficacy of Pictorial Health Warnings for Cigarettes*, 19 *NICOTINE & TOB. RESEARCH* (2017).

Choosing English and Spanish could impact health disparities by ensuring effective delivery of the information to a Spanish-speaking reader.

Alternatively, the FDA could also consider requiring rotation of both panels, so that each pack would carry two separate warnings, one on each panel. While it may not take a person who smokes heavily very long to gain exposure to all of the warnings, for an occasional smoker, it could take much longer. Doubling exposure to the warnings could increase a smoker's knowledge of the health harms of smoking.

Both of these suggestions support the FDA's interest in providing information. After the implementation of this final rule, when the FDA eventually updates the GWL policy, the agency could consider developing two separate graphics for each warning so that any given package features the same warning text on each side but a different graphic depiction of the warning. These multiple graphic depictions could also increase smokers' information.³⁵

C. Display of warnings in retail environment

The FDA appropriately anticipates efforts a manufacturer could take to manipulate the GWL and undermine the FDA's interest. However, the proposed rule does not necessarily anticipate all of the efforts a retailer could take to do the same. If the final rule is implemented with fidelity, the retail environment will carry dozens of warnings simultaneously. However, it is possible that retailers could attempt to manipulate how they display cigarettes to prevent the display of graphic warnings on behind-the-counter retail displays (often referred to as "the powerwall").

Proper display of packages with warnings at retail could have a significant impact on youth initiation. Most of the research about youth attitudes to graphic warnings has focused on the packaging or advertising, but not necessarily the powerwall. In examining the connection between GWL and appeal, Niederdeppe et al. found that GWL on advertisements reduce the appeal of cigarette brands and cigarette brand appeal is the strongest predictor of youth susceptibility to start using commercial tobacco products.³⁶ Research also demonstrates that youth whose parents smoke and are exposed to the warnings elicit negative emotions, are inspired to talk to their parents about quitting, and believe that warnings help smokers quit and prevent youth from starting smoking.³⁷ If 20% of advertisement space could impact the strongest predictor of youth initiation, it is logical to conclude that a powerwall

³⁵ Evans, A.T., Peters, E., Strasser, A.A., Emery, L.F., Sheerin, K., & Romer, D. (2015). Graphic warning labels elicit affective and thoughtful responses from smokers. *PLoS ONE*, *10*(12): e0142879. doi:10.1371/journal.pone.0142879.

³⁶ <https://academic.oup.com/her/article/34/1/38/5144584>

³⁷ Kaitlyn Brodar et al., "That's Probably What my Mama's Lungs Look Like": How Adolescent Children React to Pictorial Warnings on their Parents' Cigarette Packs, 18 BMC PUB. HEALTH 1125 (2018).

full of GWL would be another source of information likely to impact youth. The powerwall is essentially a large tobacco product advertisement and it should display a sufficient warning.

In the final rule, the FDA should require that, GWL on packaging should be unobstructed from view in the retail environment. To address this potential problem, we suggest adding a subsection (4) under §1140.10(c) to read:

(4) The required warning must be visible and entirely unobstructed on any packages or advertisements that are displayed in any facility operated by a retailer that offers cigarettes for sale.

D. Clearly addressing all types of visual advertising

In the proposed rule, the FDA makes clear that the regulations will apply to “print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence).” The FDA could consider adding to the example list by including price promotions and coupons. Many apps, mailers, and pop up ads contain only coupons or price promotions, like QR codes. Manufacturers may need clarification from the FDA that a GWL is required on such communications as well.

E. Alternative languages

The FDA anticipates correctly that manufacturers or retailers could attempt to undermine the effectiveness on GWL on advertisements by using a language in the warning that is not appropriate to the audience reading or experiencing the advertisement. The FDA should provide official translations for many languages, rather than only English and Spanish, instead of relying on the advertiser to develop a “true and accurate translation.” If the FDA does not decide to provide warning translations in many different languages, the FDA should require that any translated warning be submitted to the FDA for review before the product can be advertised in that medium.

III. The Changing Legal Landscape

In addition to the growth of the depth and breadth of the scientific evidence base that supports a new graphic warning rule for cigarettes, there has also been several important developments in First Amendment jurisprudence that should make the defense of this proposed graphic warning rule significantly easier for the FDA.

The legal discussion in the FDA’s new proposed rule does not fully articulate the significant changes that have occurred, particularly in the District of Columbia Circuit. Curiously, the proposed rule notes that the Court of Appeals’ decision in the original rule’s challenge was “overruled on other grounds” by *American Meat Institute v. U.S. Department of Agriculture (AMI)*.³⁸ This characterization is incorrect and does not reflect how the government itself represents the *AMI* decision in current litigation. The signal comes from the district court decision in *Cigar Association of America v. U.S. Food and Drug Administration*.³⁹ The court took the signal from the plaintiff tobacco product manufacturers’ briefs. The government’s briefs in that lawsuit do not use this characterization, and in fact make clear that the *AMI* decision has significant repercussions.⁴⁰ We are only aware of one recent occurrence where the government has cited both *R.J. Reynolds* and *AMI* together, noting their relationship and the government uses the phrase “overruled in part.”⁴¹ That phrase is a much more accurate description of the *AMI* decision as the case represents a direct and deliberate decision by the D.C. Circuit to abandon the analysis that helped shape the outcome of the cigarette manufacturers’ challenge to the first graphic warning rule.

In finding that the FDA’s graphic warning rule violated the First Amendment, the Court of Appeals for the D.C. Circuit found that review under the *Zauderer* test was not appropriate in part because the *Zauderer* standard was only applied in cases where “the State’s interest [was] in preventing deception of consumers,” which, it found, was not the case for the prior GWL rule.⁴²

Less than two years after the appeals court’s ruling in *R.J. Reynolds*, an en banc panel of the D.C. Circuit issued a decision in *AMI* overruling this portion of the case. In *AMI*, the full panel of the D.C. Circuit joined other circuit courts in concluding that there are “government interests in addition to correcting deception” that would warrant the application of the *Zauderer* standard.⁴³ Relevant to this proposed rule, it specifically found that a governmental interest in informing consumer decisions, particularly when that decision might have health-related implications, was a sufficiently important governmental interest to invoke the *Zauderer* standard. The court noted that “[t]o the extent that other cases in this circuit may be read as holding to the contrary and limiting *Zauderer* to cases in which the government points to an interest in correcting deception, we now overrule them,” specifically

³⁸ Proposed rule at 42757

³⁹ 315 F.Supp. 3d 143, 166 (D.D.C. 2018)

⁴⁰ Reply in support of defendants’ cross-motion for partial summary judgment

⁴¹ See, Defendant’s memorandum of points and authorities in support of its cross motion for summary judgment and in opposition to plaintiffs’ motion for summary judgment, *AAP v. FDA* (D. Mass. 2019)

⁴² *R.J. Reynolds v. FDA* (or US Food & Drug Admin., 696 F.3d 1205, 1213 (D.C.Cir. 2012)

⁴³ *American Meat Inst. v. U.S. Dept. of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014).

listing *R.J. Reynolds* among those cases.⁴⁴ Given the significance of this decision, directly implicating the prior GWL decision, it is concerning that the FDA’s proposed rule makes no mention of *AMI* in the agency’s discussion of the First Amendment and that the only reference to the case incorrectly characterizes the significance of the ruling.

Since the decision in *AMI*, the *Zauderer* standard has been implicated in three other decisions that are worth discussing. First, *National Association of Manufacturers v. Securities and Exchange Commission (NAM)*, reconsidered in light of the D.C. Circuit’s decision in *AMI*, found that *Zauderer*’s application was limited to disclosures on advertising or product labeling at the point of sale.⁴⁵ It therefore found that *Zauderer* did not apply to a required declaration in reports—about whether or not minerals were “conflict free”—that companies were required to file with the Securities and Exchange Commission and post on their websites. This part of the ruling should have no impact on this proposed rule mandating graphic health warnings on tobacco product packages and advertisements; these required disclosures would be subject to the *Zauderer* test as the disclosures are required in advertising and labeling.

The *NAM* decision goes on to analyze the SEC’s rule under the *Zauderer* test and conclude that the rule violates the First Amendment. However, as the panel found that *Zauderer* was inapplicable to this particular policy, the rest of the panel’s findings are arguably dicta. Nonetheless, we note that according to the court, the SEC’s rule did not provide any evidence that it would further the government’s purpose. By contrast, the FDA has strong data on the effectiveness of such warnings to draw from, referenced throughout the FDA’s proposal and also referenced above.

We also believe that there is a very high likelihood that cigarette manufacturers or retailers who will challenge this rule will argue that *National Institute of Family and Life Advocates et al. v. Becerra (NIFLA)* will have a significant impact on the outcome of a challenge to this rule, when in reality, it should have very little impact.⁴⁶ Cigar and pipe tobacco manufacturers have begun to rely heavily on *NIFLA* in their briefs challenging the FDA’s warning labels for cigars in the final deeming rule.⁴⁷ However, that reliance is misplaced. In *NIFLA*, the Supreme Court analyzed two parts of a government disclosure policy. Regarding the threshold question of whether the

⁴⁴ *Id.* at 22.

⁴⁵ *Nat’l Ass’n of Mfrs. v. Sec. and Exch. Comm’n*, 748 F.3d 359 (D.C. Cir. 2014).

⁴⁶ *National Institute of Family and Life Advocates et al. v. Becerra*, 138 S.Ct. 2361 (2018).

⁴⁷ See Brief for Appellants, Cigar Ass’n of Am. et al. v. U.S. Food and Drug Admin. (D.C. Cir. 2018) (No. 18-5195)(citing *NIFLA* fifteen times); Reply Brief for Appellants, Cigar Ass’n of Am. et al. v. U.S. Food and Drug Admin. (D.C. Cir. 2018) (No. 18-5195)(citing *NIFLA* eleven times); and Final Brief for Appellants, Cigar Ass’n of Am. et al. v. U.S. Food and Drug Admin. (D.C. Cir. 2018) (No. 18-5195)(citing *NIFLA* fifteen times).

policy was “factual and uncontroversial,” the Court found that a policy related to abortion was certainly controversial. The Court then applied the *Central Hudson* test to the challenged policy. Whether or not one finds abortion to be a controversial topic, there is little question that the health effects of cigarette smoking are not “controversial” in the same way as abortion. The most important point is that this portion of the *NIFLA* decision does not alter the application of the *Zauderer* test; it merely identifies a policy that does not meet *Zauderer’s* threshold question.

In the second part of its decision, the Supreme Court walked through the *Zauderer* analysis of the policy but explicitly stated that it had not decided that the test applied and that it did not need to decide whether it applied. Arguably, this portion of the decision is merely dicta. But even if not, the Court again does not modify the *Zauderer* analysis. The decision does assert that the harm to be remedied by the disclosure requirement must be “real not purely hypothetical.”⁴⁸ It then concludes that California had not sufficiently proved that the harm it sought to address — that women would not know that unlicensed crisis pregnancy centers are staffed by unlicensed professionals — was real. This does not meaningfully modify the application of *Zauderer* except to potentially require some evidence that the problem the government seek to address is a real one. This is a bar that the FDA should easily be able to meet, given the evidence presented in the GWL rule.

The Court’s decision also states that a disclosure can be “no broader than reasonably necessary.” In the next sentence, the Court states that the challenged policy must not be unduly burdensome and so the “no broader than reasonably necessary” language does not establish a new standard of review under *Zauderer*, it merely uses different language for the test. Ultimately, this portion of the policy fails for only attempting to remedy a theoretical harm. This is certainly not the case with graphic warning labels on cigarette packages and advertisements. Whether the asserted interest is increasing knowledge or attempting to persuade smokers to quit, there are real dangers to be addressed with the FDA’s proposed rule. Finally, the Court intentionally made clear that the holding did not impact other types of warnings, stating specifically that, “we do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.”⁴⁹

Finally, challengers of this FDA rule will also likely rely heavily on a recent decision by the Court of Appeals for the 9th Circuit. An *en banc* panel of that court recently struck down mandatory warning labels for sugar-sweetened beverages in *American Beverage Association v. City & County of San Francisco*.⁵⁰ This case, while cited less frequently than *NIFLA*, also features prominently in the challenges to the FDA’s

⁴⁸ *National Institute of Family and Life Advocates et al. v. Becerra*, 138 S.Ct. 2361, 2377 (2018).

⁴⁹ *National Institute of Family and Life Advocates et al. v. Becerra*, supra note 48, at 2376.

⁵⁰ *Am. Beverage Ass’n v. City & Ct’y. Of S.F.*, 916 F.3d 749 (9th Cir. 2019).

warning labels to cigars. While we strongly support effective and accurate warning labels on sugar-sweetened beverages, the 9th Circuit ultimately found that the record supporting San Francisco's ordinance did not show that a warning covering 20% of the package would be any more effective as a warning covering 10%, thus rendering the policy unduly burdensome. In the case of GWLs, however, the size of the warnings has already been litigated in the 6th Circuit.⁵¹ In upholding the Tobacco Control Act's GWL requirement, the court found that "[a]mple evidence supports the size requirement for the new warnings."⁵²

In sum, *AMI* significantly shifted the legal landscape—and undermined the basis of the previous *R.J. Reynolds* decision—by making it clear that the FDA's interest in requiring GWLs is sufficient to invoke the *Zauderer* test. The FDA must then show how its required warnings are "factual and uncontroversial," which—as explained in the rule itself—it can clearly do. The three cases following *AMI* that have found other warnings or disclosures to violate the First Amendment largely raise questions that the FDA can easily answer or that are inapplicable in the context of GWLs.

IV. Future Considerations

As the United States plays catchup on requiring GWL on cigarette products, there is an opportunity to use the momentum of a final rule to consider adopting stronger warnings on other commercial tobacco products. Many other countries require GWL on smokeless tobacco and such warnings would likely also be effective in the United States.⁵³ Additionally, it has long been acknowledged that there is very little distinction between cigarettes and little cigars in terms of the risks of health harms to the user.⁵⁴ To that end, many of these GWL could and should be required in the future on little cigars. Finally, the combination of skyrocketing youth use of ENDS, the health crisis posed by lung injuries from using ENDS, and emerging research demonstrating potential health harms like cardiac disease associated with using ENDS, the FDA should take the opportunity to immediately propose a GWL on ENDS products.⁵⁵ As noted, the evidence that exists regarding the impact of GWL on youth initiation and youth cessation is promising.⁵⁶ For example, at least one study

⁵¹ *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509 (6th Cir. 2012).

⁵² *Id.* at 567.

⁵³ Seema Mutti et al., *Perceived Effectiveness of Text and Pictorial Health warnings for Smokeless Tobacco Packages in Navi Mumbai, India, and Dhaka, Bangladesh: Findings from an Experimental Study*, 25 TOB. CONTROL 437-443 (2015).

⁵⁴ WORLD HEALTH ORG. INT'L AGENCY FOR RESEARCH ON CANCER, *Tobacco Smoke and Involuntary Smoking*, 83 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS (2004), at 58-59.

⁵⁵ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html; <https://www.ahajournals.org/doi/10.1161/JAHA.119.012317>

⁵⁶ Diane Francis et al., *Impact of Tobacco-Pack Pictorial Warnings on Youth and Young Adults: A Systematic Review of Experimental Studies*, 17 TOB. INDUCED DISPARITIES 1-11 (2019);

concluded that when comparing a pictorial warning conveying information about lung cancer vs. information about nicotine causing addiction, the former was the most impactful for youth.⁵⁷ This research demonstrates the need for clearer answers on the impact of the current ENDS warnings and the FDA should act quickly to establish effective warnings.

V. Conclusion

We fully support the FDA's efforts to implement GWL on cigarette packages and advertisements. For too long the United States has lagged behind the rest of the world in requiring strong, effective warning labels on the most dangerous tobacco product. We request that the agency meet its court-imposed deadline of May 15, 2020, for a final rule or issue the final rule even sooner. The agency must ensure that the final rule includes all the information that will be necessary to mount a robust legal defense of the FDA's action. Once the final rule is implemented, we urge the FDA to begin developing GWL for additional tobacco products and researching ways in which GWL for cigarettes can continue to be improved.

Respectfully,

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Ellen Peters

<https://academic.oup.com/her/article/34/1/38/5144584>; & Kaitlyn Brodar et al, "That's Probably What my Mama's Lungs Look Like": How Adolescent Children React to Pictorial Warnings on their Parents' Cigarette Packs, 18 BMC PUB. HEALTH 1125 (2018).

⁵⁷ Jessica Pepper et al., *Non-Smoking Male Adolescents' Reactions to Cigarette Warnings*, 8 PLoS ONE 1-7 (2013).