

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILLIP MORRIS USA, INC., SHERMAN
GROUP HOLDINGS, LLC,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 20-cv-1181 (KBJ)

**BRIEF OF AMICUS CURIAE THE PUBLIC HEALTH LAW CENTER
IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT
AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT
AND A PRELIMINARY INJUNCTION**

CORPORATE DISCLOSURE STATEMENT

The Public Health Law Center is a private, non-profit organization. It has no parent company, and no publicly held company holds more than 10% of its stock.

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INTRODUCTION AND INTEREST OF AMICUS¹

Accurate, factual statements and images depicting the negative health impacts of smoking cigarettes may be “scary,” “shock[ing],” and “gross” to viewers for the simple reason that the health effects of smoking are scary, shocking, and gross. Smoking kills half of its long-term users and leads to many other horrible health consequences: throat cancer and tumors, underweight newborns, blindness, amputation, erectile dysfunction, and heart disease requiring surgery, among others. These are all terrible things to see, and being alerted to these dangers naturally provokes negative emotions. But, contrary to the plaintiffs’ argument, that emotional reaction does not mean that a warning label is nonfactual or controversial, subject to heightened First Amendment scrutiny. Facts, and factual images, make us feel.

While Congress decided not to ban cigarettes in the Tobacco Control Act of 2009 (TCA), it did want to ensure that consumers had the facts every time they went to buy cigarettes. So the TCA mandates that cigarette packages and advertisements carry prominent factual warnings “depicting the negative health consequences of smoking” with color graphic images—a well-established means of communicating information. Fulfilling this mandate, the Food and Drug Administration’s (FDA or agency) recent graphic warnings rule, promulgated after notice and comment, requires eleven new rotating graphic warnings with explanatory text depicting the health risks of smoking, particularly those risks that are “less-known.” 85 Fed. Reg. 15,638, 15,640, 15,686, 15,708–10 (Mar. 18, 2020). The FDA’s purpose with these new graphic warnings is to correct “misperceptions about the health risks caused by smoking.” *Id.* at 15,638. So it is critical that the warning be seen, read, and understood, and then that the information be remembered by viewers.

¹ No party opposes the filing of this brief. No counsel for any party to this proceeding authored any part of this brief. No party or party’s counsel, or person other than amicus curiae and its members, contributed money to the preparation or submission of this brief.

Government-mandated warning labels that are “factual, accurate, and uncontroversial,” like the ones at issue in this case, are subjected to lenient rational-basis review under the First Amendment, called “*Zauderer*” review after the case that announced the standard. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985). The D.C. Circuit concluded that the FDA’s first attempt at graphic warnings were not “purely factual” and could not be reviewed under the *Zauderer* standard in part because they were “*primarily intended* to evoke an emotional response,” and were not aimed at “convey[ing] information” but instead were “unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting.” See *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1216–17 (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) (emphasis added). In promulgating the new warnings, the FDA was careful to ensure that the images were targeted to inform consumers and not designed with the purpose of provoking emotion. During the rulemaking, the FDA addressed several comments challenging whether these new paired images and textual warnings were “factual, accurate, and uncontroversial,” as required for disclosure mandates under *Zauderer*. The agency explained that the new images were not “designed to evoke an emotional response,” 85 Fed. Reg. at 15,646, and it explicitly rejected calls for it to make the images more “shocking” or “gross,” *id.* at 15,670. Instead, the agency outlined the “science-based, iterative research process” it used to design “factually accurate” warnings, *id.* at 15,663. Through this process—undertaken in direct response to this Court’s concerns in *R.J. Reynolds*—FDA medical experts from a range of different specialties and a “certified medical illustrator” worked together to “develop high quality, factually accurate photorealistic images” that “depict[] common visual presentations of the health conditions and/or show[] disease states and symptoms as they are typically experienced.” *Id.* at 15,646. Further addressing the concern in *R.J. Reynolds*, the FDA made

sure to pair each medical image with a related, specific health warning, and tested the final sets to ensure they were “unambiguous and unlikely to be misinterpreted.” *Id.*

Regardless, the plaintiffs—Phillip Morris USA and Sherman Group Holdings (collectively, the “Tobacco Industry”)—challenge these new warnings as a violation of their First Amendment rights and focus their constitutional argument on the fact that these graphic images of smoking risks evoke negative emotional reactions. MSJ at 47–60.² Because these graphic warnings are disturbing to some consumers, the Tobacco Industry argues that they are not (and presumably any graphic image that evokes a negative emotional response can never be) “factual” and “uncontroversial,” and hence cannot be reviewed under *Zauderer*. Rather, the Industry argues, they are subject to (and fail) heightened scrutiny. The Industry faults the FDA for not examining the focus group participants’ emotional reactions to the warnings, MSJ at 49–50, and emphasizes that some participants’ feelings of disgust render the warning unconstitutional. But it makes sense that the FDA did not ask about “feelings” because its goal was not to target emotion—its goal was to provide information, and it gave viewers factual text and images.

That some viewers described the FDA’s newly designed graphic images depicting the harms of smoking as “startling” or “disgusting” is not the FDA’s fault. *Id.* at 47. It is the *plaintiffs’* fault for designing and selling such a dangerous product that has the depicted—and indeed many other serious—health consequences. It is the plaintiffs’ product, not any graphic warning, that is “heartbreaking.” The FDA has designed “factual, accurate, and noncontroversial” pictorial images of the results of smoking. And to the extent that these factual images evoke an emotional response, that reaction is merely an expected and inseparable byproduct of the warnings’ ability to effectively communicate the real and serious health risks of smoking. As the agency put it: “the possibility that

² “MSJ” refers to the “Memorandum in Support of Plaintiffs’ Motion for Summary Judgment and a Preliminary Injunction” (Doc. No. 22-1).

factual content may evoke an emotional reaction does not render the content less factual.” 85 Fed. Reg. at 15,646. Facts, quite simply, provoke emotion.

The Tobacco Industry’s First Amendment argument, therefore, rests on a false dichotomy between fact and emotion. Facts make us feel, so warnings that evoke emotion are not thereby rendered ineligible for *Zauderer* review. That is a matter of common sense; if one gets the news that a loved-one has cancer, it provokes a sad emotion; learning about slavery can provoke feelings of shock and disgust, and can be “grotesque”—it does not make it any less accurate or true. Reading the number of calories contained in a Chipotle burrito can also be off-putting (and make consumers feel bad if they have eaten or want to eat one). The emotion does not transform the information into being nonfactual or ideological propaganda. Instead, fact and emotion are intrinsically linked.

Scientific research, moreover, provides a robust account of the relationship between receiving factual information, experiencing feelings, and then learning the information. As described below, emotion often links the conveyance of information with the receiver’s learning and retention. Indeed, if there was no emotional response to information about the grave harms caused by smoking, one might question whether it was an accurate disclosure or properly conveying information, because we do not expect consumers to be callous about death, disease, addiction, and the other health consequences of smoking. Likewise, if the FDA only promulgated graphic warnings of the minor effects of smoking, like a cough, or only used small text that is quickly bypassed, those warnings would arguably be misleading because they could suggest that smoking’s harms are less severe than they really are. It is factual, accurate, and noncontroversial that smoking leads to grave harms; a picture showing as much does not change that.

Accordingly, the Public Health Law Center submits this brief to provide the Court with detailed information about the science behind graphic warnings and the relationship between warnings and emotions. Understanding that relationship is critical in this case because it

demonstrates why the Tobacco Industry's attempt to evade *Zauderer* review rests on a false distinction between information and emotion. The incidental emotion provoked by these carefully crafted warnings does not mean the warnings require heightened scrutiny. Instead, these graphic warnings will further the government's goal of combatting misperceptions about smoking's risks. Amicus curiae is an expert not just in the efficacy of public health warnings—as it works closely with scholars and scientists across the country—but also in the First Amendment concerns that such warnings raise.

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.³ For over twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws. This work is evidence-based, informed by the leading empirical research on policy interventions. As such, the Center is particularly suited to provide its expertise regarding warning labels. The Center has filed more than sixty amicus briefs; among the briefs are more than twenty addressing the regulation of commercial speech. Because graphic warning labels are an important tool for informing the public about the dangers of smoking, the Center has a strong interest in supporting the government's ability to require tobacco companies to effectively warn consumers about the dangers of their products.

³ 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 consequences of tobacco use, including: 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.

ARGUMENT

When the government requires businesses to place “purely factual and uncontroversial” warning labels on their products, the First Amendment requires that the commercial disclosure be reviewed under the more lenient *Zauderer* rational-basis review. 471 U.S. at 651. And that makes sense. “Protecting commercial speech under the First Amendment is principally justified by protecting the flow of accurate information, and requiring factual disclosures furthers that goal.” *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 555 (6th Cir. 2012). Thus, the Tobacco Industry’s “constitutionally protected interest in *not* providing any particular factual information in [its] advertising is minimal.” *Zauderer*, 471 U.S. at 651. Under *Zauderer*, the government cannot “force citizens to confess by word or act” what it believes “shall be orthodox in politics, nationalism, religion or other matters of opinion.” *Id.* (quoting *West Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943)). But mandated factual disclosures about the impacts of dangerous products like cigarettes—which Congress could ban outright—do not run afoul of the First Amendment under *Zauderer*.

The Tobacco Industry does not want *Zauderer* review to apply to the FDA’s new mandated graphic warnings, no doubt because it knows the FDA’s carefully crafted new warning labels survive that standard. It urges heightened scrutiny instead. But its attempt to evade *Zauderer* rests on an artificial distinction between fact and emotion, arguing that because the warnings evoke emotion they (somehow) are not “factual and uncontroversial” and thus fail the *Zauderer* threshold. That is wrong. Contemporary scientific evidence demonstrates what is understood as a matter of common sense: facts can evoke emotions, and, indeed, those emotions are critical to the learning process. The Tobacco Industry has conducted the master class in deceiving customers, and the graphic warning labels are unfortunately necessary to provide consumers with factual information to combat historic

and current deceptive practices. This Court, therefore, should analyze (and uphold) the FDA’s new graphic warnings requirements under the *Zauderer* standard.⁴

I. The Tobacco Industry’s First Amendment argument rests on a false distinction between fact and emotion.

The plaintiffs argue that their challenge to the FDA’s new rule cannot be subject to the more lenient standard for commercial disclosures under *Zauderer* because the graphic warnings evoke negative emotions and thus, in their view, cannot be “purely factual.” *See* MSJ at 47 (citing *R.J. Reynolds*, 696 F.3d at 1216–17). This argument lacks merit and rests on an artificial distinction between fact and emotion. Images have long been used as an important tool for communicating factual information, and the recognition that factual images (or even informational text) may incidentally provoke emotion does not transform them into impermissible ideological opinion speech the government cannot compel. Rather, as the research demonstrates, information evokes emotion and it is that natural emotional response that helps viewers learn the facts conveyed—precisely the purpose of the FDA’s warnings.

A. Images are an important tool for communicating factual information.

Courts considering First Amendment challenges have long recognized that images are an effective means of “impart[ing] information” in an accurate and non-ideological manner. *Zauderer*, 471 U.S. at 647. The Supreme Court’s decision in *Zauderer* “itself eviscerates the argument that a picture or a drawing cannot be accurate and factual.” *Disc. Tobacco*, 674 F.3d at 560. In addition to challenging the mandated disclosures, the attorney in *Zauderer* challenged Ohio’s attorney professional-conduct rule forbidding the use of illustrations in ads because one of his ads featured a drawing of a medical device. The state argued, much as the Tobacco Industry does here, that the use of images misleads, manipulates, and confuses the public because “subtle uses of illustrations” can

⁴ This brief focuses on why *Zauderer* is the appropriate standard to apply. Amicus curiae adopts the arguments of the FDA as to why the graphic warnings survive *Zauderer* review.

“play on the emotions” and “convey false impressions” to the public. *Zauderer*, 471 U.S. at 648. But *Zauderer* “foreclosed this argument,” reasoning instead that “the use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience . . . and it may also serve to impart information directly.” *Disc. Tobacco*, 674 F.3d at 560 (quoting *Zauderer*, 471 U.S. at 647). The Supreme Court thus upheld the attorney’s use of an “accurate representation” of the medical device. *Zauderer*, 471 U.S. at 627. Building off this holding, the Tobacco Industry has itself contended in other contexts—contrary to its argument in this case—that images are not necessarily aimed at emotional manipulation but can impart factual information. In *Discount Tobacco*, for instance, the Industry used this argument to challenge TCA advertising regulations that would have prohibited the use of all color and images in tobacco advertisements. 674 F.3d at 548. The Sixth Circuit agreed, adopting the Tobacco Industry’s argument that a ban on images and color was overbroad, explaining that some images “teach adult consumers how to use novel products, . . . merely identify products and producers, and . . . communicate information about the nature of a product.” *Id.*

That same principle holds true for images in required warning labels. While the discussion of images in *Zauderer* dealt with restrictions on commercial advertising rather than required disclosures, “the Court’s reasoning demonstrates that a picture can be accurate and factual.” *Id.* at 560. The Sixth Circuit recognized as much in this exact context. In another section of *Discount Tobacco* (a case the Tobacco Industry conspicuously fails to cite), the Sixth Circuit rejected a facial challenge to the TCA’s graphic warnings requirement—the same challenge the Industry makes here. As the Sixth Circuit reasoned, if a picture could “accurately represent” a medical device in *Zauderer*, there is “no reason why a picture could not also accurately represent a negative health consequence of smoking, such as a cancerous lung.” *Id.* The court explained that the Industry’s position that “pictures can never be factually accurate . . . stands at odds with reason.” *Id.* at 559. Citing the use of medical

images in biology, anatomy, and medical school textbooks, the court outlined a “nonexhaustive” list of images that would “constitute factual disclosures under *Zauderer*.” *Id.* On that list, the Sixth Circuit recommended “a picture or drawings of a person suffering from a smoking-related medical conditions” or of “the internal anatomy of a person suffering from a smoking-related medical condition,” *id.*—exactly what the FDA’s new graphic warnings mandate.

The Sixth Circuit also rejected the Tobacco Industry’s argument that images depicting the negative consequences of smoking are (somehow) not factual simply because not everyone suffers of the warned diseases or experiences them in the same way. It is well-understood that “[b]y virtue of our genes and environment, every person is different” and will not experience health risks in the same way. *Id.* But that does not mean a depiction of the health risks, especially with explanatory language, is transformed into an impermissible opinion. *Id.* “[A]rguing that a representation of a medical condition becomes an opinion when people could have that medical conditions in ways that deviate from the representation would lead to the insupportable conclusion that textual or pictorial descriptions of standard medical conditions must be opinions as well.” *Id.* That is absurd. A sign on the side of the highway warning of falling rocks by (as is custom) depicting rocks falling from above onto the roof of a car does not mean that all persons driving down the highway will experience falling rocks, or that if there are falling rocks they will necessary fall on the top of one’s car, as opposed to hitting one’s windshield or already being on the road. No one, though, would argue that the pictorial description is nonfactual, is controversial, and constitutes impermissible opinion. The same is true here; that everyone may not experience these outcomes or suffer from tobacco in the same way does not make these images the ideological opinions the Tobacco Industry paints them to be. The Industry deems the heart disease warning depicting a large scar across the chest as “ideological” because “not everyone suffering from [heart disease and stroke] will need surgery, much less giant incisions.” MSJ at 52–53. True—some of them might not need surgery because their

heart disease is not as severe; others will not need surgery because their heart disease kills them before a chance for surgery. But the variance in possibilities does not make this depiction inaccurate or ideological.

B. The plaintiffs’ assumption that images cannot be “purely factual” because they “evoke[] an emotional response” contravenes contemporary scientific understanding of how people process information.

Nor is there merit to the Tobacco Industry’s argument that these graphic warnings fail *Zauderer*’s “factual, accurate, and uncontroversial” threshold because they provoke emotional responses from some viewers. *See* MSJ at 47–54. The plaintiffs claim that images that provoke emotion fail *Zauderer* “no matter how factually accurate those images may be,” *id.* at 53, because there must be (it assumes) either some way to convey information without provoking emotion or an obligation on the agency to convey information about smoking in the least emotive way possible. But fact and emotion are not so separable, and the agency is not required to select more benign facts to convey just to avoid an emotional response. The images accurately and evenhandedly portray the effects of smoking—those effects are just “disgusting” and “scary,” and they are recognized as such by some viewers.

The link between the facts conveyed in the graphic warnings and these negative emotions is not the result of the agency trying to peddle an ideological message; it is a matter of science. The Tobacco Industry’s argument is essentially that, in order to be factual and evenhanded, a warning must not trigger emotion. And it faults the agency for being “willfully blind[]” to how any “reasonable viewer would interpret the [...] disclosure.” *Id.* at 50. But that contention rests on an artificial distinction between fact and emotion that contemporary psychology rejects. Current science of human brain function and behavior demonstrates that information triggers emotions, and this emotional reaction, in turn, helps ensure that the information is understood and remembered. The FDA was not willfully blind to the fact that some viewers may have emotional reactions; that just

was not its target. The emotion is inescapably triggered by basic factual information about smoking’s risks.

Scientists now believe that the tools humans use to process factual and emotional information are inextricably linked. Although “[t]raditional approaches to the study of cognition emphasize[d] an information-processing view that . . . generally excluded emotion,” the “emergence of cognitive neuroscience” has revealed the interaction between emotion and comprehension.⁵ As one review of research on the link between emotion and decision making put it, “it is now believed that emotion and cognition are not separate systems, per se; they interact continuously”⁶ The plaintiffs assert that for a warning to be “*purely* factual” under *Zauderer* it must be devoid of “extraneous emotion” (and it apparently views any negative emotion here as *extraneous* because it thinks that depictions of the risks of smoking cannot be scary). MSJ at 50 (emphasis added). That is scientifically false. “*Purely* factual” information evokes emotion—even strong emotions. The emotional response to any information may of course be on a spectrum; some information provokes stronger emotional responses (positive or negative). But the emotional reaction does not render the underlying information any more or less factual.

Contemporary research in psychology further demonstrates that the emotional valence attendant to an informational message plays a significant role in several different parts of the process of learning and incorporating new information.⁷ Recall of past events and information involves “at least three memory phases”: recording or encoding; consolidation “into a stable and lasting

⁵ Elizabeth A. Phelps, *Emotion and Cognition: Insights from Studies of the Human Amygdala*, 57 *Ann. Rev. Psychol.* 27, 27 (2006).

⁶ Jennifer S. Lerner et al., *Emotion and Decision Making: Online Supplement*, 66 *Ann. Rev. Psychol.* 33.1 (2015).

⁷ Kevin S. Labar & Roberto Cabeza, *Cognitive Neuroscience of Emotional Memory*, 7 *Nature Revs. Neurosci.* 54 (2006) (“Emotion has powerful influences on learning and memory that involve multiple brain systems engaged at different stages of information processing.”)

representation”; and retrieval.⁸ “There is evidence to indicate that when an experience elicits an arousal response, there are emotion-specific processes that are engaged at each of these stages”⁹ Emotion may play a significant role in allowing individuals to better retrieve that information from their memory, long after it is first conveyed.¹⁰ Studies have repeatedly found that individuals’ “recall rates” are correlated with the emotional response associated with the information they received.¹¹

Research in this context—graphic warnings on tobacco products—underscores this point. For example, a 2017 study compared three kinds of warnings: text-only; warnings with graphic images related to smoking; and warnings with graphic images unrelated to smoking but similarly evoking negative emotions.¹² The second set of warnings, with images associated with the label text and triggering negative emotions, were rated as more believable and were more memorable at follow-up than the text-only labels were.¹³ By contrast, smokers rated the warning labels with the irrelevant images as less believable, and they were less likely to remember them a week later.¹⁴ This study supports the conclusion that, to the extent the FDA’s newest graphic warning labels trigger an emotional response, they will improve smokers’ memory and perceptions of the warning content, and they will do so precisely because the images serve an *informational* purpose. By contrast, stripping away the images from the FDA’s labels in order to reduce “emotion” would inhibit the agency’s ability to accurately convey factual information about cigarettes’ risks.

⁸ Elizabeth A. Kensinger, *Remembering the Details: Effects of Emotion*, 1 *Emotion Rev.* 99, 101 (2009).

⁹ *Id.*

¹⁰ See Tony W. Buchanan, *Retrieval of Emotional Memories*, 133 *Psychol. Bull.* 761, 776 (2007).

¹¹ See Elizabeth A. Kensinger & Daniel L. Schachter, *Memory and Emotion*, in *HANDBOOK OF EMOTIONS* 601, 602 (Michael Lewis et al. eds., 2008) (collecting studies testing a variety of stimuli, including words, sentences, pictures, and narrated slide shows).

¹² Zhenhao Shi et al., *The Importance of Relevant Emotional Arousal in the Efficacy of Pictorial Health Warnings for Cigarettes*, 19 *Nicotine & Tobacco Res.* 750, 751–52 (2017).

¹³ *Id.* at 753.

¹⁴ *Id.*

The upshot: information and emotion are intrinsically related. Information provokes emotion and whether and how humans remember information—i.e., learn—depends in part on the emotional content of that information. This does not mean that the underlying information is any less factual or that the FDA was “targeting” emotion; it is simply the case that information triggers different levels of emotion and that emotion is part of how information is noticed, remembered, and recalled.

C. The FDA’s factual graphic images do not become “ideological” or “controversial” merely because some people feel scared by the accurately depicted facts.

Not only do the plaintiffs claim that any emotional reaction associated with the graphic images renders them nonfactual, they also claim that the emotional reaction of some focus group participants demonstrates that the images are “ideological.” MSJ at 52. Not so. The “ideological” test under *Zauderer* is not asking whether someone likes or does not like an image, or finds it “scary.” It tests whether the disclosure conveys factual information or a particular ideological viewpoint of “what shall be orthodox in politics, nationalism, religion, or other matters of opinion.” *Zauderer*, 471 U.S. at 651 (quoting *West Virginia*, 319 U.S. at 642). The FDA’s new graphic warnings are not “ideological.”

The plaintiffs do not dispute that the graphic warnings depict realistic factual consequences of smoking. But they still argue that the images are controversial “no matter how factually accurate those images may be.” MSJ at 53. That is oxymoronic and leads to perverse consequences. Essentially they are saying that the government is just not allowed to warn consumers about some facts because, “no matter how factually accurate those images may be,” it makes some people scared or disgusted. Is the government, then, only allowed to warn of the most banal things? Or if it does warn of negative health consequences, must it do so in the most minimal way such that no one even notices the warning or understands the extent of the health risks? Of course that is not the rule.

Regardless, the Industry wants this Court to ignore the conceded factual nature of the images, and argues that because the images provoke emotion in some viewers, they impermissibly convey “an ideological message that no one should smoke at all.” *Id.* at 52. They say the images go beyond “identifying health risks” to “conveying how the government wants consumers to weigh those risks.” *Id.* But the FDA is not telling people how to act through these graphic images: it is requiring that the Tobacco Industry give factual information. That’s it. The warning labels do not say: “Do Not Smoke.” Unlike the previous graphic warnings, they do not include the information about a “Quit Line” for people to get help with smoking cessation, suggesting that quitting is the “right” thing to do.¹⁵ What the warnings do is give consumers factual information and then let consumers draw their own conclusions—just like a bottle of alcohol warns about the effect it may have on a baby if consumed by a pregnant woman, but does not say: “You are a bad mother if you drink this while pregnant.” It lets consumers make the decision based on factual information.

That, indeed, was the central legislative purpose behind the graphic warnings. Congress decided not to make the choice for individuals and ban cigarettes outright, but it wanted individuals to have the information to make their own choices every time they buy a pack of cigarettes. The Industry does not want consumers to have that information because its products have all sorts of negative health consequences that it would rather its consumers forget (or never learn), but it is still just that—factual information.

To the extent some people viewing the factual information draw the conclusion that it is a bad idea to smoke cigarettes, that is a byproduct of the facts, not the government expressing what

¹⁵ In the TCA, one of Congress’s original warnings was: “Quitting smoking now greatly reduces serious risks to your health.” That is a factual statement that allows consumers to weigh their actions with the knowledge that quitting would have an impact on their health. Even so, the FDA decided not to include that warning as part of its new graphics warning rule to avoid any appearance that it was telling consumers how they should act, so as avoid coming close to *Zauderer*’s line. *See* 85 Fed. Reg. at 15,686.

“shall be orthodox.” The Industry is wrong that the agency’s recognition that some viewers may be turned off by the images “underscores that FDA’s graphic warnings are advocacy.” MSJ at 50. To the contrary, it shows that the agency, though it did not aim for any particular emotional response, recognizes that, as humans, most people do not want death or disease and therefore may be scared or sad when given factual information that a product can cause such outcomes. That is humanity, not advocacy. And that human reaction to death and disease cannot itself transform a factual warning into an ideological message, or else there could never be a required disclosure of the negative health effects of a product.

To this, all the Tobacco Industry can muster is its assertion that if “agencies could always blame the regulated product for provoking emotion, *Zauderer* would be a dead letter,” and then it proffers a hyperbolic parade of horrors made to scare the Court about peanut butter having huge labels about asphyxiation. MSJ at 50–51. Hardly. Cigarettes are not peanut butter; peanut butter can be consumed safely by approximately 98% of the population, cigarettes cannot be consumed safely by a single person. Cigarettes cause nearly half a million deaths in the U.S. every year; peanut butter allergies account for perhaps 100. The government could not place large graphic warnings on peanut butter under *Zauderer* because there is no demonstrated need, as there is here, so such a label would be “unduly” burdensome. *See Zauderer*, 471 U.S. at 651. The Industry’s scare tactics fall flat. It has taken the FDA over a decade and a lawsuit compelling it into action to place a noticeable, factual, graphic label on the most deadly product in the United States that kills 480,000 Americans each year and that has no safe use. It is fearmongering to suggest that now there will be massive graphic warning labels on all sorts of items. (Notably, there already are textual and graphic warning labels on many of the items the plaintiffs list because state tort law and responsible manufacturers want to ensure customers are aware of the risks.)

It is, instead, the plaintiffs' argument that would render *Zauderer* a "dead letter." If this Court were to adopt the Industry's view that a negative emotional response renders a disclosure nonfactual and ideological, it would spell an end to graphic warnings, and even many textual warnings (which too evoke emotion), about the negative health effects of a product. The plaintiffs in *R.J. Reynolds et al. v. FDA*, a challenge to the same graphic warnings pending in the U.S. District Court for the Eastern District of Texas, argued there that the TCA's graphic warnings requirement was facially unconstitutional because any graphic depictions of the health consequences of tobacco use were necessarily evocative. Doc. 34, No. 6:20-cv-176 (E.D. Tx.), at 47. In this case, the plaintiffs do not make such a strident claim explicitly, but it is the import of their argument nonetheless. Indeed, what accurate graphic depiction of the negative health consequences of smoking, as Congress mandated, would not, by its factual nature, be associated with some adverse emotional response? The plaintiffs, unsurprisingly, do not say. They claim to "in no way diminish the risk that smoking can cause many serious health conditions," MSJ at 51, but at the same time argue that depicting those consequences somehow makes the warning "ideological" and nonfactual "no matter how factually accurate those images may be," *id.* at 52–53. The Industry cannot have it both ways. Adopting its argument would mean that no graphic warning on tobacco products—or on any other product that has adverse consequences—could ever be subject to *Zauderer* review, effectively overruling that precedent. *Id.* The Court should reject their argument.

* * *

In short: the psychological research reveals that the plaintiffs' claims rest on an inaccurate view of the role that emotion plays in shaping human learning and behavior. Even though the agency did not design the graphic warnings to trigger emotion, emotion is inseparable from factual text and images about the effects of smoking. This natural emotional response to basic factual information does not trigger heightened scrutiny; *Zauderer* applies.

II. **Graphic warnings are necessary to counteract continued widespread misunderstandings about the risks of smoking cigarettes.**

The plaintiffs' constitutional argument suggests that the only permissible warnings on cigarettes can be those that exist now: nongraphic textual warnings that few people notice and that fail to convey any new information about the risks of smoking. This argument rests on a misinterpretation of *Zauderer*, as explained above. And, critically, it would eviscerate Congress and the FDA's power to combat the historical and ongoing deception the Tobacco Industry has perpetrated on the American public. Decades of Tobacco Industry deception mean that smokers do not understand the full risks of smoking, and studies demonstrate that the way cigarette manufacturers and marketers continue to package and advertise their products misleads current consumers about the health risks of smoking. Textual warning labels have proven insufficient to correct these deceptions. Instead, studies demonstrate that graphic warning labels depicting the effects of smoking—which may naturally evoke emotional responses—are the most effective corrective to this deception.

A. Misperceptions regarding the dangers of smoking tobacco products persist.

Among American smokers, there are continued widespread misperceptions about the risks of smoking, despite decades of textual warnings. Even though general information about the negative effects of smoking emerged in the 1950s, extensive research demonstrates that there are still significant gaps in smokers' knowledge of the specific risks of smoking.¹⁶ Moreover, there is

¹⁶ See, e.g., K. Michael Cummings et al., *Are Smokers Adequately Informed About the Health Risks of Smoking and Medicinal Nicotine?*, 6 *Nicotine & Tobacco Res.* S333, S333 (2004); Victor J. Strecher et al., *Do Cigarette Smokers Have Unrealistic Perceptions of Their Heart Attack, Cancer, and Stroke Risks?*, 18 *J. Behav. Med.* 45, 52 (1995). The FDA's consumer research studies found that the warning labels the plaintiffs challenge here presented "new information" to a large percentage of viewers. See 85 Fed. Reg. at 15,671–78.

considerable evidence that smokers, even after decades of exposure to the Surgeon General's limited warnings, still underestimate their risks of experiencing certain serious health effects of cigarettes.¹⁷

Specifically, there is considerable evidence that American consumers continue to hold inaccurate beliefs about the health risks of smoking due to unethical and misleading practices of the Tobacco Industry.¹⁸ The longstanding deceptive practices of the Tobacco Industry are well-documented. *See generally United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009). That deception was not limited to the Mad Men days but continued as the Tobacco Industry rolled out new cigarettes that falsely purported to reduce risk (e.g., the so-called "light" and "low tar" cigarettes), secretly redesigned cigarettes to make them more addictive, misled the public about the harms of secondhand smoke, and much more. *See id.* at 308–384, 430–561, 692–801.

To be sure, following years of public health messaging, consumers now "have some knowledge of smoking's major health risks."¹⁹ Yet studies have still found that "in-depth knowledge of tobacco's health risks is low."²⁰ People may understand that smoking is generally unhealthy and fatal, but fail to understand many of the various negative health risks that follow or how likely they are. Specifically, studies demonstrate that smokers have an "optimistic bias," underestimating their personal risk of contracting diseases and overestimating the likelihood that some of the most serious health effects—like lung cancer—are curable.²¹

¹⁷ Christina Lee, *Perceptions of Immunity to Disease in Adult Smokers*, 12 J. Behav. Med. 267, 274–76 (1989); Sue Boney McCoy et al., *Perceptions of Smoking Risk as a Function of Smoking Status*, 15 J. Behav. Med. 469, 487 (1992).

¹⁸ *See Cummings et al.*, *supra* note 16, at S333.

¹⁹ Ellen Peters et al., *Emotion in the Law and the Lab: The Case of Graphic Cigarette Warnings*, 2 Tobacco Reg. Sci. 404, 405 (2016).

²⁰ *Id.*; *see also Philip Morris*, 449 F. Supp. 2d at 578.

²¹ Peters et al., *supra* note 19, at 405.

Moreover, public knowledge of the risks of smoking is necessarily far from complete, as medical experts continue to discover new links between smoking and diseases. For instance, the U.S. Surgeon General’s Report on the health consequences of smoking only recently linked tobacco use to age-related macular degeneration, diabetes, and erectile dysfunction²²—three health effects highlighted in the FDA’s new graphic warnings rule. The Industry cannot claim these risks are well-known to the public when they were acknowledged by the Surgeon General less than a decade ago.

And to this day the deceptive practices continue. Current cigarette packaging and retail practices—including by the plaintiffs in this case—contribute to confusion about smoking’s risks. Manufacturers and retailers have found new ways to package their products to “positively influence consumer perceptions” of this inherently dangerous product²³ and effectively deceive consumers about the risks of smoking.²⁴ For instance, the use of “more white space, less action, and muted colors” on cigarette packages is “intended to reinforce the lower tar delivery message” of particular brands—a message that implies, wrongly, that these brands are safer.²⁵ Phillip Morris, one plaintiff in this case, has used that strategy to great effect. Take the example of “Marlboro Silver”—the brand name that Phillip Morris gave to its former “ultralight” cigarette brand, after the TCA prohibited the use of “light” descriptors.²⁶ While not using the word “light,” the Marlboro Silver package, by using

²² See Office on Smoking & Health, U.S. Dep’t of Health & Human Servs., *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General* 10–11 (2014) (hereinafter “SGR”).

²³ Vaughan W. Rees et al., *Assessing Consumer Responses to PREPs: A Review of Tobacco Industry and Independent Research Methods*, 18 *Cancer Epidemiology, Biomarkers & Prevention* 3225 (2009).

²⁴ Noar et al., *Impact of Strengthening Cigarette Pack Warnings*, *supra* note 37, at 118 (“Tobacco product packaging is a key part of marketing efforts to make tobacco use appealing.”). See also Melanie Wakefield et al., *The Cigarette Pack as Image: New Evidence from Tobacco Industry Documents*, 11 *Tobacco Control* i73, i78–i79 (2002); Crawford Moodie & Gerard Hastings, *Tobacco Packaging as Promotion*, 19 *Tobacco Control* 168 (2010).

²⁵ Rees et al., *supra* note 23.

²⁶ Mary Falcone et al., *Awareness of FDA-Mandated Cigarette Packaging Changes Among Smokers of ‘Light’ Cigarettes*, 30 *Health Educ. Res.* 81, 84 (2015).

color identifiers, conveys to consumers the same thing: that these cigarettes are the “lighter” and “safer” alternative.²⁷ But they are not.²⁸

This Court, too, cannot ignore that there is something uniquely and inherently deceptive about the sale of cigarettes. Cigarettes are *sui generis* because they are the only consumable product on the market that cannot be used safely in any quantity and that kills at least half of the people who use the product as intended.²⁹ Given the very real and serious health risks of smoking, courts have found that tobacco advertising and promotion “deceive[] consumers if [they] do[] not warn consumers about tobacco’s serious health risks.” *Disc. Tobacco*, 674 F.3d at 562. The Supreme Court, for instance, cited approvingly the Federal Trade Commission’s conclusion that “[t]o avoid giving a false impression that smoking [is] innocuous, the cigarette manufacturer who represents the alleged pleasures or satisfactions of cigarette smoking in his advertising must also disclose the serious risks to life that smoking involves.” *Id.* at 562–63 (citing *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 527 (1992)). No one expects that boxes of poison be sold without a warning, and companies that actively market poison and encourage the public to use it are already required to use a graphic warning—a skull and crossbones symbol—prominent enough to be noticed and to convey the poison’s danger. *See* 16 C.F.R. § 1500.121. No one suggests that this violates the First Amendment. Yet that is the import of what the Tobacco Industry is arguing for here.

B. Graphic warnings are necessary to combat misperceptions regarding the health consequences of smoking cigarettes.

Research indicates graphic warning labels like the FDA has mandated here are likely one of the most effective tools to use to further the agency’s stated purpose of “correct[ing] consumer

²⁷ *Id.*; *see also* Gregory N. Connolly & Hillel R. Alpert, *Has the Tobacco Industry Evaded the Intent and Purpose of the FDA’s Ban on ‘Light’ Cigarette Descriptors?*, 23 *Tobacco Control* 140 (2013).

²⁸ *See* SGR, *supra* note 22, at 157, 178–185.

²⁹ *See* World Health Org., *Fact Sheet: Tobacco* (May 27, 2020), <https://perma.cc/M59C-QH65>; World Health Org., *WHO Report on the Global Tobacco Epidemic, 2013: Enforcing Bans on Tobacco Advertising, Promotion, and Sponsorship* 23 (2013), <https://perma.cc/MDW5-QNLZ>.

misperceptions regarding the risks presented by cigarettes.” 85 Fed. Reg. at 15,645. The Surgeon General’s textual warning labels, last updated in 1984, have proven insufficient at combating these implied messages of safety; indeed, they are barely even seen by consumers.

Graphic warnings are better able to draw consumers’ attention to warning labels that otherwise “go unnoticed and are effectively ‘invisible.’” *Id.* at 15,638. A 2016 meta-analysis of experimental studies on tobacco warnings, for example, found that pictorial warnings—combining both images and text—were better able to attract study participants’ attention, and held that attention for longer.³⁰ These graphic warnings resulted in more “cognitive elaboration” and were seen as more credible by study participants.³¹ A systematic review of observational studies in countries that had implemented graphic warnings likewise found “significant support for the proposition that enhancing cigarette warnings increases warning attention and stimulates message processing.”³²

Experimental studies demonstrate that graphic warnings are more effective in other stages of the learning process as well. Images—particularly large ones—have been shown to be “stickier,” leading to greater recall. For example, one study exposed smokers to graphic warnings in their natural context—on the packs of their preferred brand of cigarettes for several weeks. The study demonstrated that “compared to text-only” labels, “graphic warning labels . . . elicited greater scrutiny of the warning message[] and enhanced label memory.”³³ In that study, smokers exposed to graphic warning labels also rated the message as more “credible” than those shown additional textual

³⁰ Seth M. Noar et al., *Pictorial Cigarette Pack Warnings: A Meta-Analysis of Experimental Studies*, 25 *Tobacco Control* 341, 346 (2016).

³¹ *Id.* at 347–48.

³² Seth M. Noar et al., *Effects of Strengthening Cigarette Pack Warnings on Attention and Message Processing: A Systematic Review*, 94 *Journalism & Mass Comm. Q.* 416, 434 (2016).

³³ Abigail T. Evans et al., *Graphic Warning Labels Elicit Affective and Thoughtful Responses from Smokers: Results of a Randomized Clinical Trial*, 10 *PLoS One* (2015).

detail.³⁴ Brain imaging studies confirm that “labels rated high on emotional reaction,” which triggered “greater neural activation in brain regions mediating emotional memory,” were ultimately “better remembered.”³⁵

Buttressing this experimental data is the experience of the dozens of countries that have introduced graphic warning labels and found them more effective at informing consumers than text alone. Among high-income countries, the U.S. now stands relatively alone in its continued use of limited, textual warning labels for smoking products. Between 2001 and 2016, more than a hundred countries and jurisdictions implemented policies requiring pictorial warnings on cigarette packages.³⁶

Additional research backs the FDA’s conclusion. A 2016 comprehensive review found that a country’s move to strengthen cigarette-pack warnings—most commonly by introducing graphic warnings—was associated with “increased knowledge about smoking risks,” among other public health outcomes.³⁷ A review of studies conducted in Australia, Mexico, Thailand, and the United Kingdom after those countries introduced graphic warnings found that smokers spent more time “looking at and reading the warnings,” leading to an overall increase in attention.³⁸ Researchers also found that the possibility that graphic warnings could elicit negative emotions did not undercut their efficacy.³⁹ Additionally, researchers have found that when countries introduced graphic warning labels, it was a more effective tool to convey health information *already* being imparted to consumers in other ways. In Australia, for instance, the introduction of graphic images on cigarette labels

³⁴ *Id.*

³⁵ An-Li Wang et al., *Emotional Reaction Facilitates the Brain and Behavioural Impact of Graphic Cigarette Warning Labels in Smokers*, 24 *Tobacco Control* 225, 225, 227 (2015).

³⁶ *Cigarette Package Health Warnings: International Status Report*, Canadian Cancer Soc’y (5th ed. Oct. 2016), <https://perma.cc/TJP5-DYFH>.

³⁷ Seth M. Noar et al., *The Impact of Strengthening Cigarette Pack Warnings: Systematic Review of Longitudinal Observational Studies*, 164 *Soc. Sci. & Med.* 118, 125 (2016).

³⁸ Noar et al., *Effects of Strengthening Cigarette Pack Warnings*, *supra* note 32, at 427.

³⁹ David Hammond et al., *Graphic Cigarette Package Warning Labels Do Not Lead to Adverse Outcomes: Evidence from Canadian Smokers*, 94 *Am. J. Pub. Health* 1442, 1444 (2004).

improved smokers' knowledge of specific health harms—even though the information conveyed had already been part of a national advertising campaign starting nearly a decade earlier.⁴⁰

To the extent that a graphic image of the consequences of smoking (which are scary and disgusting) could be fashioned to evoke only minimal emotional response, it not only would fail to accurately portray the gravity of the risk of smoking, it would also fail to convey factual information effectively. As one nationally representative study of adult and teen smokers found, information conveyed alongside images that evoked little emotion actually *reduced* the perception of smoking's risks relative to a text-only warning.⁴¹ That result reflects consumers' common-sense expectation that if a product is truly harmful, that danger will be accurately reflected in the product's warning. Images that evoked negative emotions, by contrast, were more likely to accurately convey the factual message of the accompanying text and were more likely to be recognized by study participants later on.⁴² In short: the FDA's warnings are necessary to correct the misperceptions about smoking and inform customers more fully about smoking's risks. And any attendant emotional valence does not render that unconstitutional or subject to heightened scrutiny.

The First Amendment protects powerful rights, but it does not allow those who sell poison or addictive, deadly, and harmful products to avoid the government's requirement to communicate basic factual information about health risks in an effective manner. The FDA's warnings may incidentally evoke negative emotions because the bare facts about the health impacts of smoking “disgust and frighten” reasonable consumers. Those emotions may help consumers learn the risks of

⁴⁰ Ryan David Kennedy et al., *Positive Impact of Australian 'Blindness' Tobacco Warning Labels: Findings from the ITC Four Country Survey*, 95 *Clinical & Experimental Optometry* 590 (2012).

⁴¹ Abigail T. Evans et al., *Cigarette Graphic Warning Labels Are Not Created Equal: They Can Increase or Decrease Smokers' Quit Intentions Relative to Text-Only Warnings*, 19 *Nicotine & Tobacco Res.* 1155, 1161 (2017).

⁴² *Id.*

smoking, combatting the decades of deception that continues today, but they do not justify elevated First Amendment scrutiny. The FDA's graphic warnings are factual and noncontroversial and properly subject to *Zauderer* review.

CONCLUSION

For these reasons, amicus respectfully requests that the Court deny the Tobacco Industry's motions for a preliminary injunction and for summary judgment and grant the FDA's motion for summary judgment, upholding the congressionally mandated graphic warnings.

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Respectfully submitted,

/s/ Susannah Landes Weaver

Susannah Landes Weaver
Donahue, Goldberg, Weaver & Littleton
1008 Pennsylvania Avenue SE
Washington, DC 20003
(202) 569-3818
susannah@donahuegoldberg.com

Rachel Bloomekatz
Lead Attorney
1148 Neil Avenue
Columbus, OH 43201
(614) 259-7611
rachel@bloomekatzlaw.com

Counsel for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States District Court for the District of Columbia by using the CM/ECF system. All participants are registered CM/ECF users and will be served by the CM/ECF system.

October 14, 2020

/s/ Susannah Landes Weaver
Susannah Landes Weaver