

No. 23-40076

**In the United States Court of Appeals
for the Fifth Circuit**

R.J. REYNOLDS TOBACCO, ET AL.,
Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Texas
Case No. 6:20-cv-00176, Hon. J. Campbell Baker

**AMICUS CURIAE BRIEF OF THE PUBLIC HEALTH LAW CENTER
IN SUPPORT OF APPELLANTS**

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Amicus curiae is a non-profit organization committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

INTRODUCTION AND INTEREST OF AMICUS CURIAE ¹

The truth can be uncomfortable. Accurate information and reminders about the health implications of our everyday choices can be unpleasant to contemplate and might feel like criticism. As the district court in this case recognized, facts can be “provocative”—they may provoke emotion, learning, and reflection. ROA.10205.

But the “provocative” nature of factual images does not make those pictures any less true. Nor does it preclude pictorial warnings from being “factual and uncontroversial,” subject to review under the First Amendment standard articulated in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

Consider a commonplace worksite warning, such as “Danger of Death: High Voltage.”² Even without an image attached, this warning may provoke fear because it communicates that there is a deadly object in proximity. Because the warning informs the viewer that something bad could happen,

¹ No party’s counsel authored this brief in whole or in part, no party or party’s counsel contributed money intended to fund this brief, and no person other than amicus curiae, its members, and its counsel contributed money to fund this brief. All parties consent to the filing of this brief.

² <https://perma.cc/FCE4-GAY3>

it may be perceived a “value-laden message” suggesting that it would be a “mistake” to enter the worksite or touch the high voltage object. ROA.10205. Yet no one would deem that warning to be non-factual or ideological in nature, and the addition of a visual or pictorial depiction would not change that. No one would consider the commonplace pairing of that text with a graphic of someone being hit with electricity as false, subjective, or controversial.

The same is true of cigarettes and the eleven pictorial warnings required by the Food and Drug Administration’s (FDA) final rule. 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.³ Accordingly, Congress treats cigarettes differently from any other product. In the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), Congress mandated that cigarette packages and advertisements carry prominent pictorial warnings “depicting the negative health consequences of smoking” to ensure that

³ 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>.

consumers were reminded of the facts every time they went to buy cigarettes. 15 U.S.C. §1333. Fulfilling this mandate, FDA's Rule requires rotating pictorial warnings with explanatory text depicting the health risks of smoking, particularly those risks that are "less-known." 85 Fed. Reg. 15,638, 15,640-15,709 (Mar. 18, 2020).

Because the health effects of smoking cigarettes are so grave, it is unsurprising that factually accurate warnings about their use may be "provocative." If the warnings provoke a reaction, it is because the plaintiffs (collectively, the Tobacco Industry) designed and sell a product that has the depicted consequences. FDA simply designed "factual, accurate, and noncontroversial" pictorial images to accurately reflect those real-life risks. As detailed below, FDA adopted scientific and medically-based drawings, akin to an encyclopedia or medical textbook, and went out of its way to avoid stoking emotion.

In addition to "provocative," the district court deemed *all* the warnings impermissibly "value-laden" because a viewer could interpret the images as suggesting not to smoke. Consumers seeing the risks of smoking presented in a straightforward, scientific, and understandable manner may process the information as a message against smoking. Indeed, people generally want to

avoid tumors, underweight newborns, cataracts, amputation, erectile dysfunction, or heart disease. But, again, that implication is caused by factually communicating the harms of smoking and does not convert the objective truth into an ideological or controversial opinion.

The upshot: if this Court were to adopt the district court’s analysis that the images are not “factual and uncontroversial,” there could never be any pictorial images on cigarettes—the singular product for which Congress mandated pictorial warnings to address its unique harms. That determination both invalidates Congress’s determination that such warnings are necessary for cigarettes and defies basic scientific understanding and commonsense about the ability of images to convey truthful information.

The Public Health Law Center submits this brief to demonstrate not only that pictorial images can be factual and uncontroversial, as required by *Zauderer*, but that the eleven warnings meet that standard. The 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. 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, including more than twenty addressing commercial speech. The Center has a strong interest in this case because pictorial warning labels are a critical tool for effectively informing the public about the myriad dangers of smoking.

ARGUMENT

When the government requires businesses to place “purely factual and uncontroversial” warning labels on their products, courts evaluate the law under the more lenient *Zauderer* standard. 471 U.S. at 651. 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. 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 do not run afoul of the First Amendment under *Zauderer*.

The district court held that *Zauderer* review does not apply to FDA’s new mandated warnings because the warnings – all eleven – are not “factual and uncontroversial.” Its analysis is flawed. *First*, the district court’s decision would preclude all pictorial images of the negative risks of cigarettes (the only product where Congress mandated images). But, as described below, pictorial images are a well-established method of conveying truthful and nonmisleading information. Through its work with scientists, doctors, and health professionals, the Center regularly sees the many ways images are used to convey important facts. Factual images are indeed a fixture of everyday life (so common it is rarely remarked upon). To design these factual images, FDA used a medical illustrator and an iterative science-based method to avoid any appeal to emotion or misinterpretation. The district court’s reasons for nonetheless concluding that these scientific pictures – *e.g.*,

of lungs, a glucose meter, or a urine sample – are not “factual” are without merit.

Second, the district court did not analyze each of the warnings as required by the TCA and the Rule’s severability provisions. When considered individually, this brief demonstrates that each warning depicts a negative consequence of smoking in a straightforward, scientific, and understandable manner that is not contrived to either provoke emotion or send an ideological message. All eleven warnings, therefore, are consistent with *Zauderer*.

I. Pictorial warnings can be “factual and uncontroversial,” subject to *Zauderer* review.

A. Pictorial images are a widely-recognized method of conveying facts in health, science, and everyday life.

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. His ads featured a drawing of a medical device. The state argued, much as the Tobacco Industry did below, that the use of images misleads, manipulates, and confuses the public because “subtle uses of illustrations” can “play on the emotions” and “convey false impressions” to the public. *Zauderer*, 471 U.S. at 647. But *Zauderer* “foreclosed this argument,” reasoning instead that “the use of illustrations or pictures in advertisements serves important communicative functions” and may “serve to impart information directly.” *Disc. Tobacco*, 674 F.3d at 560 (quoting *Zauderer*, 471 U.S. at 647). The Supreme Court upheld the attorney’s use of an “accurate representation” of the medical device. *Zauderer*, 471 U.S. at 649.

Building off this holding, the Tobacco Industry has itself contended in other contexts—contrary to its argument here—that images are not necessarily aimed at emotional manipulation but can impart factual information. In *Discount Tobacco*, for instance, the Tobacco Industry challenged 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. In another section of *Discount Tobacco*, the Sixth Circuit rejected a facial challenge to the TCA’s warnings requirement because 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 odd with reason.” *Id.* at 559.

Myriad examples demonstrate that images have long been used as an important tool for communicating facts. The medical and health fields, which amicus know well, are replete with photos, sketches, graphics and other pictorial representations of anatomy, health conditions, proper use of equipment, and the molecular structure of pathogens. Citing the use of medical images in biology, anatomy, and medical school textbooks, the Sixth

Circuit 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 FDA’s Rule mandates.

The ability of pictorial representations to communicate factual and nonideological information is widely recognized outside of science and medicine too. Those in the legal profession are accustomed to plain text, but even lawyers appreciate the importance of a visual demonstrative—the map of a crime scene, photos of evidence or injuries, and patent drawings, to name a few. A judge may exclude a photograph from trial if it *unduly* appeals to emotion, but will otherwise allow visual representations because they convey facts. *See* Fed. R. Civ. P. 403.

Factual images likewise fill our everyday lives. They tell us how to assemble IKEA furniture; identify birds, plants, and animal tracks; sort recycling; avoid slippery floors; and navigate hazards on roadways. In these and many other contexts, images convey facts, and it would be nonsensical to deem them “controversial” or “ideological.”

B. FDA’s iterative process for drawing these images followed best medical practices to ensure accuracy and avoid misinterpretation.

FDA followed a detailed, evidence-based process—involving medical specialists, scientists, focus groups, health communications research, and large quantitative consumer research studies—to ensure that its warning images were objectively accurate and would not be misinterpreted. FDA first conducted a large consumer research study to assess the public’s knowledge of the harms of smoking. Then FDA focused on four key goals for visually depicting the lesser-known harms. 85 Fed. Reg. at 15,654. Ensure that the images:

- (1) Are factually accurate;
- (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced;
- (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and
- (4) are concordant with the accompanying text statements on the same health conditions.

Id. at 15,670. Responsive to the D.C. Circuit’s concerns from a decade ago, FDA’s intention was not “to evoke negative emotions such as fear, shame,

and disgust, but rather to promote greater public understanding of the negative health consequences of cigarette smoking.” *Id.*; *see also id.* at 15,645 (“FDA used different criteria to select and study the images and warnings for this rule than it did in the 2011 rulemaking.”).

Given these goals, FDA hired a medical illustrator who worked with FDA experts, medical specialists, and health researchers to create “high-quality, factual, medically accurate photorealistic images” largely of “external symptoms and disease states” caused by smoking. *Id.* at 15, 671. Following health communications research, detailed in section VI of the proposed rule, FDA determined that photorealistic images – as opposed to photographs or stylized drawings – would be the “most appropriate visual depiction format” because this format is “best” for “depict[ing] common presentations of the health conditions in a realistic and objective format devoid of non-essential elements.” *Id.* at 15,661. As to selecting “what to depict in the photorealistic illustrations, FDA consulted the medical literature and internal Agency medical experts to identify common, visual presentations of each health condition described by the textual warning statements.” *Id.*

All that was just to get the drawing started. As detailed step-by-step in the proposed rule, FDA conducted an iterative process whereby photorealistic drawings were tested in individual interviews, focus groups, and even a large-scale consumer research study, and then edited multiple times in response to each set of testing. When testing revealed that images were confusing or ineffective, FDA discarded them. It changed and tweaked others. Then all were retested. 84 Fed. Reg. 42770 (Aug. 16, 2019). This iterative process allowed FDA to continuously refine each image. It required repeatedly “testing potential text statements, potential images, and potential pairings of text statements with images to ensure that the final required cigarette health warnings are unambiguous, are unlikely to be misinterpreted or misunderstood by consumers, and do convey factually accurate information.” 85 Fed. Reg. at 15661. Based on feedback from focus groups, for example, “FDA further refined some images for additional clarity and eliminated other images that were not well understood or where potential confusion could not be resolved through additional revisions.” 84 Fed. Reg. at 42770. In the final stages, FDA conducted a second large consumer research study—with several thousand adolescents and adults

reviewing sixteen already-refined text-and-image pairings – and then FDA narrowed the warnings from there, ultimately settling on the final eleven.

This rigorous process produced the intended outcome: each of the eleven warnings are medically accurate, objective, devoid of non-essential elements, and unambiguously convey basic facts about the lesser-known consequences of smoking.

C. The district court’s reasoning means that the government could never use realistic images to warn consumers of the grave harms caused by smoking cigarettes.

Despite the scientific evidence supporting the warnings’ accuracy, objectivity, and understandability, the district court concluded that *all* the warnings failed *Zauderer’s* “factual and uncontroversial” requirement. ROA.10206. Though the district court did not identify any false aspects of the images, it reasoned that the imagery is “provocative” and that “consumers would take from it a value-laden message that smoking is a mistake.” ROA.10205-06. This rationale precludes any factual image depicting the negative consequences of cigarettes – the one uniquely deadly product for which Congress mandated such warnings.⁴

⁴ In two footnotes, the district court explains that it is not holding “that all conceivable imagery in a disclosure” is unconstitutional, giving the

Quite simply, the health effects of smoking are gross, scary, and often tragic. It follows that realistic depictions of those effects may be “provocative” because seeing bad things may provoke emotion, learning, and reflection. Indeed, if there was no emotional response to information about the grave harms of smoking, one might question whether it was an accurate disclosure or properly conveying information because we do not expect consumers to be indifferent to death, cancer, strokes, and other health consequences of smoking. That is common sense, but cognitive neuroscience has also scientifically demonstrated the interaction between factual comprehension and emotion.⁵ Likewise, if FDA only warned 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

examples of “a map showing on which continent food was farmed,” and a “symbol denoting the presence of a given chemical.” ROA.10206 ns. 138, 139. But it did not leave room for any “photorealistic” images, which it deemed “provocative,” and it conspicuously did not suggest any example of an image depicting the negative harms of smoking that would satisfy its standard. While it agreed with the Sixth Circuit’s decision that the tobacco warnings could include “words” or “handwriting,” it did not approvingly cite that court’s conclusion that medical images of lungs and other diseases would satisfy *Zauderer*. The import of the district court’s reasoning, then, is to facially invalidate the pictorial warning provision of the TCA.

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

suggest that smoking's harms are less severe than they really are. *See* 21 U.S.C. 321(n) (labeling can be misleading when it "fails to reveal . . . consequences which may result from use of the article").

FDA—heeding the D.C. Circuit's decision—did not design the images "to invoke an emotional response"; to the contrary, it explicitly rejected calls to make the images more "shocking" or "gross." 85 Fed. Reg. at 15,645, 15,670. Still, FDA recognized that "some viewers may experience the information contained in the images—which appropriately convey the serious health consequences in a factually accurate, realistic manner—as concerning." *Id.* at 15,670. To the extent these images are deemed "provocative," it not because they are nonfactual or controversial; rather, it is "because the severe, life-threatening and sometimes disfiguring health effects of smoking are indeed concerning." *Id.*

The district court's view that the images are "value-laden" also crumbles upon closer analysis. Many people do not want to engage in behavior that causes *inter alia* cancer, strokes, low-birthweight babies, and diabetes. Informing them that a particular behavior—smoking—risks those results may thus connote that smoking is a "mistake." That is inherent in warning anyone about any negative risk—it is not a fault of FDA's warnings.

And that does not convert all warnings into ideological or controversial messages. Indeed, consumers expect that boxes of poison will carry a warning, and companies that actively market poison 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. Under the district court’s analysis, that would be a “value-laden” message insofar as the label accurately suggests that it would be a “mistake” to ingest the substance. But no one would seriously argue that such a label violates the First Amendment. Yet the import of the district court’s decision is that factual warnings of negative consequences, because they may imply that one should not engage in particular conduct, fail *Zauderer*.⁶

Adopting this analysis would have perverse implications. Applying the district court’s logic, the government would never be permitted to require realistic images (or even text) to accurately warn consumers about

⁶ The “value-laden” message that smoking is a “mistake,” which the district court found impermissibly implied in depicting the negative health impacts of smoking, is a message that R.J. Reynolds explicitly states as one of its “guiding principles”: “Minors should never use tobacco products, and adults who don’t use tobacco or have quit tobacco should not start.” Guiding Principles and Beliefs, available at <https://rjrt.com/transforming-tobacco/guiding-principles-and-beliefs/> (March 15, 2023).

any risk of injury because it could be perceived as being “provocative” or sending a “value-laden” message. Yet it could, as the district court concedes, use images like maps to identify the continental origins of food, or it could make-up innocuous symbols to indicate label ingredients. ROA.10206 n.138. This result is itself misleading because consumers’ common-sense expectation is that if a product is truly harmful, that danger will be accurately reflected in the product’s warning. *See Disc. Tobacco*, 674 F.3d at 562 (tobacco advertising and promotion “deceive consumers if [they] do[] not warn consumers about tobacco’s serious health risks.”); *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 527 (1992); 21 U.S.C. § 321(n). Yet the district court stripped Congress of the power to warn consumers with objectively factual images for the one product that kills when used as directed.

D. The district court, departing from *Zauderer*, improperly imposed a requirement that the warnings depict the “most common” iteration of the warned-of disease.

Finally, the district court added a legal requirement to the *Zauderer* standard: that a warning depict the “most common” harm (or presentation of a disease). Otherwise, to the district court, an image would be ambiguous or reasonably misinterpreted. ROA.10206. Many of the warnings that the district court did not mention do, in fact, pass this extra “most common” test

(as explained in Part II *infra*). Regardless, the district court's test is not supported by *Zauderer*.

Zauderer requires that warnings be objectively accurate and nonideological, not that they focus on the "most common" harm or circumstance. Indeed, the government may have a stronger interest in warning the public about (1) graver dangers of a product, (2) outcomes that are less known, or (3) consequences that are more understandable and easier to depict visually (such as external manifestations of disease).

Moreover, the district court's new rule is inconsistent with how individuals generally understand warnings. 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. *Disc. Tobacco*, 674 F.3d at 559. Accordingly, a depiction of health risks, especially with explanatory language, does not suggest that everyone—or even most people—will experience the harm as depicted. *See id.* That is common sense. 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 the "most common" experience of driving down that highway is falling rocks, or that if there are falling rocks, the "most common" consequence is that they will

fall on the top of one's car, as opposed to hitting one's windshield or already being on the road.⁷ No one, though, would argue that the pictorial description is nonfactual or controversial. The same is true here.

To be sure, if the government selected only the most disgusting images of rare outcomes, then a court may justifiably interpret that as fear-mongering or conveying an ideological message—as the D.C. Circuit held. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). But that is not the case here.

II. All eleven pictorial warnings are “factual and uncontroversial” because they are accurate and scientific depictions of typical health risks associated with smoking.

Although the district court's decision only specifically analyzed three warnings, it deemed all eleven—and indeed “imagery” more generally—subject to misinterpretation and hence capable of carrying false messages. ROA.10205-08. That too is error. As described above, FDA's multi-step, iterative process eliminated images that were ambiguous or susceptible to reasonable misinterpretation. And, even accepting the district court's

⁷ <https://perma.cc/2Y2U-8LDY>

concerns about the three warnings it identified, it should have severed those and preserved the other eight. *See* 21 U.S.C. § 387 (note); 85 Fed. Reg. 15,695.

An individual review of the eleven warnings reveals that each is a straightforward, science-based, objectively truthful depiction of the accompanying text.

A. “WARNING: Tobacco smoke can harm your children.”

The text of FDA’s warning conveys the undisputed truth that children can suffer harm from their parent or caregiver’s secondhand smoke.



FDA Warning



Canada Warning (2012)

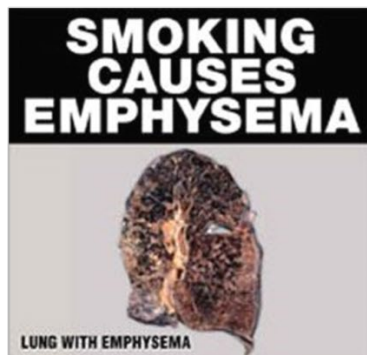
The image is a realistic image of a child suffering the consequences of secondhand smoke. As FDA described in detail, “it is not rare or atypical for children with chronic asthma resulting from secondhand smoke exposure to receive nebulizer treatments in either an emergency department or inpatient setting.” 85 Fed. Reg. at 15,672. Nor is the image designed to provoke emotion. The health condition is presented in a realistic format without

unnecessary details—like scary medical equipment—and the child is not crying or in visible pain. *Id.* The child has features consistent with chronic asthma (e.g., “allergic shiners” under the eyes), *id.* but the image is not angled or stylized to emphasize suffering. And, unlike other countries, FDA did not choose to show perhaps the most devastating harm of secondhand smoke on children—death from SIDS.

B. “WARNING: Tobacco smoke causes fatal lung disease in Nonsmokers.”



FDA Warning



Australia Warning (2012)



EU Warning (2016)

FDA’s image is basic anatomy, exactly the type of medical textbook image the Sixth Circuit concluded would be “factual and uncontroversial.” *Disc. Tobacco*, 674 F.3d at 560. The textual warning statement that “tobacco smoke causes fatal lung disease in nonsmokers” is factually accurate and the image is a realistic depiction of just that—fatal diseased lungs from a nonsmoker. The lungs are held in gloved hands because it is post-mortem,

and the lungs have the coloring and characteristics common for fatal lung disease in nonsmokers. 85 Fed. Reg. at 15,673. FDA avoided the gruesome lung images common to cigarette packages in other countries. And it did not appeal to emotion, as in the 2011 warnings or the European Union, by depicting the emotional toll on families.

C. **“WARNING: Smoking causes head and neck cancer.”**



FDA Warning



India Warning (2015)

That smoking causes head and neck cancer is both undisputed and largely unknown. *Id.* at 15,674 (unknown by over 80% of FDA’s study participants). FDA’s warning provides this critical missing knowledge and a concordant factual pictorial representation of a woman with a visible tumor protruding from her neck.

The district court concluded that the image was “ambiguous” or could be “misinterpreted” because “one person” might view the image as “the sort of neck cancer caused by smoking before a person could seek medical treatment,” and “[a]nother person” might just view it as an “exaggerated representation . . . to provoke repulsion.” ROA.10205. This analysis, as an initial matter, ignores the text. The text does not purport to indicate the size of the tumor as it arises on day one; it states only that “smoking causes head and neck cancer” –and the image provides an example. It is also well-understood that people do not experience health conditions—especially cancers—in exactly the same way. *Disc. Tobacco*, 674 F.3d at 559. But that does not mean all depictions of health risks, especially with explanatory language, are ambiguous. *See id.*

Additionally, as FDA detailed, the image is both realistic and not atypical for those experiencing head and neck cancer from smoking. “The location (i.e., on the neck, under the jawline) and appearance of the tumor” is typical of a lymph node cancer, and, in fact “[c]ancers of the head and neck commonly metastasize to the cervical lymph nodes.” 85 Fed. Reg. at 15,674. In responding to comments that believed, as did the district court, that “there would be other signs of the cancer before the patient would develop a

metastasis of the size and presentation in the proposed graphic,” FDA explained that, scientifically, such an assertion “is not accurate.” *Id.* Specifically, “[i]t is not unusual for cervical lymph node metastasis to be the first symptom of head and neck carcinoma that causes the patient to seek treatment.” *Id.* In short, this is a scientifically-accurate, typical presentation of a cervical lymph node metastasis caused by head or neck cancer. FDA did not pick a dramatic depiction of neck cancer, as in other countries. To be sure, a tumor might still be scary to see. But it is factual.

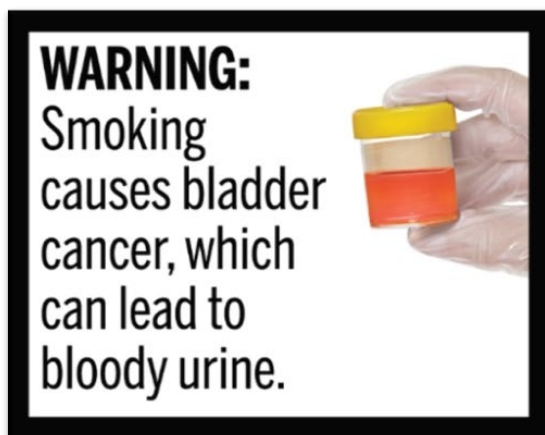
Likewise, the district court’s concern that some individuals may view the image as “stylized” or unrealistic cannot transform a truthful image into a false one. ROA.10205. FDA included this image precisely to teach consumers what many do not know. The government should not be limited to images already within the public’s understanding; that would defeat the purpose of warnings. Studies demonstrate that smokers have an “optimism bias,” underestimating their personal risk of contracting diseases and overestimating the likelihood of successful treatment if they do.⁸ But the

⁸ See Ellen Peters et al., *Emotion in the Law and the Lab: The Case of Graphic Cigarette Warnings*, 2 Tobacco Reg. Sci. 404, 405 (2016).

Zauderer inquiry is not about what consumers might think is factual, it is about what is actually “factual and uncontroversial.” This is.

Finally, the district court stated that some “might interpret the depicted person’s gaze, in conjunction with the text, as expressing regret at her choice to smoke,” thus conveying an ideological message that “smoking is a mistake.” ROA.10205. The gaze in this photo is unremarkable. It is – and was intentionally designed to be – unemotional, even though someone with such a tumor would likely have strong feelings about their diagnosis. To conclude that this gaze is impermissibly ideological would mean FDA could never depict a person’s face in a realistic manner; yet smoking harms individuals and, indeed, their heads and faces, so truthful and accurate representation requires such images.

D. “WARNING: Smoking causes bladder cancer, which can lead to bloody urine.”



FDA Warning



Australia Warning (2012)

The photorealistic image accompanying FDA’s warning depicts a nondescript gloved hand “holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking,” – exactly what the text says. 85 Fed. Reg. at 15,767. This image, too, is clinical. In “most cases,” blood in one’s urine is the first visible sign of bladder cancer, so the district court’s made-up test that the images must depict the “most common” consequences of the warned-of disease, even if adopted (it shouldn’t be), is satisfied here. FDA did not depict bloody urine in a toilet (even though that is a natural context), as other countries do, avoiding unnecessary repulsive elements. Unsurprisingly, the district court did not identify any aspect of this text-and-image pairing that could be misinterpreted because there is none.

E. “WARNING: Smoking during pregnancy stunts fetal growth.”



FDA Warning

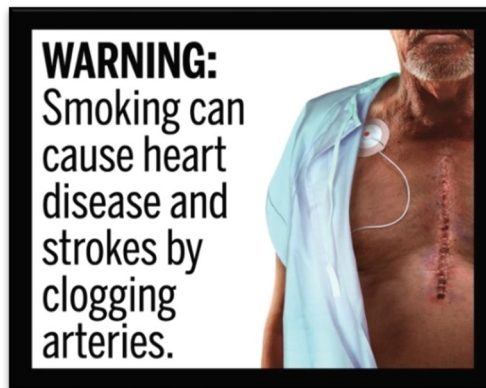


EU Warning (2011)

The tobacco industry cannot deny that “smoking during pregnancy stunts fetal growth,” and FDA’s image depicting this text is an objective, scientific consequence of that harm. *Id.* at 15,677. The image depicts a newborn baby on a scale (crying as healthy newborns do when placed on the scale⁹), registering a typical “low birthweight” –4.0lbs—as defined in medical literature (not an “extremely” low birthweight). *Id.* FDA’s extensive testing and iterative process demonstrated that because the image is paired with the text, even when “study participants did not know the definition of low birth weight, this image was understood as intended.” *Id.* Moreover, FDA excluded the more dramatic aspects included in its 2011 warning and in the European Union warning that could unduly provoke emotion. For instance, though low birthweight babies are often in an incubator, have breathing tubes, or are hooked up to medical devices, this image does not include any such features. It is a baby on a scale.

⁹ Crying “well and loudly” correlates with higher APGAR scores, indicating a healthy newborn. *APGAR Score*, available at <https://my.clevelandclinic.org/health/diagnostics/23094-apgar-score>.

F. **“WARNING: Smoking can cause heart disease and strokes by clogging arteries.”**



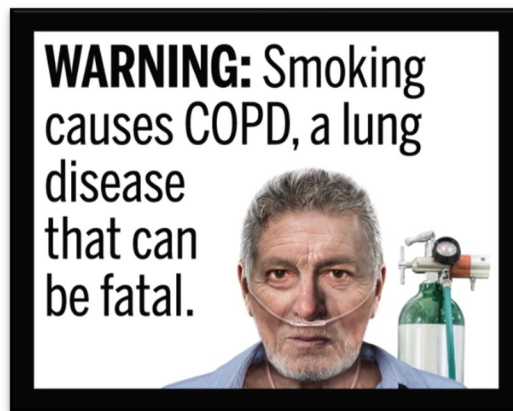
FDA Warning

This warning is accompanied by a photorealistic image of the torso of a man who “recently underwent heart surgery to treat heart disease caused by smoking.” *Id.* The man has a “recently-sutured incision running down the middle of his chest” near a probe for post-operative monitoring. Open-heart surgery, such as for a coronary artery bypass, is a “common” result for individuals suffering from heart disease. *Id.* at 15,678.

Nevertheless, the district court concluded that this image was ambiguous because consumers could interpret the image as warning that open-heart surgery is the “most common” or “best” treatment for heart disease, when in fact in-patient interventions are more common. ROA.10206. As explained in Part I.D., *Zauderer* does not require that a warning only include the “most common” risks or “best” treatments for them – only that

the warning be “factual and noncontroversial.” With 350,000 people getting open heart surgery for a coronary bypass in 2014, as the Rule states, it certainly is a factual and realistic depiction of the consequence of heart disease. Considering the text and image together, there is no ambiguity: smoking can cause heart disease, and the image is what can happen. “[T]he image aids in understanding the negative health consequence that is the focus of the textual warning statement, and vice versa.” 85 Fed. Reg. at 15,679.

G. “WARNING: Smoking causes COPD, a lung disease that can be fatal.”

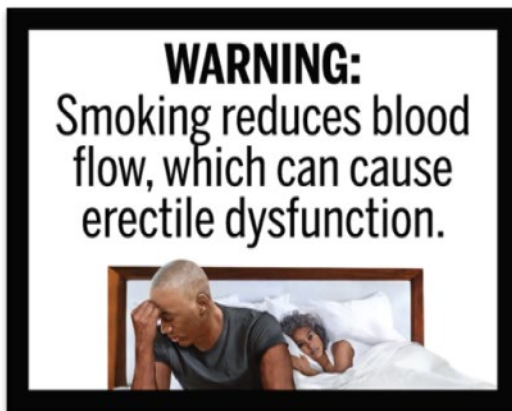


FDA Warning

Smoking is the leading cause of chronic obstructive pulmonary disease (COPD), which includes emphysema and chronic bronchitis. *Id.* Patients with COPD often receive oxygen treatments, many for several years. Given that COPD is one of the most painful smoking-related conditions, advocates

pressed FDA to include images of the suffering associated with the need for oxygen. *Id.* Following its unemotional and clinical approach, FDA instead chose this straightforward, medical image that demonstrates a typical, objective, and accurate result of COPD. Again, it is unsurprising that the district court did not discuss this image; if this image-and-text pairing does not count as “factual and noncontroversial” image, none ever will.

H. “WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.”



FDA Warning



UK Warning (2008)

This warning contains the only image that is not an anatomical or clinical portrayal. But FDA’s discretion to portray erectile dysfunction in this understated manner demonstrates that it avoided inflammatory depictions targeted to invoke shame. *Id.* at 15,680. And it is also factually accurate. The text truthfully states that smoking can cause erectile dysfunction, and the

image depicts a man on the side of a bed, head in hands, with a female partner in the background—a “common visual presentation of this negative health consequence.” *Id.* The text and image paired together are unambiguous because the text makes clear what is causing the man’s reaction and why a bedroom is portrayed.

Because erectile dysfunction is a lesser-known consequence of smoking, many countries have added it to their warnings. Playing on emotion (and arguably mocking those suffering from smoking-related erectile dysfunction), other countries use a flopping cigarette to depict erectile dysfunction. By contrast, FDA’s warning is not targeted to evoke an emotional response and “presents the health condition in a realistic and appropriately contextual format.” *Id.*

I. “WARNING: Smoking reduces blood flow to the limbs, which can require amputation.”



FDA Warning



Brazil (2008)

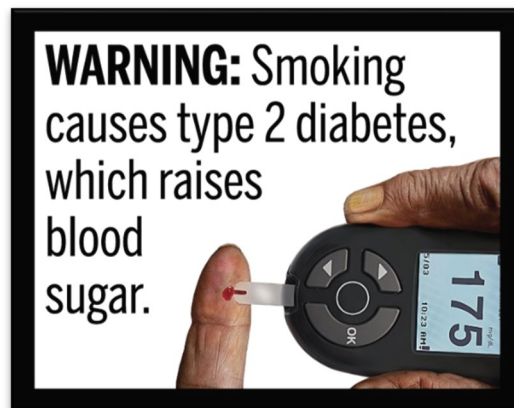


EU Warning (2016)

FDA's image is a factually accurate, photorealistic image of feet with several toes amputated. It is not pleasant to look at. But that is because the consequences of smoking are unpleasant, not because the image is false, controversial, or ambiguous. The textual warning is truthful as a matter of science, and adding a "factually accurate, common visual presentation" of the text does not transform the warning into a false or ideological statement.

If anything, FDA's image downplays the health consequences. FDA depicted amputated toes, as opposed to amputated limbs common in the warnings in other countries. It also omitted elements that could evoke emotional responses, such as a person in pain, or surgical instruments used for amputation. Nor is it extremely close-up. The district court did not specify any infirmity with this medical image, and there is none.

J. "WARNING: Smoking causes type 2 diabetes, which raises blood sugar."



FDA Warning

This image shows a personal glucometer pricking an individual's finger (a common action for diabetics) and registering a blood sugar level indicating type 2 diabetes. *Id.* at 15,682. Even if one does not know 175 is a high blood sugar level, the text makes that clear. Together, the text and image are unambiguous. FDA rejected requests to depict more "serious complications" of diabetes, including kidney disease, numbness, and premature death, instead opting for a straightforward, clinical depiction of a glucose monitor. *Id.* Like the other warnings, FDA's image is not inflammatory or targeted to evoke emotion.

K. "WARNING: Smoking causes cataracts, which can lead to blindness."



FDA Warning

This image is a medically-accurate depiction of a man with a large cataract on his right eye. *Id.* The district court concluded that this image was

subject to misinterpretation because it does not indicate “whether it shows cataracts or blindness,” and because some consumers may interpret the image as “depicting the most common result of cataracts” when cataracts are “typically treated long before they progress to the stage shown.” ROA.10207. The court’s concern, however, that viewers might not be able to precisely identify the eye condition is beside the point. It is clear from the text that the individual has cataracts (“smoking causes cataracts”) and discerning whether the individual also is blind (“which can lead to blindness”) is not necessary for a consumer to receive the information the text conveys. Either way, the image reinforces that smoking can cause grave eye problems. That many individuals have cataracts treated before reaching this level of severity does not detract from the fact that many others, particularly in low-income populations (which have higher smoking rates¹⁰), do not get treatment before cataracts advance to this stage. This is an accurate representation of a typical condition, and that it may not be the “most common” result is not required by *Zauderer*. Like the other ten warnings, it is a factual and

¹⁰ American Lung Association, *State of Tobacco Control 2023: Top 10 Populations Disproportionately Affected by Cigarette Smoking and Tobacco Use*, available at <https://perma.cc/WH9M-X9MR>.

noncontroversial depiction of a scientifically-proven consequence of smoking.

CONCLUSION

For these reasons, amicus curiae respectfully requests that the Court reverse and remand this case to the district court with instructions to correctly apply the *Zauderer* standard.

Dated: May 17, 2023
New York, NY

Respectfully submitted,

By: /s/ Agatha M. Cole

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,547 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Book Antiqua font size 14.

/s/ Agatha M. Cole

Agatha M. Cole

CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Agatha M. Cole

Agatha M. Cole