United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 10, 2012 Decided August 24, 2012

No. 11-5332

R.J. REYNOLDS TOBACCO COMPANY, ET AL.,
APPELLEES

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLANTS

Consolidated with No. 12-5063

Appeals from the United States District Court
for the District of Columbia
(No. 1:11-cv-01482)

Mark B. Stern, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were *Tony West*, Assistant Attorney General, *Beth S. Brinkmann*, Deputy Assistant Attorney General, *Alisa B. Klein*, *Sarang V. Damle*, *Daniel Tenny*, and *Lindsey Powell*, Attorneys, *William B. Schultz*, Acting General Counsel, U.S. Department of Health and Human Services, *Eric M. Blumberg*, Deputy

Chief Counsel, and *Karen E. Schifter*, Senior Counsel. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Gregory A. Beck and *Allison M. Zieve* were on the brief for *amici curiae* American Academy of Pediatrics, et al. in support of appellants.

Lawrence G. Wasden, Attorney General, Office of the Attorney General for the State of Idaho, *Brett T. DeLange*, Deputy Attorney General, *John J. Burns*, Attorney General, Office of the Attorney General for the State of Alaska, *Tom Horn*e, Attorney General, Office of the Attorney General for the State of Arizona, *Dustin McDaniel*, Attorney General, Office of the Attorney General for the State of Arkansas, *Kamala D. Harris*, Attorney General, Office of the Attorney General for the State of California, *George Jepsen*, Attorney General, Office of the Attorney General for the State of Connecticut, *Todd S. Kim*, Solicitor General, Office of the Attorney General for the District of Columbia, *David M. Louie*, Attorney General, Office of the Attorney General for the State of Hawai'i, *Lisa Madigan*, Attorney General, Office of the Attorney General for the State of Illinois, *Thomas J. Miller*, Attorney General, Office of the Attorney General for the State of Iowa, *William J. Schneider*, Attorney General, Office of the Attorney General for the State of Maine, *Douglas F. Gansler*, Attorney General, Office of the Attorney for the State of Maryland, *Jim Hood*, Attorney General, Office of the Attorney General for the State of Mississippi, *Steve Bullock*, Attorney General, Office of the Attorney General for the State of Montana, *Michael A. Delaney*, Attorney General, Office of the Attorney General for the State of New Hampshire, *Gary K. King* Attorney General, Office of the Attorney General for the State of New Mexico, *Michael DeWine*, Attorney General, Office of the Attorney General for

the State of Ohio, *Peter F. Kilmartin*, Attorney General, Office of the Attorney General for the State of Rhode Island, *Marty J. Jackley*, Attorney General, Office of the Attorney General for the State of South Dakota, *Mark L. Shurtleff*, Attorney General, Office of the Attorney General for the State of Utah, *William H. Sorrell*, Attorney General, Office of the Attorney General for the State of Vermont, *Vincent F. Frazier*, Attorney General, Office of the Attorney General for the Virgin Islands, *Robert M. McKenna*, Attorney General, Office of the Attorney General for the State of Washington, and *Darrell V. McGraw, Jr.*, Attorney General, Office of the Attorney General for the State of West Virginia, were on the brief for *amici curiae* States.

Noel J. Francisco argued the cause for appellees. With him on the briefs were *Warren D. Postman*, *Philip J. Perry*, *Jonathan D. Hacker*, *Floyd Abrams*, *Joel Kurtzberg*, and *Patricia A. Barald*.

Bert W. Rein, *John E. Barry*, *Robin S. Conrad*, *Kathryn Comerford Todd*, and *Sheldon Gilbert* were on the brief for *amicus curiae* Chamber of Commerce of the United States of America in support of appellees.

Daniel J. Popeo, *Cory L. Andrews*, and *Richard A. Samp* were on the brief for *amicus curiae* Washington Legal Foundation.

Robert Corn-Revere and *Ronald G. London* were on the brief for *amici curiae* Association of National Advertisers Inc., et al. in support of appellees.

Jeffrey Light was on the brief for *amicus curiae* Defending Animal Rights Today & Tomorrow in support of neither party.

Before: ROGERS and BROWN, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* BROWN.

Dissenting opinion filed by *Circuit Judge* ROGERS.

BROWN, *Circuit Judge*: The Family Smoking Prevention and Tobacco Control Act ("the Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), directed the Secretary of the U.S. Department of Health and Human Services to issue regulations requiring all cigarette packages manufactured or sold in the United States to bear one of nine new textual warnings, as well as "color graphics depicting the negative health consequences of smoking." *See id.* § 201(a). Pursuant to this authority, the Food and Drug Administration ("FDA") initiated a rulemaking proceeding through which it selected the nine images that would accompany the statutorily-prescribed warnings. Five tobacco companies ("the Companies") challenged the rule, alleging that FDA's proposed graphic warnings violated the First Amendment. *See* Compl. at 35-36.[1] The district court granted the Companies' motion for summary judgment on February 29, 2012.[2] FDA appeals, and we affirm.

---

[1] The Companies also alleged the graphic warnings violated the Administrative Procedure Act ("APA"), specifically 5 U.S.C. §§ 553(b)(3) and 706(2)(A). *See* Compl. at 37. Because we hold the graphic warnings violate the First Amendment, we do not reach the Companies' APA claims.

[2] FDA originally appealed the district court's grant of the Companies' motion for a preliminary injunction, but that ruling was superseded by the court's subsequent ruling on the merits.

I. Background

The Act gives FDA the authority to regulate the manufacture and sale of tobacco products, including cigarettes. In addition to requiring cigarette packages and advertisements to bear one of nine new warning statements, the Act mandates that the new warning labels comprise the top 50 percent of the front and rear panels of cigarette packages and 20 percent of the area of each cigarette advertisement. Act § 201(a), 123 Stat. at 1842–45. The Act directs the Secretary to issue final regulations identifying the graphic component of the warnings by June 22, 2011, and provides that the revised health warnings will take effect by September 22, 2012. *See* 15 U.S.C. § 1333 note.

Pursuant to the statutory directive, FDA issued a Proposed Rule seeking comment on thirty-six potential images for the new graphic warning labels. Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,534 (Nov. 12, 2010) (hereinafter Proposed Rule). At the outset of the Proposed Rule, FDA asserted the government's "substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use." *Id.* at 69,525. In accordance with the requirements of the Act, FDA proposed a dramatic expansion of the existing health warnings, which it justified based on scientific literature and a "strong worldwide consensus"[3] regarding the

[3] Countries/jurisdictions that have implemented pictorial warning requirements for tobacco packaging include Australia, Belgium, Brazil, Brunei, Canada, Chile, Colombia, Cook Islands, Djibouti, Egypt, Hong Kong, India, Iran, Jordan, Latvia, Malaysia, Mauritius, Mexico, Mongolia, New Zealand, Pakistan, Panama, Paraguay, Peru, Romania, Singapore, Switzerland, Taiwan, Thailand, Turkey,

relative effectiveness of graphic warnings compared to the text-only warnings the United States currently requires. *Id.* The agency explained that by "clearly and effectively convey[ing] the negative health consequences of smoking," the new warnings would discourage nonsmokers, particularly minors, from "initiating cigarette use," and encourage current smokers to quit. *Id.* at 69,526.

FDA promulgated the final set of nine images—one for each warning statement—by regulations issued on June 22, 2011. *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011) (hereinafter Final Rule). FDA also required each graphic image to bear the phone number of the National Cancer Institute's "Network of Tobacco Cessation Quitlines," which uses the telephone portal "1-800-QUIT-NOW." *Id.* at 36,681.

FDA based its selection of the final images on an 18,000-person internet-based consumer study it commissioned. The study divided respondents into two groups: a control group that was shown the new text in the format of the current warnings (located on the side of cigarette packages), and a separate treatment group that was shown the proposed graphic warnings, which included the new text, the accompanying graphic image, and the 1-800-QUIT-NOW number. *Id.* at 36,638. Each group then answered questions designed to assess, among other things, whether the graphic warnings, relative to the text-only control, (1) increased viewers' intention to quit or refrain from smoking; (2) increased

---

United Kingdom, Uruguay, and Venezuela. Countries/jurisdictions with pending requirements include France, Guernsey, Honduras, Malta, Norway, the Philippines, and Spain. It is worth noting that the constitutions of these countries do not necessarily protect individual liberties as stringently as does the United States Constitution. Proposed Rule at 69,525 n.4.

viewers' knowledge of the health risks of smoking or second-hand smoke; and (3) were "salient," which FDA defined in part as causing viewers to feel "depressed," "discouraged," or "afraid." *Id.*

In selecting these nine images, FDA reviewed and responded to over a thousand public comments, including joint comments submitted by plaintiffs-appellees RJ Reynolds, Lorillard, and Commonwealth Brands. *See id.* at 36,629. Several comments—including comments from cancer researchers, nonprofits, and academics—criticized the single exposure study design, noting it prevented the government from assessing the long-term or actual effects of the proposed warnings. Two of these comments recommended FDA conduct longitudinal research or post-market surveillance to assess actual long-term effects. *Id.* at 36,639. FDA conceded the study did not permit it to reach "firm" conclusions about the "long-term, real-world effects" of the proposed warnings, but claimed the existing scientific literature "provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation." *Id.* Still other comments asserted that FDA's research study failed to provide evidence that the proposed warnings would actually affect smoking rates, significantly affect consumers knowledge of the risks of smoking, or bring about actual behavior change. *See id.* at 36,640. But FDA disagreed, again relying on the "substantial research" showing the effectiveness of similar graphic health warnings in other countries. *Id.* (citing Proposed Rule at 69,531-34).[4] Another comment asserted that the study's

[4] Tobacco manufacturers also criticized the "study's use of intentions to measure behavioral change and stated that FDA should have presented data showing actual effects on behavior."

selection bias constituted a serious methodological flaw. Namely, participants were recruited from an internet panel and offered the opportunity to participate in an FDA-sponsored research study. *Id.* at 36,643. FDA avoided the substance of this argument by conceding that its study "provides insight on the relative effectiveness of the various warnings under consideration," not on the "absolute effects of the warnings in general." *Id.*

Some comments also criticized the lack of statistical evidence supporting FDA's belief that requiring cigarette packages to bear the graphic warnings would reduce smoking rates. *See id*. For example, the Companies noted that the Canadian data revealed no statistically significant decline in smoking rates for adolescents and adults after the introduction of similar graphic warnings, which implied that the warnings were ineffective and that FDA's warnings would be ineffective as well. *Id*. FDA summarily disagreed, stating that the images it selected would satisfy its "primary goal, which is to effectively convey the negative health

---

Final Rule at 36,642. FDA disagreed that intentions were an inappropriate variable, explaining that while intentions do not perfectly predict future behavior, they are a "necessary precursor." *Id*. FDA also cites the "scientific literature['s]" shocking conclusion "that one's intentions to quit smoking must be increased before one makes the actual quit attempt." *Id.* In response to comments raising concerns about the lack of strong statistically significant results concerning intention, FDA explained that although *its* study made no attempt to show that increased intention to quit translated to actual (let alone successful) quit attempts, "the overall body of scientific literature" provides sufficient evidence that the warnings, "by increasing public understanding of and thoughts about the health risks of smoking, will be effective in encouraging smoking cessation and discouraging smoking initiation." *Id.*

consequences of smoking on cigarette packages and in advertisements," which can help "both to discourage nonsmokers . . . from initiating cigarette use and to encourage current smokers to consider cessation." Final Rule at 36,633. FDA also explained that the data from Canada did not indicate that the warnings had been ineffective, because other studies showed that the warnings had been "effective at providing . . . smokers with health information, making consumers think about the health effects of smoking, and increasing smokers' motivations to quit smoking." *Id.* at 36,634.

After FDA finalized the Rule, the Companies filed suit in the district court, claiming the cigarette warnings required under the Act and FDA's implementing regulations violated the First Amendment. The district court granted the Companies' motion for a preliminary injunction on November 7, 2011, and subsequently granted their motion for summary judgment. FDA appeals, and we review *de novo* the district court's decision to grant summary judgment. *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009).

II. Level of Scrutiny

The Companies do not dispute Congress's authority to require health warnings on cigarette packages, nor do they challenge the substance of any of the nine textual statements mandated by the Act. The only question before us is whether FDA's promulgation of the graphic warning labels—which incorporate the textual warnings, a corresponding graphic image, and the "1-800-QUIT-NOW" cessation hotline number—violates the First Amendment. We begin our analysis by determining the applicable level of scrutiny.

Both the right to speak and the right to refrain from speaking are "complementary components of the broader concept of individual freedom of mind" protected by the First Amendment. *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). Any attempt by the government either to compel individuals to express certain views, *see id.* at 714-15, or to subsidize speech to which they object, *see United States v. United Foods, Inc.*, 533 U.S. 405, 410-11 (2001), is subject to strict scrutiny. The general rule "that the speaker has the right to tailor the speech[] applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573-74 (1995). This holds true whether individuals, *see W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943), or corporations, *see Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (plurality opinion), are being compelled to speak.

This case contains elements of compulsion and forced subsidization. The Companies contend that, to the extent the graphic warnings go beyond the textual warnings to shame and repulse smokers and denigrate smoking as an antisocial act, the message is ideological and not informational. "[B]y effectively shouting well-understood information to consumers," they explain, "FDA is communicating an ideological message, a point of view on how people should live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking." In effect, the graphic images are not warnings, but admonitions: "[D]on't buy or use this product."[5] No one doubts the

[5] The question here is whether the graphic warnings actually *do* constitute the type of disclosure requirements that are reviewable

government can promote smoking cessation programs; can use shock, shame, and moral opprobrium to discourage people from becoming smokers; and can use its taxing and regulatory authority to make smoking economically prohibitive and socially onerous. And the government can certainly require that consumers be fully informed about the dangers of hazardous products. But this case raises novel questions about the scope of the government's authority to force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest—in this case, by making "every single pack of cigarettes in the country [a] mini billboard" for the government's anti-smoking message.[6]

Even assuming the Companies' marketing efforts (packaging, branding, and other advertisements) can be properly classified as commercial speech, and thus subject to

---

under *Zauderer*'s relaxed standard"—what the dissent characterizes as "attempts 'only to prescribe what shall be orthodox in commercial advertising,'" Dissent at 8 (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985))—or whether they are more akin to attempts to "prescribe what shall be orthodox in . . . matters of opinion," *Zauderer*, 471 U.S. at 651, as the Companies contend. The dissent overlooks the element of compulsion, which at least creates an argument in favor of applying strict scrutiny.

[6] FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010), *available at* http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm ; *see also* Press Briefing by Press Secretary Jay Carney, Health and Human Services Secretary Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser.

less robust First Amendment protections, a thorny question remains: how much leeway should this Court grant the government when it seeks to compel a product's manufacturer to convey the state's subjective—and perhaps even ideological—view that consumers should reject this otherwise legal, but disfavored, product? Neither the Act nor the agency's regulation squarely addresses this question. However, for present purposes, we can assume, without deciding, that *if* such compulsion is constitutionally permissible, the state's actions must still withstand the applicable level of scrutiny.

Courts have recognized a handful of "narrow and well-understood exceptions" to the general rule that content-based speech regulations—including compelled speech—are subject to strict scrutiny. *See Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994). There are two primary exceptions in the commercial speech context. First, "purely factual and uncontroversial" disclosures are permissible if they are "reasonably related to the State's interest in preventing deception of consumers," provided the requirements are not "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651. Second, restrictions on commercial speech are subject to less stringent review than restrictions on other types of speech. For a statute burdening commercial speech to survive, the government must affirmatively prove that (1) its asserted interest is substantial, (2) the restriction directly and materially advances that interest, and (3) the restriction is narrowly tailored. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). While this test is not quite as demanding as strict scrutiny, it is significantly more stringent than *Zauderer*'s standard, which is akin to rational-basis review.

The district court concluded the graphic warnings were "*not* the type of purely factual and uncontroversial" disclosures reviewable under the less stringent *Zauderer* standard. *R.J. Reynolds Tobacco Co. v. FDA*, Civ. Case No. 11-1482, at 11 (D.D.C. Feb. 29, 2012) (hereinafter "Merits Opinion"). Applying strict scrutiny, the court held that FDA failed to satisfy its burden of demonstrating that the Rule is narrowly tailored to achieve a compelling government interest. *See id.* at 17-19. FDA argues that the district court erred in finding the *Zauderer* standard inapplicable. Alternatively, it contends that the district court erred by failing to apply the intermediate-level scrutiny generally afforded to commercial speech, and that the graphic warnings pass constitutional muster under *Central Hudson*. We address each argument in turn.

a. Applicability of the *Zauderer* Standard

In *Zauderer*, the Court applied a lower level of scrutiny to regulations requiring attorneys to fully disclose information about the actual cost and consequences of services. 471 U.S. at 651-52. Noting that the First Amendment's protection of commercial speech is premised on its informational value to consumers, the Court reasoned that an advertiser's constitutional interest in *not* providing additional factual information was "minimal." *Id.* at 561. Although the Court acknowledged that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech," it "h[e]ld that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.*; *see also Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1340 (2010) (applying the *Zauderer* standard to

disclosure requirements "intended to combat the problem of inherently misleading commercial advertisements").

The Supreme Court has never applied *Zauderer* to disclosure requirements not designed to correct misleading commercial speech. FDA argues that *Zauderer*'s lenient standard of scrutiny applies to regulations that serve a different governmental interest: disclosure of the health and safety risks associated with commercial products. *See* Appellant's Br. at 26.

But by its own terms, *Zauderer*'s holding is limited to cases in which disclosure requirements are "reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651. *Zauderer* "carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages." *Glickman v. Wileman Bros. & Elliot, Inc.*, 521 U.S. 457, 491 (1997) (Souter, J., dissenting, joined by Rehnquist, C.J., and Scalia and Thomas, JJ.) (explaining why *Zauderer* was inapplicable in that case).[7] In *United States v. United Foods*, for example, the Court declined to apply the *Zauderer* standard when evaluating a federal law requiring mushroom producers to pay an assessment to support generic advertising. The Court distinguished *Zauderer* because there was no suggestion "that the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make voluntary advertisements non-misleading for consumers." 533 U.S. at 416. And as the Court explained in *Pacific Gas*, "[n]othing in *Zauderer* suggests . . . that the

[7] Justice Souter noted that, although it was not cited by the government in *Glickman*, *Zauderer* represented "the closest pass at authority for his limited rationale of commercial speech protection" because it was "our only examination of a commercial-speech mandate before today." 521 U.S. at 490.

State is equally free to require [entities] to carry the messages of third parties, where the messages themselves are biased against or are expressly contrary to the [entity's] views." 475 U.S. at 15 n.12 (plurality opinion).

Ibanez v. Florida Department of Business and Professional Regulation also suggests that *Zauderer* should be construed to apply *only* when the government affirmatively demonstrates that an advertisement threatens to deceive consumers. In that case, the state Board of Accountancy contended that an attorney's use of her Certified Financial Planner designation in an advertisement was "potentially misleading," and thus entitled the Board to require her to include a disclaimer. 512 U.S. 136, 146 (1994). But the Court declined to apply *Zauderer*, finding that "given the state of this record," the Board failed "to point to any harm that is potentially real, not purely hypothetical." *Id.* Put simply, the government could not seek review under the lenient *Zauderer* standard absent a showing that the advertisement at issue would likely mislead consumers.

In fact, the Court's *only* recent application of the *Zauderer* standard involved a disclosure requirement that "share[d] the essential features of the rule at issue in *Zauderer*." *Milavetz*, 130 S. Ct. at 1340. In *Milavetz*, a law firm challenged a provision of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 ("BAPCPA") that required professionals qualifying as debt relief agencies to "clearly and conspicuously disclose in any advertisement of bankruptcy assistance services . . . that the services or benefits are with respect to bankruptcy relief under this title." 11 U.S.C. § 528(a)(3). BAPCPA also required qualifying professionals to state that "[w]e are a debt relief agency. We help people file for bankruptcy relief under the Bankruptcy Code." *Id.* § 528(a)(4). The Court upheld the

statute's disclosure requirement because, as in *Zauderer*, the law firm's advertisements were "inherently misleading"—in this case, because they "promis[ed] . . . debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." *Milavetz*, 130 S. Ct. at 1340. One Justice even cautioned against interpreting the Court's holding as a "presumptive[] endorse[ment of] laws requiring the use of government-scripted disclaimers in commercial advertising," noting that *Zauderer* does not stand for the proposition that government "can constitutionally compel the use of a scripted disclaimer in any circumstance in which its interest in preventing consumer deception might plausibly be at stake." *Id.* at 1343-44 (Thomas, J., concurring in part and concurring in the judgment).

Zauderer, *Ibanez*, and *Milavetz* thus establish that a disclosure requirement is only appropriate if the government shows that, absent a warning, there is a self-evident—or at least "potentially real"—danger that an advertisement will mislead consumers. *Ibanez*, 512 U.S. at 146. In this case, the proposed disclosure requirements would apply to both cigarette advertisements and cigarette packages. The Act bans any labeling or advertising representing that any tobacco product "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products," "contains a reduced level of a substance or presents a reduced exposure to a substance," or "does not contain or is free of a substance." 21 U.S.C. § 387k. The Act also bans advertising or labeling using the descriptors "light," "mild," "low," or similar descriptors. *Id.* In light of these restrictions, and in the absence of any congressional findings on the misleading nature of cigarette packaging itself, there is no justification under *Zauderer* for the graphic warnings.

The dissent's argument that cigarette packages and other advertisements that fail to prominently display the negative health consequences of smoking are misleading, *see* Dissent at 12-13, seems to blame the industry for playing by the government's rules. The Companies have never argued that *no* disclosure requirements are warranted; they merely object to the form and content of the specific requirements proposed by the FDA. Indeed, it seems likely the FDA did not make any such claims because the industry has complied precisely with all of the government's previous disclosure requirements, and continues to do so. Moreover, the Companies generally acknowledge the need for effective warnings and concede in their brief that they would be amenable to a number of new disclosure requirements, including putting the Act's new text on the side of packages, the bottom front of packages and advertisements, or using less shocking graphics. Appellees' Br. at 58.[8]

The amicus States suggest that the graphic warnings be evaluated in the context of the years of deception that preceded them.[9] States' Br. at 7. Citing *Warner-Lambert Co.*

---

[8] The dissent also claims that the government has provided "more than sufficient evidence that cigarette packages and other advertisements remain likely to mislead consumers notwithstanding the existing warnings." Dissent at 11. In the Final Rule, the FDA found that consumers are uninformed about "the nature and extent of the health risks associated with smoking cigarettes," Final Rule at 36,632, such as "the severity and magnitude" of those risks, their personal risks, the effects of secondhand smoke, and the highly addictive nature of cigarettes. *See id.* at 36,632-33. But none of the proposed warnings purport to address the information gaps identified by the government.

[9] To the extent that there is a concern about the Companies' past deception, the Act precludes them from "portray[ing] the use of tobacco as . . . healthful to minors," *see* Act § 2(17), 123 Stat. at

v. FTC, 562 F.2d 749 (D.C. Cir. 1977) they claim this Court has found that even advertisements that do not appear deceptive in isolation can constitute "part of a continuing deception of the public" absent highly visible warnings. *Id.* at 769. But the States' argument overlooks the broader context of that decision. *Warner-Lambert* involved a petition for review of an FTC order requiring the Warner-Lambert company to cease and desist from advertising that its product, Listerine mouthwash, prevents, cures, or alleviates the common cold. *Id.* at 752. As a remedial measure, the Commission required Warner-Lambert to include the following disclosure in every future advertisement for Listerine for a defined period: "Contrary to prior advertising, Listerine will not help prevent colds or sore throats or lessen their severity." *Id.* at 753. In other words, the disclosure statement was required as part of a corrective order which the Commission found necessary to "dissipate the effects of respondent's deceptive representations." *Id.* at 769; *see also Novartis Corp. v. FTC*, 223 F.3d 783, 788-89 (D.C. Cir. 2000) (upholding the Commission's corrective order imposing disclosure requirements on drug manufacturer).

By contrast, FDA does not frame *this* rule as a remedial measure designed to counteract specific deceptive claims made by the Companies, nor did it offer a remedial justification for the graphic warnings during the rulemaking proceeding. While the Companies' representations about "light" or "low tar" cigarettes might have been misleading, *see United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1124-26 (D.C. Cir. 2009), the Act now prohibits such

---

1778, by precluding the Companies from using "light" and other descriptors. *See* 21 U.S.C. § 387k. And Congress's objection to the Companies' portrayal of smoking as "socially acceptable" is likewise remedied by the constraints of the Act.

statements. *See* 21 U.S.C. § 387k. Unlike in *Warner-Lambert*, FDA has not shown that the graphic warnings were designed to correct any false or misleading claims made by cigarette manufacturers in the past.[10] Nor did it show that absent disclosure, consumers would likely be deceived by the Companies' packaging in the future. Rather, FDA framed the warnings as general disclosures about the negative health effects of smoking. The warnings thus represent an ongoing effort to discourage consumers from buying the Companies' products, rather than, as in *Warner-Lambert*, a measure designed to combat specific deceptive claims.

Moreover, the graphic warnings do not constitute the type of "purely factual and uncontroversial" information, *Zauderer*, 471 U.S. at 651, or "accurate statement[s]," *Milavetz*, 130 S. Ct. at 1340, to which the *Zauderer* standard may be applied. The disclosures approved in *Zauderer* and *Milavetz* were clear statements that were both indisputably accurate and not subject to misinterpretation by consumers. *See Zauderer*, 471 U.S. at 633 (describing the disciplinary rule that required "that any advertisement that mentions contingent-fee rates must disclos[e] whether percentages are computed before or after deduction of court costs and expenses"); *Milavetz*, 130 S. Ct. at 1330 (describing BAPCPA disclosure requirements, including, *inter alia*, a statement that "[w]e are a debt relief agency. We help people file for relief under the Bankruptcy Code.").

The FDA's images are a much different animal. FDA concedes that the images are not meant to be interpreted literally, but rather to symbolize the textual warning

[10] Such matters are the subject of a pending—and entirely separate—line of litigation against the Companies. *See Philip Morris USA Inc.*, 566 F.3d 1095.

statements, which provide "additional context for what is shown." Final Rule at 36,655. But many of the images chosen by FDA could be misinterpreted by consumers. For example, the image of a man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking—a more logical interpretation than FDA's contention that it symbolizes "the addictive nature of cigarettes," which requires significant extrapolation on the part of the consumers. *Id.* at 36,649. Moreover, the graphic warnings are not "purely" factual because—as FDA tacitly admits—they are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning. *See* Appellant's Br. at 33 (citing research showing that "pictures are easier to remember than words"); *id.* at 38 (citing FDA's finding that a substantial body of scientific literature shows that emotional responses, such as worry and disgust, "reliably predict the likelihood that consumers will understand and appreciate the substance of the warnings").

In fact, many of the images do not convey *any* warning information at all, much less make an "accurate statement" about cigarettes. For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words "I QUIT" do not offer any information about the health effects of smoking. And the "1-800-QUIT-NOW" number, when presented without any explanation about the services provided on the hotline, hardly sounds like an unbiased source of information. These inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting. *See* Final Rule at 36,697 ("[R]isk information is most readily

conveyed by warnings that elicit . . . strong emotional and cognitive reactions . . . ."). While none of these images are patently false, they certainly do not impart purely factual, accurate, or uncontroversial information to consumers. Consequently, the images fall outside the ambit of *Zauderer*.

b. Applicability of *Central Hudson*

Because this case does not fall within the narrow enclave carved out by *Zauderer*, we must next determine which level of scrutiny—strict or intermediate—is appropriate. The district court held that compelled speech that falls outside the *Zauderer* framework is subject to strict scrutiny. *See* Merits Op. at 14-16. *See also Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 554 (6th Cir. 2012) (deciding between applying strict scrutiny or *Zauderer* to compelled commercial speech); *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006) (same). The government argues that we should view the graphic warnings as restrictions on commercial speech, which are analyzed under the less rigorous standard established by *Central Hudson*. Despite the contrary views of other circuits, our governing precedent makes clear that *Central Hudson* is the appropriate standard.

This Court recently evaluated the constitutionality of compelled commercial speech in *United States v. Philip Morris*, where it reviewed a district court order requiring the defendant tobacco manufacturers to publish corrective statements on their websites, in newspapers, and on major television networks. 566 F.3d at 1142-43. This Court began by noting that "[b]ecause commercial speech receives a lower level of protection under the First Amendment, burdens imposed on it receive a lower level of scrutiny from the courts." *Id.* After acknowledging that "the standard for

assessing burdens on commercial speech has varied," the Court concluded that "the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are narrowly tailored to achieve a substantial government goal." *Id.* at 1143. *See also Novartis Corp.*, 223 F.3d at 789 (evaluating a corrective remedy involving corrective statements under *Central Hudson*). Because this case also involves a compelled commercial disclosure, we follow the lead of *Philip Morris* and apply the intermediate standard set forth in *Central Hudson.*

III. Evaluating the Graphic Warnings Under Intermediate Scrutiny

Under *Central Hudson*, the government must first show that its asserted interest is "substantial." 447 U.S. at 566.[11] If so, the Court must determine "whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.* The party seeking to uphold a restriction on commercial speech bears the burden of justifying it. *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). Because this case involves a challenge to final agency action, the Administrative Procedure Act governs our review of the record. *See* 5 U.S.C. § 706(2)(B) (providing that the APA applies to allegations that agency action is "contrary to constitutional right, power, privilege, or immunity"). The APA requires us to "hold unlawful and set aside agency action, findings, and

[11] *Central Hudson* also provides that commercial speech only receives First Amendment protection if it is a lawful activity and is not misleading or fraudulent. 447 U.S. at 566. Neither party seriously disputes that the cigarette packaging and advertisements regulated by the Act satisfy this threshold requirement.

conclusions found to be . . . unsupported by substantial evidence." 5 U.S.C. § 706(2).

Unlike rational-basis review, the *Central Hudson* standard does not permit this Court to "supplant the precise interests put forward by [FDA] with other suppositions." *Edenfield*, 507 U.S. at 768. We thus begin by identifying FDA's asserted interests.

A review of the statute and the administrative record makes clear that the graphic warnings are intended to encourage current smokers to quit and dissuade other consumers from ever buying cigarettes. One of the Act's many stated purposes is "promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases." Act § 3.9. The *only* explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates. The Proposed Rule states in its preamble that the government has a "substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products." Proposed Rule at 69,525. And the preamble to the Final Rule reiterates the same interest. Final Rule at 36,629.[12] Although

[12] Moreover, the Institute of Medicine Report, on which FDA relies for some of its evidence supporting the Rule, states unequivocally that "the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products . . . as a means of reducing tobacco-related death and disease." Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 291 (2007), *available at* http://www.nap.edu/catalog.php?record_id=11795. The Report goes on to state that "[e]ven though tobacco products are legally available to adults, the paramount public health aim is to reduce the number of people who use and become addicted to these products,

counsel attempted to disclaim this interest at oral argument, the administrative record shows otherwise: the primary objective of the Rule was "both to discourage nonsmokers from initiating cigarette use and to encourage current smokers to consider quitting." *Id.* at 36,630.

Assuming FDA's interest in reducing smoking rates is substantial,[13] we next evaluate whether FDA has offered substantial evidence showing that the graphic warning requirements "directly advance[] the governmental interest asserted," *Cent. Hudson*, 447 U.S. at 566, to a "material degree," *Fl. Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995). The government bears the burden of justifying its attempt to restrict commercial speech, *Edenfield*, 507 U.S. at 770, and its burden is not light. A restriction that "provides only ineffective or remote support for the government's purposes," *id.* at 770, is not sufficient, and the government cannot satisfy its burden "by mere speculation or conjecture." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). The requirement that a restriction directly advance the asserted interest is "critical," because without it, the government "could [interfere with] commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Id.*

---

through a focus on children and youths," and recommends that the "warnings must be designed to promote this objective." *Id.*

[13] Like the district court, we are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences. Nonetheless, the Supreme Court has at least implied that the government could have a substantial interest in reducing smoking rates because smoking poses "perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

FDA has not provided a shred of evidence—much less the "substantial evidence" required by the APA—showing that the graphic warnings will "directly advance" its interest in reducing the number of Americans who smoke. FDA makes much of the "international consensus" surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, Proposed Rule at 69,532, and FDA might be correct that intentions are a "necessary precursor" to behavior change, Final Rule at 36,642, it is mere speculation to suggest that respondents who report increased *thoughts* about quitting smoking will actually follow through on their intentions. And at no point did these studies attempt to evaluate whether the increased thoughts about smoking cessation led participants to actually quit. Another Australian study reported increased quit *attempts* by survey participants after that country enacted large graphic warnings, but found "no association with short-term quit success." Proposed Rule at 69,532. Some Canadian and Australian studies indicated that large graphic warnings *might* induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent. *See id.* But again, the study did not purport to show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates.

FDA's reliance on this questionable social science is unsurprising when we consider the raw data regarding smoking rates in countries that have enacted graphic warnings. FDA claims that Canadian national survey data

suggest that graphic warnings may reduce smoking rates. But the strength of the evidence is underwhelming, making FDA's claim somewhat misleading. In the year prior to the introduction of graphic warnings, the Canadian national survey showed that 24 percent of Canadians aged 15 or older smoked cigarettes. In 2001, the year the warnings were introduced, the national smoking rate dropped to 22 percent, and it further dropped to 21 percent in 2002. *Id.* at 69,532. But the raw numbers don't tell the whole tale. FDA concedes it cannot directly attribute *any* decrease in the Canadian smoking rate to the graphic warnings because the Canadian government implemented other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking, during the same period. *Id.* Although FDA maintains the data "are suggestive" that large graphic warnings "may" reduce smoking consumption, *id.*, it cannot satisfy its First Amendment burden with "mere speculation and conjecture." *Rubin*, 514 U.S. at 487.

FDA's Regulatory Impact Analysis ("RIA")[14] essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates. One way in which the RIA analyzed the expected benefits of the Rule was by comparing the impact of similar warnings introduced in Canada in 2000. *See* Final Rule at 36,719-20. It (1) analyzed the change in smoking trends in Canada before and after 2000; (2) assumed any difference in the post-2000 change between Canada and the United States was solely attributable to the introduction of graphic warnings; and (3)

[14] Such an analysis is required under Executive Order 12866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), which directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the approach that maximizes net benefits.

assumed similar warnings would have an identical impact on U.S. smoking rates. *See id.* at 36,755. Describing its approach as "rudimentary," FDA acknowledged that apart from differences in cigarette taxes, the RIA "d[id] not account for potential confounding variables," *id.* at 36,720-21, such as the introduction of more stringent smoking bans and advertising restrictions in Canada during the relevant time period, or the fact that Canadian cigarette prices are generally higher than U.S. prices. Plaintiffs' Comment Letter on Proposed Rule (Jan. 11, 2010) and Statement of Robert S. Maness.

Logic dictates that these procedural shortcuts would, if anything, lead to an overly optimistic prediction of the efficacy of the proposed graphic warnings. Not so. The RIA estimated the new warnings would reduce U.S. smoking rates by a mere 0.088%, Final Rule at 36,721, a number the FDA concedes is "in general not statistically distinguishable from zero." *Id.* at 36,776. Indeed, because it had access to "very small data sets," FDA could not even reject the statistical possibility that the Rule would have *no* impact on U.S. smoking rates. *Id.*

FDA has thus presented us with only two studies that directly evaluate the impact of graphic warnings on actual smoking rates, and neither set of data shows that the graphic warnings will "directly" advance its interest in reducing smoking rates "to a material degree." *Rubin*, 514 U.S. at 487. And one of the principal researchers on whom FDA relies recently surveyed the relevant literature and conceded that "[t]here is no way to attribute . . . declines [in smoking] to the new health warnings." David Hammond, *Health Warnings Messages on Tobacco Products: A Review*, 20 Tobacco Control 327, 331 (2011), *available at* http://tobaccocontrol.bmj.com/content/20/5/327.full.pdf. In

light of the number of foreign jurisdictions that have enacted large graphic warning labels, the dearth of data reflecting decreased smoking rates in these countries is somewhat surprising, and strongly implies that such warnings are *not* very effective at promoting cessation and discouraging initiation. While APA review of final agency action is deferential, it surely does not require us to accept a flawed interpretation of Canadian survey data or the agency's own projected 0.088% decrease in the U.S. smoking rate as "substantial evidence" that its warnings will advance its stated interest.

FDA attempts to downplay the significance of the RIA by explaining that it "must be included in all federal rulemaking to improve the internal management of the Federal Government," and that it "was not intended to second-guess Congress's judgment regarding the value of new health warnings." Pet. Reply Br. at 15-16.[15] FDA attempts to rehabilitate its findings by noting the analysis made only the "unremarkable point" that it is "difficult [to] determine with statistical precision the relative causal impact of the relevant contributing factors," particularly given the very small data sets to which FDA had access. *Id.* at 16. But FDA cannot get around the First Amendment by pleading incompetence or

[15] FDA also urges us to defer to Congress's judgment regarding the efficacy of the graphic warnings. *See Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 196 (1997). But deference is only warranted where Congress "base[s] its conclusions upon substantial evidence," *id.*, and Congress's predictive judgments are not "insulated from meaningful judicial review." *Turner*, 512 U.S. at 666. Deference is not appropriate here, because we find little evidence showing that the graphic warnings will advance the stated purpose of the statute—"promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases." Act. § 3.9.

futility. Because FDA bears the burden of justifying its proposed restraint on speech, it cannot claim—rather perversely—that its own analysis was irrelevant because it lacked precision and was based on insufficient data. *Central Hudson* requires FDA to find and present data supporting its claims *prior to* imposing a burden on commercial speech.

Alternatively, FDA asserts an interest in "effectively communicating health information" regarding the negative effects of cigarettes. Appellant's Br. at 28. But as FDA concedes, this purported "interest" describes only the *means* by which FDA is attempting to reduce smoking rates: "[t]he goal of effectively communicating the risks of cigarette smoking is, of course, related to the viewer's decision to quit, or never to start, smoking." *Id.* at 47. The government's attempt to reformulate its interest as purely informational is unconvincing, as an interest in "effective" communication is too vague to stand on its own. Indeed, the government's chosen buzzwords, which it reiterates through the rulemaking, prompt an obvious question: "effective" in what sense? Allowing FDA to define "effectiveness" however it sees fit would not only render *Central Hudson*'s "substantial interest" requirement a complete nullity, but it would also eviscerate the requirement that any restriction "directly advance" that interest. *See* 447 U.S. at 566. In this case, both the statute and the Rule offer a barometer for assessing the effectiveness of the graphic warnings—the degree to which they encourage current smokers to quit and dissuade would-be smokers from taking up the habit. *See* Final Rule at 36,630, 36,707-08. As such, FDA's interest in "effectively communicating" the health risks of smoking is merely a description of the means by which it plans to accomplish its goal of reducing smoking

rates, and not an independent interest capable of sustaining the Rule.[16]

IV. Conclusion

In the Proposed Rule, FDA lamented that their previous efforts to combat the tobacco companies' advertising campaigns have been like bringing a butter knife to a gun fight. According to the FTC, tobacco companies spent approximately $12.49 billion on advertising and promotion in 2006 alone, employing marketing and advertising experts to incorporate current trends and target their messages toward certain demographics. Proposed Rule at 69,531. The graphic warnings represent FDA's attempt to level the playing field, not only by limiting the Companies' ability to advertise, but also by forcing the Companies to bear the cost of disseminating an anti-smoking message. But as the Supreme Court recently reminded us, "[t]hat the [government] finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011). The First Amendment requires the government not only to state a substantial interest justifying a regulation on commercial speech, but also to show that its regulation directly advances that goal. FDA failed to present any data—much less the substantial evidence required under the APA—showing that enacting their proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates. The Rule thus cannot pass muster under *Central Hudson*.

---

[16] The dissent accuses us of "choosing to ignore" this interest, thereby ignoring our explanation that the government's stated interest in "effectively" communicating information is illusory absent some barometer for assessing that effectiveness.

The APA directs that we "shall . . . set aside [the] agency action . . . found to be contrary to constitutional right." 5 U.S.C. § 706(2). We therefore vacate the graphic warning requirements and remand to the agency. In so doing, we also vacate the permanent injunction issued by the district court, in furtherance of our obligation to "set aside" the unlawful regulation. *See, e.g.*, *N. Air Cargo v. United States Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) ("It was quite anomalous [for the district court] to issue an injunction. When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal.").

ROGERS, *Circuit Judge*, dissenting: The threshold question in this government appeal is whether the district court applied the correct level of scrutiny in addressing the tobacco companies' First Amendment challenge to the requirement that they disclose the negative health consequences of smoking on cigarette packages and other advertisements.[1] The speech at issue — proposing the sale of cigarettes — is indisputably commercial speech. Consequently, contrary to the district court's application of strict scrutiny, the question is whether, under the traditional standards adopted by the Supreme Court, the government's warning label requirement is subject to the "less exacting scrutiny" of *Zauderer v. Office of Disciplinary Council of the Supreme Court of Ohio*, 471 U.S. 626, 650–51 (1985), or to intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980). In affirming the grant of summary judgment to the tobacco companies, the court applies the wrong level of scrutiny, disregarding the tobacco companies' history of deceptive advertising and the government's stated "primary goal, which is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements," Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,633 (June 22, 2011) ("Final Rule").

Because the warning labels present factually accurate information and address misleading commercial speech, as

---

[1] In the district court, the tobacco companies sought injunctive relief and challenged the label warning requirement under the First Amendment and the Administrative Procedure Act ("APA"). The district court granted injunctive relief and summary judgment upon applying strict scrutiny and ruling that the warning label requirement violated the First Amendment. The district court did not reach the APA claims. *See R.J. Reynolds Tobacco Co. v. FDA*, 2012 WL 653828 (D.D.C. 2012).

defined in Supreme Court precedent, *Zauderer* scrutiny applies, and the government need show only that the warning label requirement is reasonably related to its stated and substantial interest in effectively conveying this information to consumers. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339–40 (2010); *Zauderer*, 471 U.S. at 650–51; *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, No. 11-1219, slip op. at 11 (D.C. Cir. July 24, 2012). Even treating *Zauderer*'s "less exacting scrutiny" as limited to disclosure requirements serving a governmental interest in preventing consumer deception, the voluminous findings of our own courts, cited and supplemented by Congress in the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), and the Federal Drug Administration ("FDA") in the Final Rule, are more than adequate to substantiate that interest.

Regardless of which level of scrutiny applies, the court errs in failing to examine both of the government's stated interests. In the rulemaking, the FDA articulated complementary, but distinct, interests in effectively conveying information about the negative health consequences of smoking to consumers and in decreasing smoking rates. *See*, *e.g.*, Final Rule, 76 Fed. Reg. at 36,633. The court dismisses the former interest as "too vague," Maj. Op. at 29, thereby sidestepping much of the substantial evidence supporting the warning label requirement. Yet this court has "recognize[d] that the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product . . . that can affect the public's health." *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999). Tobacco products necessarily affect the public health, and to a significant degree. Unlike other consumer products, "tobacco products are 'dangerous to health' when used in the manner prescribed." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 135 (2000). They are also highly

addictive. Consequently, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Id.* at 161. Thus, the government's informational interest "take[s] on added importance," *Pearson*, 164 F.3d at 656, and merits independent consideration. Upon consideration of this interest, the government appears to have met its burden under *Central Hudson* as well as *Zauderer*, except with regard to the additional inclusion of the "1-800-QUIT-NOW" number in each label.

Accordingly, because the district court erred in applying strict scrutiny to the commercial disclosures at issue, and because those disclosures, except as discussed below, appear to survive either level of scrutiny under traditional commercial speech precedent, I would reverse the grant of summary judgment, and I respectfully dissent.

I.

The context of the challenged warning label requirement can be summarized briefly. First, it is beyond dispute that the textual statements in the warning labels required under the Tobacco Control Act convey factually accurate information. Tobacco use is the leading preventable cause of death in the United States. It causes or contributes to at least sixteen kinds of cancer, as well as heart and cerebrovascular disease, chronic bronchitis, and emphysema, thereby "kill[ing] more than 400,000 Americans every year — more deaths than from AIDS, alcohol, car accidents, murders, suicides, drugs, and fires, combined." President's Cancer Panel, *Promoting Healthy Lifestyles* 61 (2007) (hereinafter "PCP Report"); *see id.* at 61–62. The nicotine contained in tobacco is "one of the most addictive substances used by humans." Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* 5 (2007) (hereinafter "IOM Report"). Despite increasing public

awareness that smoking is dangerous to one's health, most people still lack "a complete understanding of the many serious diseases caused by smoking, the true nature of addiction, or what it would be like to experience either those diseases or addiction itself." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 578 (D.D.C. 2006). Adolescents in particular tend "to underestimate or be uninformed about the difficulty of stopping smoking," IOM Report at E-8; as a result, "they are less likely to believe that the risk of addiction and related health consequences apply to them," *id.* at E-13. Over eighty percent of adult smokers became addicted to tobacco at or below the age of eighteen; of these smokers, half will die prematurely from a tobacco-related disease. PCP Report at 64. In view of these facts, the Supreme Court has recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 161.

Second, it is also beyond dispute that the tobacco companies have engaged in a decades-long campaign to deceive consumers about these facts. Despite knowledge of "the negative health consequences of smoking, the addictiveness and manipulation of nicotine, [and] the harmfulness of secondhand smoke," tobacco company executives "made, caused to be made, and approved public statements contrary to this knowledge." *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1121 (D.C. Cir. 2009). Specifically, they "publicly denied and distorted the truth about the addictive nature of their products, suppressed research revealing the addictiveness of nicotine, and denied their efforts to control nicotine levels and delivery," all while "engineer[ing] their products around creating and sustaining [nicotine] addiction." *Id.* at 1107. The tobacco company executives "knew of the[] falsity" of their statements "at the time" and "made the statements with the intent to deceive." *Id.* at 1124.

Beginning in 1965, the government undertook to warn consumers of the health risks associated with smoking by requiring the inclusion of a health warning on the side of cigarette packages. *See* Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (1965). Congress last revised the content and format of these warning labels in 1984. *See* Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984). Since then, "evidence regarding the ineffectiveness of the prescribed warnings has continued to accumulate," supporting the conclusion that these warnings "are unnoticed and stale, and they fail to convey relevant information in an effective way." IOM Report at 291.

In view of this background, in 2009 Congress enacted the Tobacco Control Act. Congress found that "[a] consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects," and that "[n]icotine is an addictive drug." Tobacco Control Act § 2(2), (3), 123 Stat. at 1777 (codified at 21 U.S.C. § 387 Note (2011)). Additionally, Congress found that in 2005 the tobacco companies "spent more than $13 [billion] to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use," *id.* § 2(16), "often misleadingly portray[ing] the use of tobacco as socially acceptable and healthful to minors," *id.* § 2(17). Based on these and other findings, Congress required, as relevant, the rotating display of one of nine textual warnings,[2]

---

[2] "WARNING" precedes each of the textual statements, which consist of the following: "Cigarettes are addictive"; "Tobacco smoke can harm your children"; "Cigarettes cause fatal lung disease"; "Cigarettes cause cancer"; "Cigarettes cause strokes and heart disease"; "Smoking during pregnancy can harm your baby";

accompanied by "color graphics depicting the negative health consequences of smoking" to be selected by the Secretary of Health and Human Services, on cigarette packages and other advertisements. Tobacco Control Act § 201(a), 123 Stat. at 1842–45 (codified at 15 U.S.C. § 1333 Note (2011)) (hereinafter "Section 201"). These requirements become effective fifteen months from the issuance of the implementing regulations. *See id.* § 201(b).

In the Final Rule, the FDA, acting on behalf of the Secretary,[3] stated that its "primary goal" in selecting the graphic images pursuant to Section 201 was "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements." Final Rule, 76 Fed. Reg. at 36,633; *see also id.* at 36,641. The FDA also explained that "this effective communication can help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health." *See id.*; *see also id.* at 36,640. In selecting nine of the thirty-six graphic images presented in the proposed rule, *see* Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524 (proposed Nov. 12, 2010) ("Proposed Rule"), the FDA relied on the results of a consumer study conducted, in part, "to quantitatively evaluate the [relative] efficacy of the

---

"Smoking can kill you"; and "Tobacco smoke causes fatal lung disease in nonsmokers." Tobacco Control Act § 201, 15 U.S.C. § 1333 Note.

[3] Congress contemplated that the selection of the graphic images would be made by the FDA in view of its "scientific expertise . . . to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health." Tobacco Control Act § 2(44), 21 U.S.C. § 387 Note.

proposed required warnings in communicating the health harms of smoking to adults . . . , young adults . . . , and youth" ("FDA study"). Final Rule, 76 Fed. Reg. at 36,635; *see id.* at 36,637–39. In particular, the FDA focused on the salience measures reported for each of the thirty-six graphic images considered in the study; these measures included "[e]motional reactions, cognitive reactions, and [reactions as to] whether the warning was difficult to look at." *Id.* at 36,696. Echoing the Institute of Medicine in justifying its reliance on these measures, the use of which "is well-established in the scientific literature," *id.* at 36,696–97, the FDA explained that "the literature suggests that risk information is most readily communicated by messages that arouse emotional reactions, and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings . . . ." *Id.* at 36,639; *see* IOM Report at C-3. After considering the results of the FDA study "and a number of other factors," the FDA "concluded that the nine selected required warnings effectively communicate the negative health consequences of smoking." *Id.* at 36,637.

II.

"Because the degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes commercial or noncommercial speech, we must *first* determine the proper classification of the [speech] at issue here." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 65 (1983) (emphasis added). Recognizing "the 'commonsense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech," the Supreme Court has repeatedly instructed that the "Constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression," *Central Hudson*, 447

U.S. at 562–63 (citations and internal quotation marks omitted).[4] The Court has reasserted this "commonsense" distinction in the context of compelled speech, differentiating between attempts to "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein" and attempts "only to prescribe what shall be orthodox in commercial advertising." *Zauderer*, 471 U.S. at 651 (citations and internal quotation marks omitted).[5]

---

[4] Notwithstanding any intimations it may have made in cases such as *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), the Supreme Court has continued to apply the more deferential framework of *Central Hudson* to commercial speech restrictions. *See id.* at 2667–68, 72. As the court acknowledges, *see* Maj. Op. at 21–22, it therefore remains incumbent on this court to distinguish between commercial and noncommercial speech for purposes of determining the degree of protection afforded tobacco companies' speech under the First Amendment and, consequently, the level of scrutiny to apply. *See Philip Morris*, 566 F.3d at 1142–43. In any event, the Supreme Court's rationale in *Sorrell* — that "the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech," *Sorrell*, 131 S. Ct. at 2670–71 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002)) — does not apply here, where it is the tobacco companies that seek to suppress truthful information.

[5] The tobacco companies advance no argument that their cigarette packaging and advertisements propose anything other than a commercial transaction. Nor could they, in part because of this court's determination that tobacco companies' attempts to persuade the public to purchase cigarettes, even in formats that did not explicitly propose a commercial transaction, constituted commercial speech. *See Philip Morris*, 566 F.3d at 1143–44. Instead, the tobacco companies maintain that the character of the warning labels themselves triggers the application of strict scrutiny. *See* Appellees' Br. at 35–36. Turning the premise of the Supreme Court's holding in

Indeed, in view of "material differences between disclosure requirements and outright prohibitions on speech," *id.* at 650, the Supreme Court has taken this distinction a step further. Whereas in the context of noncommercial speech, "compulsion to speak may be as violative of the First Amendment as prohibitions on speech" and thus trigger the same level of scrutiny, *id.*, in the context of commercial speech, compulsion to speak may be *less* violative of the First Amendment than prohibitions on speech and thus trigger a *lower* level of scrutiny, *see id.* at 650–51. "Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," the Court explained, "disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech . . . ." *Id.* at 651 (citations omitted); *see id.* at 651 n.14; *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). Consequently, while "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech[,] . . . an advertiser's rights are adequately protected as long as

---

Zauderer on its head, they assert that "attempts to regulate 'what shall be orthodox in . . . matters of opinion' — *i.e.*, whether individuals should buy and use a lawful product — must be subject to strict scrutiny." Appellees' Br. at 31 (quoting *Zauderer*, 471 U.S. at 651). To the contrary, because matters of opinion over whether individuals should buy and use a lawful product fall squarely within the domain of commercial advertising recognized by the Supreme Court, the regulation thereof is not, as the district court ruled, subject to strict scrutiny. *See Zauderer*, 471 U.S. at 651; *Central Hudson*, 447 U.S. at 562; *Philip Morris*, 566 F.3d at 1142–44. For this reason, the court's invocation of *non*commercial compelled speech cases like *Wooley v. Maynard*, 430 U.S. 705 (1977), *West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943), and *Pacific Gas & Electric Co. v. Public Utilities Commission of California*, 475 U.S. 1 (1986), *see* Maj. Op. at 9–10, is unavailing.

disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 651; *see Milavetz*, 130 S. Ct. at 1339–40.[6]

As the Supreme Court explained in *Milavetz*, where the challenged requirements are "directed at *misleading* commercial speech," and where they "impose a disclosure requirement rather than an affirmative limitation on speech, . . . the less exacting scrutiny described in *Zauderer* governs [a court's] review." 130 S. Ct. at 1339; *see Spirit Airlines*, No. 11-1219, slip op. at 11. The warning label requirement meets both of these criteria.

First, the government need show only that the targeted commercial speech presents the "possibility of deception" or a "tendency to mislead." *Milavetz*, 130 S. Ct. at 1340 (citation and internal quotation marks omitted). If the speech is actually misleading, it enjoys no First Amendment protection. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Central Hudson*, 447 U.S. at 566. Where "the likelihood of deception" is "hardly a speculative one," the government need not produce "evidence that [the] advertisements are misleading,"

---

[6] As other circuits have recognized, in *Zauderer* the Supreme Court appears simply to have held that a government interest in protecting consumers from possible deception is *sufficient* to support a disclosure requirement — not that this particular interest is *necessary* to support such a requirement. *See Zauderer*, 471 U.S. at 650–51; *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 556 (6th Cir. 2012); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 133 & n.21 (2d Cir. 2009); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001). In view of the likelihood of consumer confusion or deception shown here, there is no need to determine whether the scope of *Zauderer* encompasses other government interests.

as the court may rely instead on experience and common sense. *Spirit Airlines*, slip. op. at 13 (alteration in original) (quoting *Milavetz*, 130 S. Ct. at 1340) (internal quotation marks omitted). In *Milavetz*, the Supreme Court concluded that a law firm's advertisements were "inherently misleading" because they "promise[d] . . . debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." *Milavetz*, 130 S. Ct. at 1340. Thus, absent any additional evidence, the Court considered the omission of a reference to a possible outcome with "inherent costs" to be sufficiently misleading as to warrant review under *Zauderer*. Even advertisements that display all the costs of a service may remain misleading. In *Spirit Airlines*, this court addressed a Department of Transportation ("DOT") rule requiring that the most prominent number displayed in airfare advertisements be the total price, inclusive of taxes. *Spirit Airlines*, slip. op. at 4. Notwithstanding the airlines' compliance with preexisting regulations requiring advertisements to display the entire ticket cost as well as the amount of any tax, the court accepted DOT's determination, based on common sense and experience, "that it was deceitful and misleading when the most prominent price listed by an airline is anything other than the total, final price of air travel." *Id.* at 13. Accordingly, the court proceeded to review the rule under *Zauderer*. *See id.* at 14.

Even absent any affirmatively misleading statements, *see* Maj. Op. at 16, cigarette packages and other advertisements that fail to display the final costs of smoking in a prominent manner are at least as misleading as the airline advertisements in *Spirit Airlines*. Existing warnings, last revised in 1984, appear on one side panel and occupy only four percent of cigarette packages. *See* Final Rule, 76 Fed. Reg. at 36,678. Common sense, experience, and substantial scientific evidence support the conclusion that these warnings are ineffective. "For example," in 2007 the Institute of Medicine "concluded that U.S. package

warnings are both 'unnoticed and stale.'" Proposed Rule, 75 Reg. at 69,530 (quoting IOM Report at 291); *see generally id.* The government has thus provided more than sufficient evidence that cigarette packages and other advertisements remain likely to mislead consumers notwithstanding the existing warnings. *See Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 562–63 (6th Cir. 2012). Yet it goes even further, demonstrating that these warnings actually "have failed to convey appropriately crucial information such as the nature and extent of the health risks associated with smoking cigarettes." Final Rule, 76 Fed. Reg. at 36,632; *see* Proposed Rule, 75 Fed. Reg. at 69,530–31 (citing studies); *see also Discount Tobacco*, 674 F.3d at 563–64. Even though "most smokers understand that smoking poses certain statistical risks to their health," studies noted by the FDA show that "many fail to appreciate the severity and magnitude of those risks." Final Rule, 76 Fed. Reg. at 36,632. Moreover, "many smokers underestimate their personal risks." *Id.* (noting, for example, studies in which only a minority of smokers believed they were at increased risk for cancer and heart disease). Many people are also unaware of the effects of secondhand smoke on others. *See id.* at 36,633. And adolescents in particular fail to appreciate the highly addictive nature of cigarettes. *See id.*; *see also Philip Morris*, 449 F. Supp. 2d at 578.

Furthermore, even if (contrary to Supreme Court and this court's precedent) these findings were inadequate to establish a "tendency to mislead," this court has recognized that certain advertisements, "although not misleading if taken alone," can "become[] misleading" when "considered in light of past advertisements." *Warner-Lambert Co. v. FTC*, 562 F.2d 749, 760 (D.C. Cir. 1977); *see id.* at n.57.[7] In other words, a

[7] The court attempts to distinguish *Warner-Lambert* on the ground that the FDA "does not frame *this* rule as a remedial measure

"tendency to mislead" may arise through efforts to "capitalize on . . . prior deceptions by continuing to advertise in a manner that builds on consumers' existing misperceptions." *Philip Morris*, 566 F.3d at 1144–45 (citing *Warner-Lambert*, 562 F.2d at 769). This court has already acknowledged the tendency of cigarette marketing to mislead consumers based on the companies' decades of deception regarding each of the risks identified in the warning labels. *See Philip Morris*, 566 F.3d at 1144; *supra* Part I.[8] Consistent with that decision, Congress found that "[t]obacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors." Tobacco Control Act § 2(17), 21 U.S.C. § 387 Note. These findings are more than "adequate to establish that

---

designed to counteract specific deceptive claims made by the Companies." Maj. Op. at 18. Even if *Warner-Lambert*'s reasoning were limited to remedial measures, surely Congress could provide the requisite "framing." Especially in view of the high level of specificity with which Congress crafted the warning label requirement, it was not incumbent upon the FDA to supplement the congressional findings already supporting the requirement. Nonetheless, the FDA *did* frame its rule as a measure designed to counteract specific gaps in consumers' knowledge of the health risks of smoking, *see* Final Rule, 76 Fed. Reg. at 36,632–33 — gaps that align with specific deceptive claims made by the tobacco companies, *see Philip Morris*, 566 F.3d at 1106–07, 1118–19.

[8] Indeed, in addressing a RICO injunction, this court recently acknowledged the "reasonable likelihood" — notwithstanding the restrictions imposed in the Tobacco Control Act — that the tobacco companies would commit future RICO violations, *United States v. Philip Morris USA Inc.*, No. 11-5145, slip op. at 9 (D.C. Cir. July 27, 2012), where their past RICO violations consisted of proven "misstatements and acts of concealment and deception . . . made intentionally and deliberately . . . as part of a multi-faceted, sophisticated scheme to defraud," *id.* at 3; *see United States v. Philip Morris USA, Inc.*, 787 F. Supp. 2d 68, 74–75 (D.D.C. 2011).

the likelihood of deception in this case 'is hardly a speculative one.'" *Milavetz*, 130 S. Ct. at 1340; *see Discount Tobacco*, 674 F.3d at 562.

Second, the warning label requirement does not impose "an affirmative limitation on speech," *Milavetz*, 130 S. Ct. at 1339; rather, the warning labels disclose information about the negative health consequences of smoking. (The one exception is discussed *infra*.) Unlike other provisions of the Tobacco Control Act, Section 201 does not restrict the information conveyed to consumers, but requires additional information to be conveyed with the aid of graphic images. Although the tobacco companies object that the warnings "monopolize all the prominent space on cigarette packages, and thereby make it impossible for manufacturers to communicate their own messages and their own viewpoints *prominently* in packaging," Joint Comments of R.J. Reynolds Tobacco Co., Lorillard Tobacco Co. & Commonwealth Brands, Inc. 9 (Jan. 11, 2010) (J.A. 216) (emphasis added), their objection rings hollow in the absence of *any* evidence of difficulty in conveying their desired messages notwithstanding a decade of experience under a similar warning label requirement in Canada. *See* Final Rule, 76 Fed. Reg. at 36,633, 36,698; Appellants' Br. at Add. 6–12; *cf. Ibanez v. Fla. Dep't Bus. & Prof'l Regulation*, 512 U.S. 136, 146–47 (1994). Consequently, they fail to show that the warning label requirement is "an affirmative limitation on speech." *Milavetz*, 130 S. Ct. at 1339; *see Spirit Airlines*, No. 11-1219, slip op. at 14. To the extent the warning labels disclose factually accurate information about the cigarettes being advertised, then, *Zauderer* offers the appropriate level of scrutiny.

The tobacco companies do not challenge the factual accuracy of the textual statements included in the warning labels. *See* Appellees' Br. at 54–55. Nor could they reasonably

do so, given the scientific consensus "that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." Tobacco Control Act § 2(2), 21 U.S.C. § 387 Note; *see* Final Rule, 76 Fed. Reg. at 36,641; Proposed Rule, 75 Fed. Reg. at 69,527–29. The question for purposes of the First Amendment analysis, then, is whether the graphic images selected by the FDA to accompany the factually accurate textual statements render the warnings nonfactual or controversial. To answer this question, the court must — although the court does not, *see* Maj. Op. at 19–20 — view the images in connection with the textual warnings they accompany. *See, e.g.*, *S. Air Transp., Inc. v. Am. Broad. Cos., Inc.*, 877 F.2d 1010, 1015 (D.C. Cir. 1989).

Contrary to the tobacco companies' suggestion, *see* Appellees' Br. at 24, the use of graphic images, even if digitally enhanced, illustrated, or symbolic, does not necessarily make the warnings nonfactual. The Supreme Court recognized in *Zauderer* that "[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart information directly." *Zauderer*, 471 U.S. at 647; *see N.Y. Times Co. v. NASA*, 920 F.2d 1002, 1005 (D.C. Cir. 1990); *see, e.g.*, 16 C.F.R. § 1500.14 (2011) (requiring skull-and-crossbones warnings on poisonous products). In the Final Rule, the FDA concluded that "the effects shown" in the images "are, in fact, accurate depictions of the effects of sickness and disease caused by smoking," Final Rule, 76 Fed. Reg. at 36,696, and the tobacco companies do not suggest otherwise. That such images are not invariably comforting to look at does not necessarily make them inaccurate. As the FDA went on to explain the obvious fact, "the severe, life-threatening and sometimes disfiguring health effects of smoking conveyed in the required warnings *are*

disturbing and the images [it] . . . selected appropriately reflect this fact." Final Rule, 76 Fed. Reg. at 36,696.

The tobacco companies further object that the graphic images were chosen not to convey information, but to evoke negative emotions and thereby discourage smoking. *See* Appellees' Br. at 26–27. The FDA explained, however, that "considerable scientific evidence shows that health warnings that elicit strong emotional and cognitive reactions," as reflected in their salience measures, "are better processed and more effectively communicate information about the negative health consequences of smoking." Final Rule, 76 Fed. Reg. at 36,642; *see id.* at 36,639, 41, 46; IOM Report at C-3. Thus, the FDA's reliance on salience measures was in the service of — not inconsistent with — the warnings' informational purpose. Moreover, factually accurate, emotive, and persuasive are not mutually exclusive descriptions; the emotive quality of the selected images does not necessarily undermine the warnings' factual accuracy.[9] Comprehending the facts about the actual

---

[9] The district court relied on *Entertainment Software Association v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), for the proposition that label requirements "ultimately communicat[ing] a subjective and highly controversial message" fall outside the scope of "purely factual and uncontroversial" disclosures permitted under *Zauderer*. *R.J. Reynolds*, 2012 WL 653828 at *6 (quoting *Blagojevich*, 469 F.3d at 652) (internal quotation marks omitted). But *Blagojevich* involved labels that were necessarily subjective and exclusively nonfactual. As the Supreme Court later explained, because video games "communicate ideas — and even social messages," they enjoy full First Amendment protection, which guards against government efforts "to restrict expression because of its message, its ideas, its subject matter, or its content." *Brown v. Entm't Merchs. Ass'n*, 131 S. Ct. 2729, 2733 (2011) (citation and internal quotation marks omitted). The labels at issue in *Blagojevich* represented exactly such an effort: the challenged provision required

harms resulting from smoking is likely to provoke emotional reactions and also to discourage the use of cigarettes. *See* Final Rule, 76 Fed. Reg. at 36,647. The tobacco companies' argument leads to the counterintuitive conclusion that the more concerning the negative health effects of a particular product, the more constrained the government is in mandating disclosures of those facts. Unsurprisingly, the tobacco companies point neither to any case law in support of this argument nor to any legally significant distinction between fact and emotion. *See* Appellees' Br. at 24–25. Rather, the greater the harms to public health, the greater the government's interest in informing consumers of those harms. *See Pearson*, 164 F.3d at 656. This interest is especially great in view of the tobacco companies' extensive advertising that Congress found was "often misleading[]" and designed to attract adolescents and new users, retain and expand consumption, and "generate favorable long-term attitudes toward smoking and tobacco use." Tobacco Control Act § 2(16)–(18), 21 U.S.C. § 387 Note.

Aside from their general objections to the inclusion of graphic images for the above reasons, the tobacco companies specifically object to five of the nine selected images. They maintain that the images of a man smoking through a tracheotomy hole in his throat and a man with chest staples on an autopsy table convey misleading messages about the consequences of smoking, and that the images of a man wearing a t-shirt reading "I QUIT," a baby enveloped in smoke, and a woman crying convey no information about the consequences of smoking whatsoever. *See* Appellees' Br. at 25–26. All of

---

the label to be placed on games deemed "sexually explicit," the state's definition of which was "far more opinion-based than the question of whether a particular chemical is within any given product." *Blagojevich*, 469 F.3d at 652. These labels were nonfactual because there were no facts to convey.

these objections pertain to the images divorced from their accompanying text and thus fail to address the relevant question — whether the images render the *overall* message conveyed by the warning labels nonfactual. Viewed with the text they accompany, none of these images has that effect.

The image accompanying the textual warning "Cigarettes are addictive" depicts a man smoking through a tracheotomy opening in his throat. Viewed with the accompanying text, this image conveys the tenacity of nicotine addiction: even after under undergoing surgery for cancer, one might be unable to abstain from smoking. Indeed, government counsel represented that this situation is not so extreme or unusual as the court and the tobacco companies suggest. *Compare* Oral Arg. Tr. at 57 (stating that fifty percent of neck and head cancer patients continue to smoke) *with* Maj. Op. at 20; Appellees' Br. at 25. This representation finds support from the President's Cancer Panel. "Smoking among cancer survivors (including individuals diagnosed with, being treated for, and surviving cancer)," the Panel reported, "is an underappreciated and understudied problem." PCP Report at 70. "[S]moking prevalence in this population is approximately equivalent to people with no history of cancer," despite "mounting evidence confirm[ing] the adverse effects of continued smoking on cancer treatment outcomes regardless of treatment modality." *Id.*[10] This image thus serves to underline the factual, and now uncontroversial, statement that cigarettes are highly addictive.

---

[10] *See also* 155 CONG. REC. S6021 (daily ed. June 3, 2009) (statement of Sen. Lautenberg) (sharing testimony of woman who, "despite the fact that she had essentially lost her voice box, . . . still smoked through the hole in her throat," and explaining that "[t]he hold on people is almost unbreakable").

Similarly, the image of a man with staples in his chest lying on an autopsy table works with, not against, the textual warning "Smoking can kill you." Assuming "autopsies are not a common consequence of smoking," Appellees' Br. at 25, neither are coffins or gravestones; yet the status evoked by images of an autopsy-scarred man, a coffin, or a gravestone — death — is a common consequence of smoking. *See* Proposed Rule, 75 Fed. Reg. at 69,526; PCP Report at 61, 64. The FDA might have opted for an image of a decaying cadaver or of a pile of ashes to portray the likely physical consequences of smoking, but it was not limited to such images in its representation of those consequences. An autopsy scar is merely one way of communicating that the man in the image is dead; viewed in connection with the textual warning, the image conveys the message that smoking can result in death.

The images of a baby enveloped in smoke and a woman crying both depict the significant harms of secondhand smoke. These images accompany the textual warnings "Tobacco smoke can harm your children" and "Tobacco smoke causes fatal lung disease in nonsmokers," respectively. Regarding the former image, commenters noted that it would "clearly inform parents that when they smoke in the presence of their children, their children will also be inhaling toxins." Final Rule, 76 Fed. Reg. at 36,650. The latter image, as the FDA explained, highlights the "emotional suffering" dimension of fatal lung disease and other "negative health consequences caused by secondhand smoke exposure." *Id*. at 36,656. Those negative health consequences are significant. Secondhand smoke "has been established as a cause of approximately 3,000 lung cancer deaths each year among nonsmokers in the United States"; it also "is a significant contributor to cardiac, respiratory, and other diseases in individuals exposed to it." PCP Report at 95; *see id.* at 95–96. As a result, secondhand smoke exposure "claims the lives of approximately 38,000 nonsmokers annually." *Id.* at 95.

Addressing potential purchasers of cigarettes, these two warning labels convey the message that smoking poses risks not only to them, but also to their family members and others.

Initially more problematic is the image of a man wearing a t-shirt that reads "I QUIT," which the tobacco companies maintain "provides no information about smoking risks (or even the benefits of quitting)." Appellees' Br. at 26. But the tobacco companies overstate the objection, for the image does address the benefits of quitting. As the FDA viewed this image, in connection with the textual warning "Quitting smoking now greatly reduces serious risks to your health," it conveys the message "I quit, and I am alive and healthy." This message comports with the evidence showing that "[s]moking cessation decreases the risk of the health consequences of smoking." Proposed Rule, 75 Fed. Reg. at 69,529. "For example, persons who quit smoking before age 50 have one-half the risk of dying in the next 15 years compared with continuing smokers." *Id.* Nothing in this image, or any other image selected by the FDA, renders nonfactual or controversial the textual warning it accompanies. The warning labels thus qualify as factually accurate, uncontroversial disclosures.

Because the warning labels are "directed at *misleading* commercial speech," and because they "impose a disclosure requirement rather than an affirmative limitation on speech, . . . the less exacting scrutiny described in *Zauderer*" should have governed the district court's review. *Milavetz*, 130 S. Ct. at 1339. While mindful that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech," the district court should have determined whether the warning label requirement was "reasonably related" to the government's interest in effectively conveying the negative health consequences of smoking to

consumers. *Zauderer*, 471 U.S. at 651; *see Milavetz*, 130 S. Ct. at 1339–40.

Under this "less exacting scrutiny," the warning label requirement appears to pass muster. The government need only justify the requirement on the basis of substantial evidence on the record. *See Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996, 1002 (D.C. Cir. 2009). In view of the scientific literature supporting the FDA's reliance on the salience measures reported in its study, *see* Final Rule, 76 Fed. Reg. at 36,638, 36,642, 36,649–57, the warning label requirement is reasonably related to the government's interest in effectively communicating information about the negative health consequences of smoking. And in view of extensive scientific literature, *see* Proposed Rule, 75 Fed. Reg. at 69,531 (citing IOM Report at C-3–4), international experience, *see id.* at 69,531–32, domestic experience, *see* Final Rule, 76 Fed. Reg. at 36,632, and common sense, the size and placement of the warning labels is also reasonably related to that interest. Although some graphic images may evoke emotional reactions, it is undisputed that smoking can cause the health consequences they depict. Given the magnitude of the government interest in informing consumers of these consequences (especially against the tobacco companies' history of consumer deception), the expert judgment exercised by the FDA in selecting the graphic images, and the absence of any evidence that similar restrictions elsewhere have hindered the tobacco companies' ability to get their own message to consumers, the burden on the tobacco companies' First Amendment rights appears neither undue nor unjustified. The warning label requirement thus appears constitutional. *See Zauderer*, 471 U.S. at 651; *cf. Discount Tobacco*, 674 F.3d at 569.

Attempting to distinguish *Zauderer*, the court adopts the view that the warning label requirement involves "elements of

compulsion and forced subsidization." Maj. Op. at 10. Commercial disclosure requirements can involve involuntary statements and compliance costs. *See, e.g.*, *Milavetz*, 130 S. Ct. at 1340–41; *Meese v. Keene*, 481 U.S. 465, 467, 481–82 (1987). Nonetheless, the Supreme Court has reviewed such requirements under a different level of scrutiny than noncommercial compelled speech, *cf. Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 8–9 (1986), and under a different set of considerations than compelled subsidies of private speech, *cf. United States v. United Foods, Inc.*, 533 U.S. 405 (2001). Contrary to the court's conclusion that "this case raises novel questions about the scope of the government's authority," Maj. Op. at 11, given the congressional findings and regulatory record supporting the government's interest in effectively informing consumers of the negative, indeed potentially lethal, consequences of smoking, the warning label requirement falls within the scope of the Supreme Court's traditional First Amendment treatment of commercial disclosures.

Unlike the graphic images envisioned in Section 201, however, the additional inclusion of the telephone number "1-800-QUIT-NOW" on each warning label does not directly disclose factual information about the health consequences of smoking. The FDA imposed this requirement, pursuant to separate statutory authority, 21 U.S.C. § 387f(d), s*ee* Final Rule, 76 Fed. Reg. at 36,681, in order "to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support," Proposed Rule, 75 Fed. Reg. at 69,540. In the FDA's view, inclusion of the number would also enhance the effectiveness of the warning labels. *See* Final Rule, 76 Fed. Reg. at 36,681. To the extent the purpose is directed toward reducing smoking rates, the constitutionality of the number's mandatory inclusion in the warning labels requires

examination under a different standard than *Zauderer*, to which I now turn.

III.

Where *Zauderer* scrutiny is inapplicable to a commercial speech regulation, "the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are 'narrowly tailored' to achieve a substantial government goal." *Philip Morris*, 566 F.3d at 1143 (quoting *Bd. of Trs. v. Fox*, 492 U.S. 469, 480 (1989)); *see Milavetz*, 130 S. Ct. at 1339. In applying this level of intermediate scrutiny, the court must determine (1) whether the speech "concern[s] lawful activity and [is] not . . . misleading," such that it enjoys First Amendment protection; (2) whether the government asserts a substantial interest; (3) "whether the regulation directly advances" that interest; and (4) whether the regulation "is not more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566. With regard to the third prong of this test, the Supreme Court has clarified that, although the government "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree," it may do so "by reference to studies and anecdotes pertaining to different locales altogether, or even . . . based solely on history, consensus, and simple common sense." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (citations and internal quotation marks omitted). And with regard to the fourth prong, "[t]he government does not have to show that it has adopted the least restrictive means for bringing about its regulatory objective; it does not have to demonstrate a perfect means—ends fit; and it does not have to satisfy a court that it has chosen the best conceivable option." *Nat'l Cable*, 555 F.3d at 1002. "The only condition is that the regulation be proportionate to the interests sought to be advanced," *id.* — that

there be "a reasonable fit between the means and ends of the regulatory scheme," *Lorillard*, 533 U.S. at 561; *see id.* at 556.

Even assuming that the graphic images, by depicting the actual negative consequences of cigarette smoking and thereby evoking emotional reactions, "go beyond . . . purely factual and accurate commercial disclosures," Maj. Op. at 11, there would still appear, with one exception, no basis to conclude that the warning label requirement violates the tobacco companies' First Amendment rights. The court reaches the opposite conclusion by dismissing one of the two government interests stated in the rulemaking. Its analysis is directed to a red herring of its own creation. Although there are statements in the rulemaking record regarding the government's interest in reducing smoking rates, *see, e.g.*, Final Rule, 76 Fed. Reg. at 36,629; Proposed Rule, 75 Fed. Reg. at 69,525, nothing in that record, much less the White House press briefing cited by the court, *see* Maj. Op. at 11 n.6, suggests these statements were intended to override the clearly stated interest in effectively communicating information about the negative health consequences of smoking to consumers. (Nor does the Institute of Medicine's characterization of the objectives of tobacco regulation, *see* Maj. Op. at 23 n.12, detract from the FDA's own statement of the government's "primary" interest.) To the contrary, in the rulemaking the FDA stated repeatedly that, "[c]onsistent with the Tobacco Control Act, the purpose of these required warnings is to communicate effectively and graphically the very real, scientifically established adverse health consequences of smoking." Final Rule, 76 Fed. Reg. at 36,641; *see id.* at 36,630, 36,633–42, 36,646–47, 36,696–97, 36,699; Proposed Rule, 75 Fed. Reg. at 69,526, 69,531–35. Even under *Central Hudson* intermediate scrutiny, the court should have fully examined both of the government's stated interests.

The government's informational interest in effectively conveying the negative health consequences of smoking clearly qualifies as "substantial" under the second prong of *Central Hudson*. "The Supreme Court has said 'there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial,'" *Pearson*, 164 F.3d at 656 (quoting *Edenfield v. Fane*, 507 U.S. 761, 769 (1993)) (alteration in original), "and that the government has a substantial interest in 'promoting the health, safety, and welfare of its citizens,'" *id.* (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995)). This court has previously "recognize[d] that the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product . . . that can affect the public's health." *Id.* And "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 161. Congress agreed. *See* Tobacco Control Act § 2(29), 21 U.S.C. § 387 Note. The government interest in effectively conveying the negative health consequences of smoking takes on even greater importance in view of the highly addictive nature of tobacco and the fact that "the most serious harmful consequences of smoking are cumulative, and occur in the distant future." *Philip Morris*, 449 F. Supp. 2d at 577.

The warning label requirement appears to meet the third and fourth prongs of *Central Hudson* as well. The rulemaking record includes substantial evidence from international experience, *see* Proposed Rule, 75 Fed. Reg. at 69,531–32, and the FDA Study, *see* Final Rule, 76 Fed. Reg. at 36,637–42, supporting the government's reasoned determination that the warnings would "directly advance" its informational interest, not least by "ensur[ing] that the health risk message[s] [are] actually *seen* by consumers in the first instance." *Commonwealth*

Brands, Inc. v. United States, 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010), *aff'd in relevant part, Discount Tobacco*, 674 F.3d at 569. "The harms [the government] recites are real" — caused in part by the "often misleading" advertising that smoking is part of a healthy lifestyle without consequences — and there is substantial evidence to support the government's conclusion that the warning label requirement "will in fact alleviate [those harms] to a material degree." *Lorillard*, 533 U.S. at 555. "[H]istory, consensus, and 'simple common sense,'" *id.* (quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995)), demonstrate as well that warning label requirement meets the fourth prong of the *Central Hudson* test. The failures of previous government efforts to convey the relevant information through small, textual warnings on the side of cigarette packages, *see* Final Rule, 76 Fed. Reg. at 36,631–32; Proposed Rule, 75 Fed. Reg. at 69,530–31, similar to the alternatives the tobacco companies now suggest, *see* Appellees' Br. at 58–59, are sufficient to show that the warning labels, with graphic images, are "not more extensive than necessary to serve" the government's substantial interest in *effectively* conveying that information to consumers.

The one exception is the "1-800-QUIT-NOW" telephone number. As mentioned, it is not designed directly to inform consumers of the health consequences of smoking, but to assist smokers in their cessation efforts. *See* Final Rule, 76 Fed. Reg. at 36,681. Under *Central Hudson* intermediate scrutiny, the government's interest in reducing smoking rates is doubtless substantial. *See, e.g.*, *Lorillard*, 533 U.S. at 564; *Brown & Williamson*, 529 U.S. at 161. There also is substantial evidence to support the FDA's determination that the display of the "1-800-QUIT-NOW" number will directly advance this interest. The biological and psychological effects of nicotine "can make smoking cessation extremely difficult," PCP Report at 62; "about 40 percent of smokers try to quit" each year, but "95

percent of those who try to quit on their own relapse," Final Rule, 76 Fed. Reg. at 36,681. In comparison to minimal or no counseling interventions, quitlines have been found to "significantly increase abstinence rates." *Id.* at 36,687 (citing U.S. Dep't Health & Human Servs., Public Health Serv., *Treating Tobacco Use and Dependence: 2008 Update* 91 (May 2008)); *see also* IOM Report at C-7. International experience referenced in the rulemaking, *see* Final Rule, 76 Fed. Reg. at 36,682, further supports the common sense proposition that informing smokers of cessation resources is likely to increase rates of successful quit attempts.

But the additional inclusion of the "1-800-QUIT-NOW" number on the warning labels does not meet the fourth prong of *Central Hudson*. The number is prominently presented in imperative terms, directing consumers to "QUIT NOW." That command directly contradicts the tobacco companies' desired message at the point of sale, thereby imposing a significant burden on their protected commercial speech. "In previous cases addressing [the] final prong of the *Central Hudson* test," the Supreme Court has "made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371. Unlike the warning label requirement imposed pursuant to Section 201 in response to the demonstrated failures of previously attempted, less burdensome warning requirements, the inclusion of the "1-800-QUIT-NOW" number follows upon no apparent consideration of the effectiveness of alternative means of connecting smokers to cessation resources, such as a package insert.[11] Absent an

[11] *See, e.g.*, Appellants' Reply Br. at 30 (citing cessation resource information displayed on the websites of one tobacco company, http://www.lorillard.com/?s=quit+smoking and the subsidiary of another, http://www.sfntc.com/Quit-Smoking/

explanation why such alternatives would be inadequate, the government has failed to show the requisite "reasonable fit," *Lorillard*, 533 U.S. at 561. *See Thompson*, 535 U.S. at 373.[12]

IV.

Finally, it bears noting that the court's understanding of the precedent governing the appropriate level of scrutiny, as well as its dismissal of a well established and substantial government interest, is inconsistent with the Supreme Court's "principal" justification for "exten[ding] . . . First Amendment protection to commercial speech" — "the value to consumers of the information such speech provides." *Zauderer*, 471 U.S. at 651. The Supreme Court has reiterated this justification in the tobacco context. Addressing "substantial" restrictions on tobacco advertising imposed by Massachusetts, the Court identified as the "countervailing First Amendment interests" the tobacco companies' "interest in conveying truthful information about their products to adults" and adults' "corresponding interest in receiving truthful information about tobacco products." *Lorillard*, 533 U.S. at 564. In view of this justification, the Court has treated disclosure requirements "as constitutionally preferable to outright suppression." *Pearson*, 164 F.3d at 657 (citing recent cases). Here, the government has required the tobacco companies not only to state, but also to show, the significant negative health consequences of using their

---

Overview.aspx).

[12] Neither the tobacco companies nor the rulemaking record suggests that the FDA would not have promulgated the Final Rule had the "1-800-QUIT-NOW" number been struck from the warning labels, and it can be severed. *See North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008).

product as intended. The court identifies no principled distinction, for purposes of determining the applicable level of scrutiny, between the stating and the showing of such information. In view of the record evidence — as well as experience and common sense — supporting the communicative power of graphic images accompanying textual warnings, no such distinction appears to exist.

Given the evidence demonstrating the tenacity of nicotine addiction, the young age at which the vast majority of smokers begin smoking cigarettes, these smokers' "incomplete understanding of the addictive nature of tobacco use that is related, in part, to their inaccurate assessment of smoking risks and their belief that they can quit at any time and therefore avoid addiction," IOM Report at 89, and the significant negative health consequences of smoking, the government has an interest of paramount importance in effectively conveying information about the health risks of smoking to adolescent would-be smokers and other consumers. The tobacco companies' decades of deception regarding these risks, especially the risk of addiction, buttress this interest. Contrary to their arguments, nothing in the Supreme Court's commercial speech precedent would restrict the government to conveying these risks in ways that have already proved ineffective or would prohibit the government from employing the communication tools tobacco companies have wielded to great effect over the years.

For these reasons, the district court erred in applying strict scrutiny in sustaining the tobacco companies' as-applied First Amendment challenge to the Tobacco Control Act and the Final Rule, and in issuing a permanent injunction. Because the warning label requirement (absent the "1-800-QUIT-NOW" number) appears to survive the First Amendment challenge under either *Zauderer* or *Central Hudson*, I would reverse. It would remain for the district court on remand to address the

tobacco companies' challenges under the Administrative Procedure Act, *see supra* note 1.