Docket No. FDA-2019-N-3065

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

Food and Drug Administration, Department of Health and Human Services

on

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED AT 84 FED. REG. 42754 (August 16, 2019)

Marc B. Robertson
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

October 15, 2019

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
(202) 588-0302

October 15, 2019

Submitted Electronically (www.regulations.gov)
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements
Proposed Rule; Docket No. FDA-2019-N-3065, 84 Fed. Reg. 42754 (August 16, 2019)

Dear Sir or Madam:

The Washington Legal Foundation (WLF) welcomes the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule that would require cigarette packaging and advertisements to bear one of the new required textual warnings and color graphics detailing the potential health consequences of cigarette smoking.

Founded in 1977, WLF is a public-interest law firm and policy center with supporters nationwide. WLF often appears before federal courts and administrative agencies to promote free enterprise, individual liberty, limited government, and the rule of law. To that end, WLF routinely defends commercial speech rights by appearing as an *amicus curiae* in state and federal courts in important First Amendment cases. *See, e.g.*, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); *United States v. Philip Morris USA Inc.*, 801 F.3d 250 (D.C. Cir. 2015).

WLF has actively litigated in favor of First Amendment limits on FDA's authority to restrict manufacturer speech. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA's authority to bar manufacturers from sharing peer-reviewed medical texts and journal articles about off-label uses of their FDA-approved products. WLF also played a pivotal role in the previous successful First Amendment challenge to FDA's compelled-speech regime for cigarettes. *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22-23 (D.C. Cir. 2014).

FDA's proposed rule seeks to remedy the First Amendment defects raised in *R.J. Reynolds*, which doomed the agency's initial attempt to compel cigarette manufacturers to display new warnings accompanied by graphic color images. FDA has since examined the scientific literature on the impact of smoking on health and engaged in studies and surveys to determine the potential success of the new warnings and color images.

Yet as we explain, FDA's compelled use of photorealistic images, depicting the negative health consequences of cigarette smoking, still fails both *Zauderer* and *Central Hudson*. The images are not purely factual and uncontroversial and are more extensive than necessary. For these reasons, the proposed rule would unduly burden cigarette manufacturers' First Amendment rights. "The right to speak and the right to refrain from speaking are complementary components." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). And one is not due more protection than the other. *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796 (1988).

I. The Proposed Rule

FDA argues that the current text-only warnings (including the Surgeon General's Warning required on cigarette packages since 1965 and modified in 1984), no longer accomplish agency's goal of promoting public awareness of the hazards of smoking. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted in 2009, grants FDA the authority to adjust the warnings if FDA finds that such a change would promote greater public understanding of the risks associated with tobacco use.

The proposed rule specifies the photorealistic color graphics that must accompany new textual warning statements. The purpose of the rule is to promote greater public understanding of the negative health consequences of cigarette smoking.

Following the D.C. Circuit's invalidation of a similar rule in *R.J. Reynolds*, FDA examined scientific literature to identify more health conditions linked to cigarette smoking. Based on this new information, FDA claims that because a significant information gap exists, the proposed rule is necessary to inform the public of these lesser-known health risks. FDA argues that only its mandated photorealistic images can achieve this goal.

II. The Proposed Rule Would Violate the First Amendment

While FDA anticipated First Amendment objections to its proposed rule, the agency's First Amendment analysis is deficient; it fails to provide adequate justification for its substantial infringement of manufacturers' free-speech rights. FDA argues that the

Government may compel speech as long as it advances a Government interest and does not unduly burden protected speech. But this analysis flouts Supreme Court precedent.

A. *Zauderer* Cannot Save FDA's Proposed Rule

FDA invokes *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), as justification for the proposed rule. *Zauderer* involved a mostly successful First Amendment challenge to Ohio's efforts to restrict truthful attorney advertising. The Court, applying *Central Hudson*'s four-pronged test, struck down (1) prohibitions on soliciting clients through ads containing advice on specific legal problems and (2) restrictions on using illustrations in attorney advertising. *Zauderer*, 471 U.S. at 639-49 (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 562-63 (1980)).

i. The Proposed Rule Does Not Target Commercial Deception

While *Zauderer* upheld Ohio's decision to discipline an attorney because he advertised his services on a "no cost" contingency-fee basis without disclosing that clients could be liable for litigation costs, *Zauderer*, 471 U.S. at 650-62, it did not create a new rule. Rather, the decision was merely a special application of the *Central Hudson* test. *See Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (describing *Zauderer* as "an application of *Central Hudson*, where several of *Central Hudson*'s elements have already been established"). The Court stated that commercial speech "may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest." *Zauderer*, 471 U.S. at 638. The Court also held that the government may compel commercial disclosures only if the "disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651.

FDA argues that the Government may compel disclosures of factual information in commercial marketing where the disclosure is justified by a Government interest and does not unduly burden protected speech. But this misreads and distorts *Zauderer*. *Zauderer* is strictly limited to cases where the compelled government speech is required "to dissipate the possibility of consumer confusion or deception." 471 U.S. at 651 (internal quotation omitted).

In its commercial speech jurisprudence, the Supreme Court has consistently held that the government may compel commercial speech only when the disclosure is "intended to combat the problem of inherently misleading commercial advertisements" with the use of only "an accurate statement." *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 250 (2010). Disclaimers, the Court instructs, must be "[n]o broader than reasonably necessary to prevent the deception," *In re RMJ*, 455 U.S. 191, 203 (1982), and they must be "necessary to make voluntary advertisements non-misleading for consumers."

United States v. United Foods, 533 U.S. 405, 416 (2001). Disclosure requirements, therefore, serve as a narrowly tailored alternative to an outright speech ban when seeking to guard against consumer deception.

Here, FDA claims that the proposed regulation is essential to alerting consumers of the potential hazards of cigarette smoking. Unlike in *Zauderer*, where the advertisement was misleading as written, here FDA does not argue that cigarette companies are deceiving the public about these dangers. Rather, FDA claims that "significant gaps" exist in the public's knowledge of these harms. It relies on this perceived "misinformation" to compel cigarette manufacturers to update their labels and advertisements. The Supreme Court has never upheld a commercial speech disclosure for that purpose.

By seeking to expand *Zauderer*'s holding to justify its compelled speech, FDA undermines the Court's historical rationale for giving commercial speech somewhat reduced—but still considerable—First Amendment protection. The "greater 'objectivity' of commercial speech justifies affording the State more freedom to distinguish false advertisements from true ones." *44 Liquormart, Inc. v. Rhode* Island, 517 U.S. 484, 499 (1996) (quoting *Virginia State Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 n.24 (1976)). But as the Court has clearly instructed, the relaxed First Amendment scrutiny is applied to compelled commercial speech only when it is intended to prevent consumer deception. When, as here, the Government seeks to compel speech for any other reason, "the greater objectivity of commercial speech" supplies no justification for treating commercial and noncommercial speaker differently.

FDA, by its own admission, wants to use cigarette companies as spokespersons for FDA's own information campaign. "Health warnings on cigarette packages can serve as prominent sources of health information for both smokers and nonsmokers." 84 Fed. Reg. 42764. But the First Amendment prohibits compelling companies to "use their private property as a 'mobile billboard' for the State's ideological message." *Maynard*, 430 U.S. at 715. Because FDA's proposed rule is not aimed at preventing deception by the cigarette manufacturers, *Zauderer* cannot justify the proposed rule.

ii. The Images Are Controversial

Even if *Zauderer* does apply outside the deception-prevention context, the proposed rule fails that test because FDA's images are controversial. A government-mandated disclosure is eligible for review under *Zauderer* only if it requires the inclusion of "purely factual and uncontroversial information." 471 U.S. at 651; *see also* Valerie C. Brannon, Cong. Research Serv., R45700, *Assessing Commercial Disclosure Requirements under the First Amendment* 20 (2019).

The Supreme Court recently clarified the narrow scope of *Zauderer* in *National Inst. of Family & Life Advocates (NIFLA) v. Becerra*, 138 S. Ct. 2361 (2018). In striking down California laws compelling crisis-pregnancy centers to notify women of California's free or low-cost health services, including abortion, the Court clarified the limited circumstance that justifies government-compelled speech. *Zauderer*'s "lower level of scrutiny" for compelled speech is limited to the mandatory "disclosure of purely factual and uncontroversial information about the terms under which … services will be available." *Id.* at 2372 (citing *Zauderer*, 471 U.S. at 651).

The images at issue in the proposed rule are designed to evoke an emotional response, and courts have looked at such compelled disclosures with skepticism. *See R.J. Reynolds*, 696 F.3d at 1216 (noting that the warnings were not "'purely' factual" because they were "primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning"). Unlike its last attempt to enact a similar compelled disclosure, FDA has been careful not to express its desire to play into a consumer's "emotions," but its reasoning for using photorealistic images insinuates as much. It asserts that the "vivid features," like the photorealistic images, are more noticeable and will be easier for consumers to remember than words and are thus more "engaging." 84 Fed. Reg. 42762. FDA also claims the new label targets nonsmokers as well, who see cigarette packs when a smoker pulls a cigarette out near them. Clearly, even though the images and warnings are factual, FDA intends for these images to be inflammatory and to prey on the emotions of consumers. *Zauderer* cannot save the proposed rule. "If the law were otherwise, there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *Nat'l Ass'n of Manufacturers v. S.E.C.*, 800 F.3d 518, 530 (D.C. Cir. 2015) (internal quotation omitted).

Because *Zauderer* does not govern the First Amendment analysis here, FDA's proposed rule must pass muster under a standard at least as stringent as that supplied by *Central Hudson*.

III. FDA's Proposed Rule Cannot Survive *Central Hudson*

The first prong of the *Central Hudson* test focuses on the speech at issue and requires that the speech "concern lawful activity" and not be inherently misleading. The next three prongs of the test focus on the regulatory scheme at issue, and are implicated here. The government must demonstrate a substantial interest in promoting greater public understanding of the negative health consequences of cigarette smoking and show that the regulation (1) "directly advances" that substantial interest and (2) is "not more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566.

FDA argues that it need not "employ 'the least restrictive means' of regulation or to achieve a perfect fit between means and ends"—it need only achieve a "reasonable" fit. 84 Fed. Reg. at 42779 (citing *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). But the existence of "numerous and obvious less-burdensome alternatives to the restriction on commercial speech" shows that the "fit" between means and ends is unreasonable. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993).

The leading case is *Thompson v. Western States Medical Center*, which involved a federal attempt to prohibit pharmacies from advertising compounded drugs. 535 U.S. 357 (2002). The federal law at issue exempted compounded drugs from FDA's rigorous drug-approval process, so long as pharmacies selling those drugs complied with several restrictions, "including that they refrain from advertising or promoting particular compounded drugs." *Id.* at 360. The advertising ban was necessary, the government insisted, to prevent "large-scale [drug] manufacturing" from occurring "under the guise of pharmacy compounding." *Id.* at 371.

But the Court held that the government may not restrict pharmacists' speech as an alternative to regulating their conduct: "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort. Yet here it seems to have been the first strategy the Government thought to try." *Id.* at 373. In other words, "if the Government could achieve its interests in a manner that does not restrict speech … [it] must do so." *Id.* at 371.

As support for compelling even more speech than is presently required, FDA presents evidence that the Surgeon General's warning has become virtually invisible to consumers and is therefore inadequate. And while FDA conducted surveys and points to results from other countries suggesting that the vivid images will promote better public understanding of the negative health effects of smoking, other studies show the opposite is true. A study of the effectiveness of similar graphic warnings in the United Kingdom concludes that, although the shocking images may have "made smoking seem less attractive," such warnings had no discernible impact on the depth of people's understanding of the health risks of smoking. *See* Heather Wardle, et al., "Final Report: Evaluating the Impact of Picture Warnings on Cigarette Packets," Public Health Research Consortium (2010). A European Union report concluded the same. *See* RAND Europe, *Final Report on Assessing the Impacts of Revisiting the Tobacco Products Directive* (September 2010). So even if people will initially be more aware of the warnings, FDA fails to consider (or refuses to acknowledge) that those images too will very likely soon become "virtually invisible." And increased understanding of health effects does not necessarily translate into behavior changes, particularly in light of smoking's persistence despite widespread understanding that smoking is very hazardous to health.

FDA need not further commandeer the speech of cigarette manufacturers to communicate health warnings to consumers. FDA has plenty of other options to educate the public of the dangers of smoking without compelling cigarette manufacturers to display graphic, photorealistic images on their packaging and advertising. It may require an update of the already-accepted Surgeon General's warning to reflect the "new information" that the public should know. FDA can engage in its own educational campaign and display its own advertisements to bring awareness to the dangers of smoking, something it already does. It could even call on Congress to further restrict the availability of cigarettes. But it cannot require cigarette manufacturers to serve as an FDA billboard. The proposed rule is thus more extensive than necessary.

IV. Conclusion

As the Supreme Court has said, "The State can express [its] view through its own speech. … But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell*, 564 U.S. at 578-79. FDA's purpose is to curb cigarette use, an admirable goal, and one that even cigarette companies themselves are striving to achieve. *See Delivering a Smoke-Free Future*, Philip Morris International (last visited October 15, 2019), https://www.pmi.com/our-transformation/delivering-a-smoke-free-future. But as long as tobacco use is legal, companies have a right to advertise, market, and label their products free from overburdensome disclosure requirements. FDA's proposed rule unconstitutionally burdens the right of cigarette manufacturers to market its legal product to consumers.

Given these constitutional defects, FDA should withdraw the proposed rule.

Sincerely,

/s/ Marc B. Robertson
Marc B. Robertson
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
mrobertson@wlf.org