UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY, *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 6:20-CV-00176

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF DEFENDANTS' COMBINED CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND A PRELIMINARY INJUNCTION

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INTEREST OF AMICUS CURIAE

Amicus curiae Public Citizen is a nonprofit consumer advocacy organization with members in all 50 states. Public Citizen appears before Congress, administrative agencies, and courts on a wide range of issues, including policies that promote public health, such as appropriate regulation of food, drug, and tobacco products by the Food and Drug Administration (FDA). Public Citizen has also participated as amicus curiae in numerous cases involving application of the First Amendment to government regulation of commercial speech. Many of these cases have addressed FDA regulation of tobacco products. *See Cigar Ass'n of Am. v. FDA*, __ F.3d __, 2020 WL 3738096 (D.C. Cir. July 7, 2020); *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part*, *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012). Public Citizen has also appeared as amicus curiae to address other tobacco-industry challenges to federal and state regulation. *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000).

Public Citizen is concerned that corporate and commercial interests are pursuing aggressive applications of commercial speech doctrine to stifle regulatory measures designed to protect consumers. Regulated entities increasingly raise First Amendment challenges to disclosure regulations that provide consumers with important information about the quality or nature of, or the risks associated with, products and services that consumers seek to purchase from commercial establishments. Commercial-speech doctrine developed from the recognition that complete prohibitions on truthful commercial speech, which historically fell outside of the protection of the First Amendment, rarely served legitimate government interests and often resulted in consumer harm. *See Va. Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 770 (1976). At

the same time, attempts by industry to blur or erase the distinctions that commercial-speech doctrine draws between disclosure requirements and restrictions on commercial speech, and between commercial speech and fully protected speech, threaten legitimate government interests and consumer harm.

Here, for example, the cigarette industry seeks to impose on the FDA's disclosure regulation a higher level of First Amendment scrutiny than is called for by applicable precedent. Adoption of this view would undermine the important public-health benefits served by the federal government's regulation of tobacco marketing and, more broadly, unnecessarily tilt the First Amendment balance against a range of laws and regulations that serve important public interests.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Supreme Court first recognized that commercial speech is entitled to some measure of constitutional protection in 1976, in *Virginia Board of Pharmacy*, 425 U.S. at 761, 770. In the ensuing four and a half decades, the Supreme Court has never applied strict scrutiny in assessing a regulation applicable solely to commercial speech. Instead, the Court has assessed the constitutionality of laws that regulate commercial speech in accordance with two principles.

First, commercial speech is accorded "less protection" than "other constitutionally safeguarded forms of expression." *Bolger v. Youngs Drug Products Corp*., 463 U.S. 60, 64–65 (1983). The lesser degree of protection follows from "the 'common-sense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech." *Id.* at 64 (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455–56 (1978)).

Second, the Supreme Court has recognized "material differences between disclosure requirements and outright prohibitions on speech." *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio,* 471 U.S. 626, 650 (1985). Under *Central Hudson Gas & Electric Corp.*

v. Public Service Commission of New York, 447 U.S. 557 (1980), and its progeny, restrictions on commercial speech are subject to "intermediate scrutiny," under which restrictions that "directly advance a substantial governmental interest and [are] no more extensive than is necessary to serve that interest" are upheld. *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (internal quotation marks and original brackets removed). In contrast, laws that compel the disclosure of commercial information, rather than restrict commercial speech, are generally subject to "a lower level of scrutiny." *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (*NIFLA*). Specifically, when a law requires "purely factual and uncontroversial disclosures about commercial products," *id*. at 2376, or about commercial services, *see id*. at 2372, it "should be upheld unless [it is] 'unjustified or unduly burdensome,'" *Id*. (quoting *Zauderer*, 471 U.S. at 651). A commercial disclosure requirement is justified if it is "reasonably related" to the governmental interest that the law is designed to address. *Zauderer*, 471 U.S. at 651.

This case involves a disclosure requirement for commercial speech—the advertising and packaging of tobacco products—and, therefore, *Zauderer* sets forth the appropriate standard for assessing whether the FDA's rule is consistent with the First Amendment. Although Plaintiffs (hereafter, RJR) ask this Court to apply a higher level of First Amendment scrutiny, the FDA's brief persuasively explains why RJR's arguments on that point lack merit. *See* FDA Br. 18–26. This amicus brief expands on a few key points made by the FDA with respect to the standard of First Amendment scrutiny appropriate for evaluating the FDA's tobacco health warnings.

ARGUMENT

I. *Zauderer* applies to commercial disclosure requirements that provide consumers with factual information about the characteristics of products and services offered for sale.

Commercial disclosure requirements are subject to a less stringent standard of review than laws that regulate non-commercial speech or that restrict the content of commercial speech,

because "the interests at stake … are not of the same order." *Zauderer*, 471 U.S. at 651. "[T]he extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides"; therefore, a commercial speaker's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id*. "[B]ecause disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, 'warning[s] or disclaimer[s] might be appropriately required … in order to dissipate the possibility of consumer confusion or deception.'" *Id*. (quoting *In re R.M.J.*, 455 U.S. 191, 201 (1982)). Neither *Central Hudson*'s intermediate scrutiny standard nor strict scrutiny applies to laws that require commercial speakers to provide factual information to consumers about their products and services. *Id.* at 650–52 & n.14.

A. *Zauderer* addressed a state disclosure standard under which attorney advertising that referred to contingent-fee arrangements was required to mention the client's liability for costs. *Id.* at 653. The Supreme Court found the state's position—that the disclosure would serve the interest in preventing possible deception of consumers, *see id*. at 651—to be "reasonable enough" to support a requirement that "the client's liability for costs be disclosed." *Id.*

Focusing on the fact that deception was the state interest presented in *Zauderer*, RJR seeks to limit *Zauderer* to situations in which disclosure is needed to prevent commercial speech from being deceptive or misleading. *See* RJR Br. 20–22. RJR thus portrays *Zauderer* as merely a tool that the government may use "to combat misleading speech … short of banning the speech." *Id*. at 20. To begin with, even if RJR were correct, the FDA has explained that tobacco health warnings are necessary "because the tobacco industry succeeded at getting millions of Americans addicted to cigarettes while lying about the health consequences of smoking." FDA Br. 20. But importantly,

RJR is not correct. Misleading commercial speech does not receive *any* First Amendment protection. *See Zauderer*, 471 U.S. at 638 ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading."); *see also Lorillard Tobacco Co.*, 533 U.S. at 554 ("For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." (quoting *Central Hudson*, 447 U.S. at 566)). The government, therefore, may prohibit misleading commercial speech without satisfying even *Zauderer*'s deferential standard. Accordingly, RJR's view, under which government action requiring a corrective disclosure is subject to greater scrutiny than government action "banning the speech," RJR Br. 20, makes no sense as a matter of logic or First Amendment principles.

To be sure, one circumstance in which the *Zauderer* test is appropriate is when a disclosure is required to cure "potentially misleading" commercial speech. *See*, *e.g.*, *Dwyer v. Cappell*, 762 F.3d 275, 281 (3d Cir. 2014) ("[T]he State may compel supplemental disclosures to clarify truthful but potentially misleading advertisements."). Thus, in *Zauderer*, the attorney advertisement stated that clients would not owe "legal fees" if their lawsuits were unsuccessful, but it failed to address court costs. 471 U.S. at 652. Because "members of the public are often unaware of the technical meanings of such terms as 'fees' and 'costs,'" the advertisement left the impression of "a no-lose proposition" in which a lawsuit could be prosecuted "entirely free of charge." *Id.* The required disclosure was permissible because it was reasonably aimed at preventing that misperception. *Id*. at 253. The Supreme Court addressed a similar situation in *Milavetz*. There, the Court applied *Zauderer* to disclosure requirements that addressed advertisements making "the promise of debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs." 559 U.S. at 250. In upholding the disclosure under *Zauderer*, the Court explained that requiring

identification of "the advertiser's legal status and the character of the assistance provided" would advance the government's interest in "combat[ting] the problem of inherently misleading advertisements." *Id.*

The common thread in *Zauderer* and *Milavetz* is the recognition that advertisements can mislead consumers if consumers lack complete information about the services being advertised—the distinction between legal costs and fees in *Zauderer* and about the nature of debt relief services in *Milavetz*. In those circumstances, the government has a legitimate interest in requiring disclosures to address that information disparity, and such disclosures are subject to First Amendment scrutiny under *Zauderer*'s deferential standard. Nothing in *Zauderer* and *Milavetz*, however, holds that addressing potential deception is the *only* legitimate interest that can justify disclosure.

Thus, as the D.C. Circuit has explained, *Zauderer* "sweeps far more broadly than the interest in remedying deception." *Am. Meat Inst.*, 760 F.3d at 22. In particular, "*Zauderer*'s characterization of the speaker's interest in opposing forced disclosure of such [factual] information [in advertising] as 'minimal' seems inherently applicable beyond the problem of deception[.]" *Id.* (citing *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114 (2d Cir. 2009); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005); and *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001)). For instance, *Zauderer* applies as well to disclosure requirements that convey factual information designed to remedy consumers' lack of knowledge and allow them to "make informed choices based on characteristics of the products they wished to purchase." *Id.* at 24; *see also* FDA Br. 18–19. That conclusion flows from two basic principles.

First, in its regulation of commerce, the government's legitimate interests are not limited to preventing deception or potential deception in advertising. For example, in *American Meat*

Institute, the D.C. Circuit upheld mandatory country-of-origin disclosures under *Zauderer* in light of "the context and long history of country-of-origin disclosures to enable consumers to choose American-made products; the demonstrated consumer interest in extending country-of-origin labeling to food products; and the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak." 760 F.3d at 23. And in *CTIA–The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832 (9th Cir.), *cert. denied*, 140 S. Ct. 658 (2019), the Ninth Circuit applied *Zauderer* to uphold a disclosure requirement concerning cell phone radiation that advanced "the governmental interest in furthering public health and safety." *Id.* at 844. Similarly, in *Sorrell*, the Second Circuit applied *Zauderer* in upholding a mercury-content labeling law as a valid means of "protecting human health and the environment from mercury poisoning." 272 F.3d at 115. In all these cases, as in the case of potentially misleading advertisements, the government used mandatory disclosures to vindicate legitimate interests harmed by lack of consumer awareness.

Second, regardless of the governmental interest being advanced, the burden on the commercial speakers' First Amendment interests when they are required to disclose factual information about their products and services is "minimal." *Zauderer*, 471 U.S. at 651. A regulation that requires tobacco companies to disclose the health risks of smoking so that consumers may make informed purchasing decisions imposes no greater First Amendment burden on the industry than a regulation that requires disclosures in response to a deceptive ad campaign portraying cigarettes as "less dangerous than you might believe." If anything, the latter regulation implicates greater First Amendment interests because it is triggered by the industry's speech, whereas the former is triggered by the non-speech act of placing a dangerous product into commerce. *Zauderer* makes clear that the latter regulation would not be subject to heightened scrutiny, and there is no principled reason why *Zauderer* should not apply to the former as well.

The consequences of adopting RJR's position would be far-reaching and exceedingly problematic. The law is replete with disclosure requirements whose sole purpose is to improve consumers' understanding of the myriad products and services available to them in the market. Federal law directs vehicle manufacturers to label each vehicle with fuel economy information, in accordance with regulations issued by the Environmental Protection Agency. 49 U.S.C. § 32908(b). With limited exceptions, the Food, Drug, and Cosmetic Act requires that a food product containing artificial coloring or flavoring bear a label so stating, 21 U.S.C. § 343(k), and requires foods be labeled with nutrition information, *id.* § 343(q). The Securities and Exchange Commission compels a securities issuer to state whether it has a code of ethics, 17 C.F.R. § 229.406, and disclose information about certain officers' executive compensation, *id*. § 229.402. Federal law requires that items of fur apparel include a label identifying the type of animal that produced the fur and the country of origin of imported fur and stating that the apparel contains used fur (if it does). 15 U.S.C. § 69b. The list goes on. "There are literally thousands of similar regulations on the books" involving "routine disclosure of economically significant information designed to forward ordinary regulatory purposes," *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 316; *see also* FDA Br. 20—most of which are not justified as a remedy for deceptive advertising.

As the First Circuit has explained, the "idea that these thousands of routine regulations require an extensive First Amendment analysis is mistaken." *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 316. The deferential test set forth in *Zauderer* is the appropriate test for considering challenges to these disclosures, even where the disclosures are not required to correct false, deceptive, or misleading commercial speech.

B. RJR incorrectly suggests that this Court is bound by precedent *not* to apply *Zauderer*. *See* RJR Br. 20, 21. Neither Supreme Court nor Fifth Circuit precedent supports this assertion.

Contrary to RJR's argument, the Supreme Court has never held that *Zauderer* applies only disclosures that cure potentially deceptive speech. In *NIFLA*, 138 S. Ct. 2361, the Supreme Court's most recent application of *Zauderer*, the Court considered disclosure requirements that California had imposed on "crisis pregnancy centers." The Court described *Zauderer* as involving the disclosure of 'purely factual and uncontroversial information about the terms under which ... services will be available,'" and it reiterated that "such requirements should be upheld unless they are 'unjustified or unduly burdensome.'" *Id.* at 2372. The Court did not, however, describe *Zauderer* as limited to disclosures relating to consumer deception or, indeed, to disclosures about terms of services.[1] Instead, the Court declined to "decide what type of state interest is sufficient to sustain a disclosure requirement" under *Zauderer*. *Id.* at 2377. It further assured that its decision to invalidate California's disclosure requirement did not call into "question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Any suggestion that the Supreme Court did not understand that the bulk of "health and safety warnings long considered permissible" advance governmental interests other than preventing or curing deceptive advertising would be incredible.

Fifth Circuit precedent likewise does not support RJR's cramped view of *Zauderer*. In *Allstate Insurance Co. v. Abbott*, 495 F.3d 151 (5th Cir. 2007), the Court did not consider application of *Zauderer* because it viewed the challenged regulation as a restriction on commercial speech to be evaluated under *Central Hudson*. *See id.* at 166 & n.60. In *Test Masters Education Services, Inc. v. Robin Singh Education Services, Inc.*, 799 F.3d 437 (5th Cir. 2015), the court

[1] The Court's references to "services" in that passage of *NIFLA* stemmed from the fact that in both *Zauderer* and *NIFLA*, the speech was by providers of services, not products; and the respect in which the regulation in *NIFLA* fell outside *Zauderer* was that it did not provide information about the speakers' own commercial activities (*i.e.*, its services), but services offered by the state. 138 S. Ct. at 2372.

applied *Zauderer* in a case involving deceptive commercial speech without commenting on whether *Zauderer* applies in other commercial contexts. *See id.* at 453. In *Hersh v. United States ex rel. Mukasey*, 553 F.3d 743 (5th Cir. 2008), the Fifth Circuit did not decide the appropriate First Amendment standard, concluding instead that the disclosure requirements at issue passed muster under heightened scrutiny. *Id.* at 768. Nothing in these decisions precludes this Court from applying *Zauderer* here.

Finally, the two out-of-circuit cases on which RJR relies are not on point. As the Supreme Court did in *Milavetz*, the Third Circuit's decision in *Dwyer* simply applied *Zauderer* in analyzing disclosure requirements addressing potentially deceptive attorney advertisements. 762 F.3d at 283. In *Central Illinois Light Co. v. Citizens Utility Board*, 827 F.2d 1169 (7th Cir. 1987), the Seventh Circuit held that "the *Zauderer* case is irrelevant" because the state law at issue did not require commercial disclosures but, rather, compelled the utility to include third-party communications in its customer billing statements. *Id.* at 1173.

In sum, no binding decision or any other precedent holds that *Zauderer* is confined to situations in which the required disclosure is aimed at preventing or curing consumer deception. This Court should recognize the government's legitimate interest in ensuring that consumers are well-informed about the characteristics of products offered for sale, especially where, as here, the product has long been recognized as highly dangerous to human life and health. *Zauderer* is the correct standard to apply in evaluating the FDA's disclosure rule in this case.

II. Under *Zauderer*, disclosure requirements may be upheld even if they are not the least restrictive means of furthering the government's interest.

RJR contends that the FDA's disclosure regulations are "unduly burdensome" under *Zauderer* because "the government cannot show that less-restrictive means are not sufficiently effective." RJR Br. 39, *see also id.* at 42–44. Disclosure requirements, however, are not subject to

a "'least restrictive means' analysis under which they must be struck down if there are other means by which the State's purposes may be served." *Zauderer*, 471 U.S. at 651–52 n.14. Indeed, disclosure requirements themselves are considered "one of the acceptable less restrictive alternatives to actual suppression of speech." *Id*. And the Supreme Court has consistently rejected least-restrictive-means analysis of any regulation of commercial speech. *See*, *e.g.*, *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989) (holding that *Central Hudson* permits restrictions on commercial speech that are "narrowly tailored to achieve the desired objective" even if they are not "the least restrictive means"); *see also Am. Meat Inst.*, 760 F.3d at 25–26.

Contrary to RJR's assertion, *NIFLA* did not alter the settled law that disclosure regulations are not subject to a least-restrictive-means analysis. *See* RJR Br. 39. In *NIFLA*, the Supreme Court considered two distinct notice requirements imposed on pregnancy clinics: one for licensed facilities and one for unlicensed facilities. The Court examined the licensed-facility notice under *Central Hudson*'s intermediate-scrutiny standard because it found the disclosures did not concern the licensed facilities' own services but the state's services and, thus, did not fall within the scope of *Zauderer*. In contrast, the Court held that the unlicensed-facility notice failed scrutiny under *Zauderer* because it was unduly burdensome. That holding, however, did *not* rest on the existence of less restrictive alternatives. Rather, the Court emphasized that the notice was a "speaker-based disclosure requirement that [was] wholly disconnected from California's informational interest," and it examined the burden that complying with the requirement would impose without considering the relative burden of other alternatives. 138 S. Ct. at 2377–78. Nowhere in its discussion did the Court characterize its decision as premised on a least-restrictive-means standard, let alone overrule *Zauderer*'s express holding rejecting such a standard.

RJR portrays *NIFLA*'s discussion of a possible governmental advertising campaign as an evaluation of alternative, less-restrictive means of achieving the government's objectives. RJR Br. 39, 42 (citing *NIFLA*, 138 S. Ct. at 2376). But *NIFLA* mentioned the possibility of a public information campaign in applying *Central Hudson*—not *Zauderer*—to the notice required of licensed facilities, 138 S. Ct. at 2376, and even then only after concluding that the notice requirement was "not sufficiently drawn" to achieve the state's stated goals of "providing low-income women with information about state sponsored services," *id*. at 2375–76. That discussion did not *sub silentio* alter the Supreme Court's longstanding precedent.

NIFLA, in short, does not curtail the government's authority to require factual disclosures about a commercial speaker's own goods and services, and it does not suggest that the government must pursue a public information campaign before it may impose such requirements. That view would require blanket condemnation of commercial disclosure requirements—an outcome *NIFLA* itself rejects. *Id*. at 2376. Rather, under *Zauderer*, "[t]o the extent that the government's interest is in assuring that consumers receive particular information," the government satisfies the First Amendment when it adopts "a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered." *Am. Meat Inst.*, 760 F.3d at 26. The question whether it is possible to conceive of a less restrictive means of furthering the government's objectives has no place in the *Zauderer* analysis.

III. Strict scrutiny does not apply to regulation of commercial speech.

RJR contends that, if *Zauderer* does not apply, the Court should apply strict scrutiny to the FDA's regulations. RJR Br. 19, 45. Putting aside that *Zauderer* does apply, RJR's argument is foreclosed by precedent. *See* FDA Br. 45–46. In the decades since the Supreme Court first extended First Amendment protection to commercial speech, *no* Supreme Court or federal appellate precedent has applied strict scrutiny to reject a disclosure requirement implicating only

commercial speech. The FDA's disclosure regulation undisputedly governs only commercial speech, and regulation of commercial speech is subject either to intermediate scrutiny under *Central Hudson* or even less demanding scrutiny under *Zauderer*.

The Supreme Court's decision in *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144 (2017), illustrates the point, and belies RJR's argument. *Expressions Hair Design* concerned a statute prohibiting merchants from imposing surcharges on purchases made with credit cards. The Court determined that the law regulated commercial speech but did not determine whether it was properly viewed as a speech prohibition or a disclosure requirement. *See id.* at 1151 & n.3. The Court remanded the case for consideration of the law either under *Central Hudson* intermediate scrutiny or, if the law was determined to be a disclosure requirement, *Zauderer*. *See id.* at 1151. Nothing in the opinion suggests that a commercial disclosure requirement might be subject to strict scrutiny.

Milavetz is the same. There, the Court noted that "the challenged provisions regulate only commercial speech." 559 U.S. at 249. The Court then considered two possible First Amendment standards that could apply to the disclosure requirements at issue: *Central Hudson* or *Zauderer*. Because "the challenged provisions impose[d] a disclosure requirement rather than an affirmative limitation on speech," the Court held that "the less exacting scrutiny described in *Zauderer* governs our review." *Id.* The Court did not entertain the possibility of applying strict scrutiny in evaluating the disclosure requirements. *See also Pub. Citizen Inc. v. Louisiana Attorney Disciplinary Bd.*, 632 F.3d 212, 219 (5th Cir. 2011) (holding that "[t]he court must review these Louisiana Rules [regulating attorney advertisements] under *Central Hudson* or *Zauderer*").

Indeed, the D.C. Circuit has squarely held that tobacco warnings—including those involving graphic images—that do not fall within *Zauderer* must be evaluated under *Central*

Hudson. In *R.J. Reynolds Tobacco Co.*, the D.C. Circuit considered an earlier FDA graphic warning requirement for tobacco products. After concluding that the disclosures in that case did not fall within *Zauderer*, 696 F.3d at 1213–17, the court stated that "*Central Hudson* is the appropriate standard." *Id.* at 1217.[2] The D.C. Circuit explained 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"; in the context of commercial speech, "the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are narrowly tailored to achieve a substantial government goal," *i.e*. the *Central Hudson* standard. *Id*. at 1217 (quoting *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1142–43 (D.C. Cir. 2009)).

Consistent with all of this precedent, none of the Supreme Court cases cited by RJR holds that regulation of commercial speech, whether in the form of a factual disclosure requirement or a speech restriction, is subject to strict scrutiny. In *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573 (1995), the Supreme Court recognized that the government has more authority to compel disclosures in the commercial-speech context than in non-commercial contexts. But the Court did not consider *when* a commercial disclosure (hypothetically) might fall outside of *Zauderer*'s reach, and thus did not address whether *Central Hudson* or strict scrutiny should apply in such a case. *Brown v. Entertainment Merchants Ass'n*, 564 U.S. 786 (2011), does not mention *Zauderer*, *Central Hudson*, or commercial speech, and the state law at issue was analyzed as a "restriction on the content of protected speech," not as a

[2] The D.C. Circuit panel in *R.J. Reynolds* held *Zauderer* inapplicable for two reasons. First, it found the disclosure requirements in that case were not factual and noncontroversial, *see id*. at 1216—a criticism that the FDA's brief (at 27–32) demonstrates is wholly inapplicable to the revised requirements at issue in this case. Second, the panel asserted that *Zauderer* only applies to disclosures to prevent deception. *See id.* at 1213. As the en banc D.C. Circuit recognized in *American Meat Institute*, that assertion was incorrect, and *American Meat Institute* therefore expressly overruled *R.J. Reynolds* on that point. *See* 760 F.3d at 22.

mandatory disclosure law applicable to commercial speech. *Id*. at 799. And *Pacific Gas & Electric Co. v. Public Utilities Commission of California*, 475 U.S. 1 (1986), turned on the Supreme Court's conclusion that the newsletter at issue in that case was entitled to "full protection of the First Amendment"—a situation that the Court distinguished from the circumstances in *Zauderer* and *Central Hudson*. *Id.* at 8.

Moreover, the courts of appeals' decisions cited by RJR are inapposite. In *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), the Seventh Circuit held that strict scrutiny applies when the government seeks to label fully protected content—in that case, video games—as "sexually explicit," a type of "subjective and highly controversial message" characterizing protected speech that the court stated was "unlike a surgeon's general's warning of the carcinogenic properties of cigarettes," *id.* at 652—a product whose sale in commerce is not entitled to any First Amendment protection. The Seventh Circuit thus recognized that its decision did not preclude the government from requiring "warning and nutritional information labels" under *Zauderer*, *id.*, and it cited the Second Circuit's decision in *Sorrell*, which, in turn, had held that a legitimate purpose of such labels can be "to better inform consumers about the products they purchase." *Sorrell*, 272 F.3d at 115. Finally, RJR claims that *Hersh* applied strict scrutiny to a disclosure requirement that was not related to consumer deception. RJR Br. 7 n.4, 21, 45. *Hersh*, however, although it upheld the requirement under heightened scrutiny, does not purport to reject *Zauderer*. To the contrary, *Hersh* found "support[]" for its conclusion in *Milavetz, Gallop & Milavetz, P.A. v. United States*, 541 F.3d 785, 796 (8th Cir. 2008), *aff'd in part, rev'd in part*, *Milavetz*, 559 U.S. 229, which applied *Zauderer* to claims "essentially parallel to those raised by Hersh." *Hersh*, 553 F.3d at 768. That portion of *Hersh* would make little sense if, as RJR contends, the court believed *Zauderer* inapplicable to the disclosure requirements at issue.

In short, commercial speech has always received less First Amendment protection than fully protected speech. RJR's position that *some* commercial-speech disclosure requirements should be evaluated under strict scrutiny is at odds with *Central Hudson, Zauderer*, and the significant Supreme Court and appellate precedent applying those decisions.[3]

CONCLUSION

The Court should deny plaintiffs' motion for summary judgment and for a preliminary injunction and grant defendants' cross-motion for summary judgment.

Dated: July 17, 2020

Respectfully submitted,

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[3] Although *Zauderer* applies here for the reasons given above and in the FDA's brief, if the Court disagrees, it should evaluate—and uphold—the FDA's disclosure rules under the *Central Hudson* standard. *See* FDA Br. 45–47 (examining rules under *Central Hudson*).

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2020, I caused the foregoing to be filed with the Clerk of the Court through the Court's ECF system, which will serve notice of the filing on all filers registered in the case.

/s/ Nandan M. Joshi
Nandan M. Joshi