

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHILIP MORRIS USA INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 1:20-cv-01181-KBJ

**BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF
DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT**

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INTEREST OF AMICUS CURIAE

Amicus curiae Public Citizen, a nonprofit consumer advocacy organization with members in all 50 states, 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, drugs, 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 which have addressed FDA regulation of tobacco products. *See R.J. Reynolds Tobacco Co. v. U.S. FDA*, No. 6:20-cv-176 (E.D. Tex.) (pending); *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56 (D.C. Cir. 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 by 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 is concerned about efforts by corporations such as Philip Morris to use commercial speech doctrine to stifle regulatory measures designed to protect consumers. In particular, corporations increasingly raise First Amendment challenges to disclosure regulations that provide consumers with important information about the quality or nature of, or risks associated with, consumer products and services. Commercial-speech doctrine developed from the recognition that complete prohibitions on truthful commercial speech, which had historically fallen outside the protection of the First Amendment, often were not needed to serve legitimate government interests and could result in consumer harm. *See Va. Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 770 (1976). Now, however, 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, impair legitimate government interests and threaten to harm consumers.

Here, for example, the cigarette-company plaintiffs ask this Court to subject the FDA’s disclosure regulation to a higher level of First Amendment scrutiny than is proper under applicable precedent. Adopting this view would undermine the important public-health benefits served by the 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.

ARGUMENT

I. The *Zauderer* standard, not strict scrutiny, is the proper basis for assessing the required disclosures about the health risks of cigarettes.

Implementing a directive of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), 15 U.S.C. § 1333(a)(2), (b)(2), the FDA issued a rule requiring cigarette manufacturers to disclose the health risks of cigarette use through textual warnings and associated photorealistic images on cigarette packaging and advertising. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) (to be codified at 21 C.F.R. pt. 1141). In challenging that rule under the First Amendment, Philip Morris does not dispute that the rule compels the disclosure of information and does not restrict the content of cigarette manufacturers’ own messages to consumers. Under Supreme Court and D.C. Circuit precedent, Philip Morris’s constitutional challenge must be assessed under the standard set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), because the FDA’s regulation requires only disclosure of truthful commercial information and does not prohibit dissemination of truthful commercial speech. *See Am. Meat Inst. v. U.S. Dep’t of Agric.*, 760 F.3d 18, 26–27 (D.C. Cir. 2014) (en banc). The Court should reject Philip Morris’s argument that the FDA’s disclosure rule should be subject to heightened scrutiny—whether intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of*

New York, 447 U.S. 557 (1980), or strict scrutiny applicable to government regulation of fully protected speech.

A. The Supreme Court first recognized that commercial speech is entitled to a measure of constitutional protection in 1976. *See 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 to assess a regulation applicable solely to commercial speech. Instead, the Court has considered 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 Prods. 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*, 471 U.S. at 650. Under *Central Hudson* and its progeny, restrictions on commercial speech are subject to “intermediate scrutiny,” under which the government may restrict speech to “directly advance a substantial governmental interest” if the restriction is “no more extensive than is necessary to serve that interest.” *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (internal quotation marks and original brackets removed). By contrast, when a regulation compels the disclosure of commercial information, as opposed to restricting commercial speech, *Zauderer’s* “lower level of scrutiny” is the appropriate First Amendment standard. *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (*NIFLA*). Specifically, a law that requires “purely factual and

uncontroversial disclosures about commercial products,” *id.* at 2376, or about commercial services, *see id.* at 2372, “should be upheld unless [it is] ‘unjustified or unduly burdensome,’” *id.* at 2376 (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.

The *Zauderer* standard is premised on the recognition that “the interests at stake” in cases involving disclosure requirements “are not of the same order” as those in cases involving outright restrictions on speech. *Id.* “Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides,” a commercial speaker’s “constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.” *Id.* Disclosure requirements thus “trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech.” *Id.* These considerations led the Supreme Court in *Zauderer* to hold that heightened scrutiny in any form (including *Central Hudson*’s intermediate scrutiny) does not apply when the government requires a commercial speaker to make factual disclosures in its advertising. Instead, judicial review of such requirements is subject to a substantially more deferential level of constitutional scrutiny. *Id.* The *Zauderer* standard thus protects legitimate First Amendment interests of commercial speakers without sacrificing the government’s substantial interest in ensuring that consumers receive important information about the nature of products and services offered for sale.

B. Here, Philip Morris contends that the FDA’s disclosure rule should be “subject to intermediate scrutiny at a minimum” because the regulation’s size and placement requirements operate as a restriction on speech. Pls. Mem. 42. Those requirements, however, are set forth in the Tobacco Control Act; and, as Philip Morris acknowledges (Pls. Mem. 44), the industry’s earlier

challenge to those requirements failed. In that case, the Sixth Circuit, applying *Zauderer*, held that the industry failed to show “that the remaining portions of their packaging are insufficient for them to market their products.” *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 567 (6th Cir. 2012).

The size and placement requirements at issue here are the same, and the Court should reach the same conclusion. *See* FDA Mem. 42. Every disclosure requires space, and efficacious disclosures will typically require more space—and perhaps more striking design elements—than ineffective ones. As the D.C. Circuit has held, those features do not transform a disclosure requirement into an “affirmative limitation on speech.” *Spirit Airlines, Inc. v. U.S. Dep’t of Transp.*, 687 F.3d 403, 413–14 (D.C. Cir. 2012) (applying *Zauderer* in upholding requirement that airlines “post the total, final price [of a ticket] in the most prominent manner” even though it “prohibit[ed] them from posting other numbers as prominently or more prominently than the total, final price”).

Moreover, the *Zauderer* standard itself incorporates consideration of whether a disclosure requirement unduly burdens speech. Thus, in *American Meat Institute*, the D.C. Circuit observed that *Zauderer* “cannot justify a disclosure so burdensome that it essentially operates as a restriction on constitutionally protected speech.” 760 F.3d at 27. And it cited *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136 (1994), in which the Supreme Court applied *Zauderer*, not *Central Hudson*, to invalidate a disclosure requirement that the Court found to be overly burdensome. *Id.* at 146–47. Although in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), the D.C. Circuit evaluated FDA tobacco disclosure requirements under *Central Hudson*, it did so based on findings that the specific warnings at issue there were not factual and noncontroversial, *see id.* at 1216—a criticism that the FDA’s brief (at 30–31) demonstrates is

wholly inapplicable here. The *R.J. Reynolds* holding was also based on the view that *Zauderer* applies only to disclosures intended to prevent deception, *id.* at 1213; on that point, the D.C. Circuit sitting en banc in *American Meat Institute* expressly overruled *R.J. Reynolds*, *see* 760 F.3d at 22.

Nonetheless, Philip Morris contends that other courts have invalidated disclosure requirements “based solely on the amount of speech the government takes away.” Pls. Mem. 43. None of the cases on which it relies, however, questions application of *Zauderer* to disclosure requirements or turns “solely” on the incidental effect that space requirements have on commercial speakers. In *NIFLA*, for example, the Court applied *Zauderer* to invalidate a California disclosure requirement imposed on unlicensed pregnancy centers. The Court concluded that, [a]t this preliminary stage of the litigation,” the state had “not demonstrated any justification” for the disclosure requirement that was not ““purely hypothetical.’” 138 S. Ct. at 2377 (quoting *Ibanez*, 512 U.S. at 146). In assessing undue burden under *Zauderer*, the Court further emphasized that the disclosure requirement was “wholly disconnected from California’s informational interest,” covering a “curiously narrow subset of speakers.” *Id.*; *see also Zauderer*, 471 U.S. at 651 (linking undue burden with the question whether the disclosure requirement is “reasonably related” to the government’s interest). Further, the disclosure would have required a “billboard for an unlicensed facility that says ‘Choose Life’” to be surrounded by “a 29-word statement from the government, in as many as 13 different languages,” with apparently no limit on the space that the statement would occupy. *NIFLA*, 138 S. Ct. at 2378. And the Court concluded its analysis by “express[ing] no view on the legality of a similar disclosure requirement that is better supported *or* less burdensome.” *Id.* (emphasis added). *NIFLA*’s record-specific analysis of California’s disclosure requirement provides no basis for evaluating the FDA’s regulation as if it were a restriction on commercial speech rather than a disclosure requirement.

Philip Morris's reliance on the Ninth Circuit's decision in *American Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749 (9th Cir. 2019) (en banc), is similarly flawed. The disclosure required in that case warned consumers of the health risks associated with sugar-sweetened drinks, and the law required product labels and advertisements for such beverages to devote 20 percent of their space to the disclosure. *Id.* at 753–54. The court applied *Zauderer* and expressly rejected application of *Central Hudson* to "health and safety warnings ... on commercial products." *Id.* at 755. Examining the "preliminary [injunction] record," the Ninth Circuit held that San Francisco had failed to carry its "burden of proving that the warning is neither unjustified nor unduly burdensome," noting in particular that San Francisco's own expert cited a study that indicated that devoting 10 percent of space to the disclosure would be effective. *Id.* at 756–57. But the court also made clear that it was not deciding that "a warning occupying 10% of product labels or advertisements necessarily is valid, [or] that a warning occupying more than 10% of product labels or advertisements necessarily is invalid." *Id.* at 757. Like *NIFLA*, *American Beverage* applies *Zauderer* to a specific evidentiary record; it does not support the use of heightened scrutiny to evaluate the FDA's disclosure requirement.

Likewise, *Entertainment Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), does not aid Philip Morris here. *See* Pls. Mem. 44. In that case, 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. The Seventh Circuit distinguished such video game labels from "warning and nutritional information labels" that are permitted under *Zauderer*. *Id.* Because the sale in commerce of cigarettes is not protected speech, and the FDA's health

warnings do not purport to regulate or label protected speech, the Seventh Circuit’s analysis in *Entertainment Software* cannot inform this Court’s First Amendment analysis of the commercial speech disclosure requirement at issue in this case.

C. Philip Morris’s plea for application of strict scrutiny, Pls. Mem. 54, is foreclosed by precedent. 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*. *See also* FDA Mem. 45 n.22.

The Supreme Court’s decision in *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144 (2017), illustrates the point. *Expressions Hair Design* concerned a statute prohibiting merchants from imposing surcharges on purchases made with credit cards. The Court held 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, under *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 suggest that strict scrutiny was a possibility for evaluating the disclosure requirements.

Indeed, the D.C. Circuit has squarely held that tobacco warnings—including those involving graphic images—are *not* subject to strict scrutiny. As the court explained in *R.J. Reynolds Tobacco Co.*, “[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.” 696 F.3d at 1217 (internal quotation marks omitted).¹

D. Philip Morris contends that strict scrutiny applies because the FDA is “requiring private speakers to adopt a particular viewpoint”—specifically, an “anti-smoking message.” Pls. Mem. 54. Putting aside that the FDA’s regulation is not viewpoint-based, *see* FDA Mem. 36–37, the two trademark registration cases on which Philip Morris relies—*Iancu v. Brunetti*, 139 S. Ct. 229 (2019), and *Matal v. Tam*, 137 S. Ct. 1744 (2017)—do not suggest that commercial speech regulation should be subject to strict scrutiny, let alone that a disclosure requirement requiring health warnings constitutes viewpoint-based regulation. In *Tam*, the Court held that the statutory prohibition on registering disparaging trademarks violated the First Amendment. The principal four-justice plurality did not decide “whether trademarks are commercial speech” because “the disparagement clause cannot withstand even *Central Hudson* review.” 137 S. Ct. at 1763–64. The other four-justice plurality, also without resolving whether *Central Hudson* applied, expressly distinguished trademark-registration restrictions from “laws relating to product labeling or otherwise designed to protect consumers.” *Id.* at 1768. Two years later, in *Brunetti*, the Court,

¹ As explained above, *supra* p.6, although *R.J. Reynolds* scrutinized the warnings under *Central Hudson*, its reasoning was overruled in part by *American Meat Institute*.

without discussing the applicable level of scrutiny, applied *Tam* to invalidate the restriction on registering immoral or scandalous trademarks. Neither of these cases has any relevance here.

Philip Morris also cannot justify strict scrutiny on the theory that the FDA's disclosure requirements constitute “[c]ontent- and speaker-based restrictions in the commercial context.” Pls. Mem. 54. The Supreme Court has never applied strict scrutiny to content- or speaker-based disclosure requirements applicable to commercial speech; indeed, the archetypal commercial speech case involves content-based regulations imposed on commercial speakers. In *Central Hudson* itself, the challenged law was plainly content-based—regulating advertisements that promoted use of electricity. See 447 U.S. at 557. Likewise, in other cases, the Supreme Court has consistently applied either *Zauderer* or intermediate scrutiny to commercial speech disclosure requirements or restrictions that can also be portrayed as content- or speaker-based. See, e.g., *Milavetz*, 559 U.S. at 249–51 (applying *Zauderer* in upholding requirement that debt relief agencies provide specific information in their advertisements); *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 176, 183–84 (1999) (applying intermediate scrutiny to prohibition on broadcast advertising of legal casino gambling); *Zauderer*, 471 U.S. at 652–53 (upholding requirement that attorneys advertising contingent-fee arrangements disclose clients' potential liability for costs). In each case, the commercial-speech restrictions or requirements turned on the subject matter of the speech and the identity of the speaker. In each case, the Court applied either *Zauderer* or *Central Hudson*.

Reed v. Town of Gilbert, 576 U.S. 155 (2015), cited by Philip Morris, is not to the contrary. There, the Supreme Court struck down a law that prohibited outdoor signs without a permit but exempted twenty-three categories of signs, including political and ideological signs and temporary directional signs. See 135 S. Ct. at 2224–25. The law did not, however, exempt the (noncommercial) signs plaintiffs sought to display. *Id.* at 2225. The Court cited noncommercial-speech cases for the

proposition that “[c]ontent-based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” *Id.* at 2226. The Court defined the phrase “content-based,” explaining that “[g]overnment regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed.” *Id.* at 2227 (citing *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011)). And it found that the ordinance in *Reed* was content-based because it “single[d] out specific subject matter for differential treatment.” 135 S. Ct. at 2230. The Court then applied strict scrutiny to the ordinance as a content-based regulation of fully protected, noncommercial speech. *Id.* at 2231. Critically, *Reed* did not hold—or even discuss the possibility—that strict scrutiny would apply to content-based commercial-speech regulations. *See Nationwide Biweekly Admin., Inc. v. Owen*, 873 F.3d 716, 732 (9th Cir. 2017) (“Although Nationwide struggles mightily to find a new First Amendment principle between the lines of *Reed*, there is simply nothing there to find.”).

Philip Morris also errs in relying on *Barr v. American Ass’n of Political Consultants, Inc.*, 140 S. Ct. 2335 (2020) (*AAPC*). In that case, the Court addressed a First Amendment challenge to a provision of the Telephone Consumer Protection Act (TCPA) that bans robocalls (including robocalls of a political nature) but permits robocalls to collect government-owned or government-backed debts. *Id.* at 2343. The plurality opinion applied strict scrutiny because the TCPA “favor[ed] speech made for collecting government debt over political and other speech.” 140 S. Ct. at 2346 (emphasis added). Nothing in the plurality’s opinion overrules precedent rejecting application of strict scrutiny to regulations solely of commercial speech. Indeed, the plurality went out of its way to explain that its opinion was “not intended to expand existing First Amendment doctrine or to otherwise affect traditional or ordinary economic regulation of commercial activity.” *Id.* at 2347. *See also id.* 2364 (Gorsuch, J., concurring in part and dissenting in part) (stating that “[t]he statute is content-based

because it allows speech on a subject the government favors (collecting its debts) while banning speech on other disfavored subjects (including *political matters*).” (emphasis added)).

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

The Supreme Court has repeatedly rejected least-restrictive-means analysis of commercial-speech regulations, “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; *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. And disclosure requirements themselves are considered “one of the acceptable less restrictive alternatives to actual suppression of speech.” *Zauderer*, 471 U.S. at 651–52 n.14.

Philip Morris suggests, however, that the FDA’s disclosure regulations fail *Zauderer* because, “[u]nder *NIFLA*, a compelled disclosure is ‘unjustified or unduly burdensome’ if the government has a less-speech restrictive alternative that ‘would accomplish [its] stated goals.’” Pls. Mem. 45 (quoting *Am. Beverage*, 916 F.3d at 756–57)). Yet *NIFLA* did not alter the settled law that commercial disclosure regulations are not subject to a least-restrictive-means analysis. *NIFLA* 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.

Philip Morris’s reliance on the Ninth Circuit’s decision in *American Beverage* is also misplaced. *See* Pls. Mem. 45. *American Beverage* does not hold that the government must demonstrate that its disclosure requirement is the least restrictive that can achieve its purposes. Rather, as noted above, in that case, San Francisco failed to carry its “burden of proving that the warning is neither unjustified nor unduly burdensome” in the “preliminary [injunction] record” that was before the court. 916 F.3d at 756. Here, the government’s brief explains why the record before this Court supports the content and design of the FDA’s disclosure requirement. FDA Mem. 39–40, 49–50.

III. The government has a substantial interest in ensuring that consumers are informed about the health risks of smoking.

Whether *Zauderer* requires a disclosure regulation to serve a substantial governmental interest is an open question in this circuit. *See Am. Meat Inst.*, 760 F.3d at 23. This Court does not need to resolve that question, however, because the government’s interest in requiring disclosures to provide consumers with relevant information about products and services, especially information related to health and safety, is substantial. Thus, in *American Meat Institute*, the D.C. Circuit held that the government had a substantial interest in mandating disclosure of country-of-origin information on meat products, citing “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.” *Id.*; see also *id.* at 24 (discussing congressional intent to “enabl[e] customers to make informed choices based on characteristics of the products they wished to purchase”).

Philip Morris does not argue that *Zauderer* requires the FDA to demonstrate a substantial interest to require disclosures about the health risks of tobacco use. Arguing for intermediate scrutiny, however, it asserts that the FDA cannot satisfy *Central Hudson*’s requirement of a substantial governmental interest absent a separate interest in having consumers “appreciate risks differently or make different choices.” Pls. Mem. 55–56. Although it again points to *R.J. Reynolds*, see Pls. Mem. 55, see also *supra* p. 5–6, the court there stated firmly that “the government can certainly require that consumers be fully informed about the dangers of hazardous products.” 696 F.3d at 1212. The FDA’s disclosure rule is aimed at advancing that substantial interest.

CONCLUSION

The Court should grant defendants’ cross-motion for summary judgment.

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