IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

R.J. REYNOLDS TOBACCO COMPANY; LORILLARD TOBACCO COMPANY; COMMONWEALTH BRANDS, INC.; LIGGETT GROUP LLC; and SANTA FE NATURAL TOBACCO COMPANY, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, Commissioner of the United States Food and Drug Administration; and KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services,

Defendants.
_____/

CIVIL ACTION NO: 11-1482(RCL)

BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF *AMICUS CURIAE*

The interests of the Washington Legal Foundation (WLF) are more fully set forth in its accompanying motion for leave to file this brief. Founded in 1977, WLF is a public interest law and policy center with supporters in all 50 states. WLF regularly participates as *amicus curiae* in litigation to promote economic liberty, free enterprise, and a limited and accountable government. In particular, WLF has devoted substantial resources over the years to defending free speech rights, both of individuals and of the business community. To that end, WLF has regularly appeared before this and other federal and state courts in cases raising important First Amendment issues, especially those involving compelled speech. *See, e.g., Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550 (2005); *United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457 (1997).

WLF strongly objects to government efforts to compel individuals or corporations to speak against their will. WLF believes that Plaintiffs have a high probability of success on the merits and supports each of the arguments made in Plaintiffs' memorandum in support of the motion for preliminary injunction (Dkt. 11). We write separately, however, to address the Government's contention that *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), supplies the appropriate level of First Amendment scrutiny in this case. Simply put, the new graphic warnings the FDA seeks to impose in this case are not ordinary disclosure requirements of the kind upheld in *Zauderer*. Rather, they are the sort of controversial, nonfactual disclosures of which *Zauderer* very clearly did not approve. Such ideological messages have *nothing* to do with protecting consumers from being misled—a bedrock requirement of *Zauderer*. If anything, *Zauderer* actually highlights the constitutional defect in the FDA's position.

WLF also doubts the empirical effectiveness of the FDA's new warnings regime. No credible evidence exists that the proposed graphic warnings would accomplish the Government's stated goal of reducing smoking rates among adults and children. Indeed, FDA's own regulatory impact analysis concluded that the estimated impact the new warnings will have on smoking rates is "not statistically distinguishable from zero." In the absence of any evidence that the new warnings will "have a significant, positive impact on public health," there can be no justification for drastically commandeering the packaging and advertising of a perfectly legal product.

STATEMENT OF THE CASE

Plaintiffs, five American tobacco manufacturers, challenge the FDA's final rule ("the Rule") implementing Section 201 of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009). *See* FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011). Although federal law has long required warnings regarding the health risks of smoking to appear on every pack of cigarettes and in every cigarette advertisement, the Rule goes much further by commandeering the manufacturer's brand and packaging in order to convey the Government's own anti-smoking message, which Plaintiffs find objectionable.

Specifically, the Rule requires cigarette manufacturers to prominently display nine new warnings on their packaging and advertising; these warnings must occupy the top 50% of the front *and* back panels of every cigarette package and the top 20% of all printed advertising. The warnings contain text accompanied by controversial graphic images, including various images of diseased body parts and an image of a body on an autopsy table. They also contain the directive "QUIT-NOW" and urge consumers to call a telephone hotline to learn how to stop smoking. These new warning and labeling requirements will become effective for all cigarette packages manufactured on or after September 22, 2012, and introduced into commerce on or after October

22, 2012.

On August 16, 2011, Plaintiffs filed suit (Dkt. 1) seeking to invalidate the Rule under both the First Amendment and the Administrative Procedure Act, 5 U.S.C. §§ 553(b)(3), 705, 706(2)(A). Plaintiffs subsequently moved for summary judgment and a permanent injunction (Dkt. 10) and simultaneously moved for preliminary injunction (Dkt. 11). The Government opposes (Dkt. 18) Plaintiffs' motion for preliminary injunction. WLF hereby submits this *amicus* brief in support of Plaintiffs' motion (Dkt. 11) for preliminary injunction.

SUMMARY OF ARGUMENT

The First Amendment guarantees "both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). As a result, the Supreme Court has repeatedly struck down laws that compel a speaker to convey a message dictated by the government. In an effort to side step the Supreme Court's longstanding compelled speech jurisprudence, the Government contends that *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), supplies the appropriate level of First Amendment scrutiny in this case. Not so.

The new graphic warnings the FDA seeks to impose on tobacco manufacturers in this case are not ordinary disclosure requirements of the kind upheld in *Zauderer*. Rather, they are the sort of controversial, nonfactual disclosures that *Zauderer* very clearly did not allow. Such ideological messages have *nothing* to do with protecting consumers from being misled—a requirement of *Zauderer*. If anything, *Zauderer* actually highlights the constitutional defect in the City's reasoning.

Even in the commercial speech context, the Supreme Court has also made clear that it is the regulators who bear the burden of justifying their regulation. *See, e.g., Edenfield v. Fane*,

507 U.S. 761, 770 (1993) ("[T]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it."). Although the Government bears the burden of establishing the empirical effectiveness of the FDA's new warnings regime, no credible evidence exists that the proposed graphic warnings would accomplish the Government's stated goal of reducing smoking rates among adults and children. Indeed, FDA's own regulatory impact analysis concluded that the estimated impact the new warnings will have on smoking rates is "not statistically distinguishable from zero."

In the absence of any evidence that the new warnings will "have a significant, positive impact on public health," there can be no justification for drastically commandeering the packaging and advertising of a perfectly legal product. WLF respectfully suggests that before the FDA imposes the severe warnings and labeling regime of the sort proposed by the Rule, it ought to have solid evidence that such drastic measures will achieve their intended objectives.

ARGUMENT

I. THE GOVERNMENT'S PURPORTED RELIANCE ON *ZAUDERER* AND ITS PROGENY IS ENTIRELY MISPLACED

Plaintiffs' supporting memorandum of law convincingly demonstrates that the FDA's new Rule cannot withstand *any* version of First Amendment scrutiny. It cannot survive either the strict scrutiny required in cases where the government seeks to compel government-preferred speech, *Wooley v. Maynard*, 430 U.S. 705, 715 (1977), or the intermediate *Central Hudson* test customarily applied to commercial speech restrictions, *Central Hudson Gas & Elec. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). WLF will not repeat those arguments here.

We write separately to refute the Government's suggestion that *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), controls this

case. The new mandatory warnings imposed by the Rule are not ordinary disclosure requirements of the kind upheld in *Zauderer*. Rather, they are the sort of controversial, nonfactual disclosures of which *Zauderer* very clearly did not approve. Indeed, the admonition to "QUIT-NOW" does not "disclose" anything; rather, it is an ideological message that has *nothing* to do with protecting consumers from being misled.

A. Because the Rule is Not Aimed at Preventing Consumer Deception, *Zauderer* Does Not Apply.

In its opposition to Plaintiffs' motion, the government seeks to invoke the dramatically reduced standard of review associated with *Zauderer* on the basis of nothing more than bald assertions. *See* Dkt. 18 at 25 (citing *Zauderer* for the proposition that "[a] still more relaxed standard applies when a regulation does not preclude the conveyance of a truthful message but, as in this case, mandates the inclusion of additional information"). Contrary to the Government's claim, *Zauderer* offers no support for the FDA's First Amendment position in this case. In *Zauderer*, the Supreme Court *overturned* a state court's reprimand of an attorney for an advertisement that was neither false nor deceptive but sustained the reprimand to the extent that the advertisement omitted a disclosure that a client would be liable for costs in the event a contingent-fee lawsuit was unsuccessful. Upholding the disclosure requirement for the sole purpose of correcting misleading commercial speech, *Zauderer* cautioned:

> We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. But we hold 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.***

471 U.S. at 651 (emphasis added). Thus, *Zauderer* squarely held that disclosure requirements are permissible only if necessary "to dissipate the possibility of consumer confusion or deception." *Id*. Indeed, the Court upheld the state's imposition of a disclaimer only after finding

that the possibility of deception was "self-evident" and that "substantial numbers of potential clients would be so misled" without the state's disclosure rule. *Id*. at 652. By its own terms, *Zauderer* applies only to mandated disclosures that serve the government's interest in preventing deception of consumers.

If anything, *Zauderer* actually highlights the constitutional defect in the FDA's Rule. And subsequent Supreme Court cases have only reaffirmed that the "reasonably related" test of *Zauderer* has real teeth. In *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), the Court invalidated under the First Amendment a federal requirement that mushroom producers pay an assessment for generic advertising, to which they objected. In its short opinion, the Court distinguished *Zauderer*:

> Noting that substantial numbers of potential clients might be misled by omission of the explanation, the [*Zauderer*] Court sustained the requirement as consistent with the State's interest in "preventing deception of consumers." There is no suggestion in the case now before us 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 (emphasis added). Time after time, the Court has cautioned that *Zauderer* does not apply unless the state demonstrates an actual likelihood that consumers will be misled absent the disclosure. *See e.g. Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339-40 (2010) (upholding a disclosure requirement directed at "misleading commercial speech" but emphasizing that *Zauderer* is limited "to combat[ing] the problem of inherently misleading commercial advertisements"); *Glickman v. Wileman Bros. & Elliott*, 521 U.S. 457, 490 (1997) (Souter, J., dissenting) ("[H]owever long the pedigree of such mandates may be, and however broad the government's authority to impose them, *Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages."); *Pacific Gas & Elec.*, 475 U.S. at 15 n.12 ("Nothing in *Zauderer* suggests . . . that the State is

equally free to require [entities] to carry the message of third parties, where the messages themselves are biased against or are expressly contrary to the [entity's] views.").

Here, the mandatory graphic warnings imposed by the Rule are not necessary to make the sale of cigarettes non-misleading. Consumers are well aware of the health risks posed by tobacco; federal law has long required warnings regarding the health risks of smoking to appear on every pack of cigarettes and in every cigarette advertisement. Nor can the government credibly claim that it requires cigarette manufacturers to convey the message "QUIT-NOW" in order to somehow prevent consumer deception—rather than merely to discourage consumers from smoking. Indeed, the FDA does not even claim that preventing consumers from being deceived or misled is a primary motivation behind the Rule. *See* Dkt. 18 at 33 (conceding that the Rule's primary purpose is "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements"). Unlike unwittingly retaining an attorney with the expectation of incurring no expenses only to be saddled with legal costs as in *Zauderer*, there is nothing inherently deceptive or misleading to consumers about buying cigarettes.

The theory underlying the new Rule appears to be that no rational person would choose to use tobacco products, and that those who do are obviously misinformed about the health risks. But that theory is belied by human experience, which demonstrates that individuals routinely choose to engage in a wide range of activities that others would consider overly risky—from mountain climbing and bungee jumping to eating red meat and sunbathing. As a good friend of Chief Justice William Rehnquist recently recounted:

> I often speculated as to why a man who was smart, disciplined, intellectually focused and strong-willed could not break the tobacco habit. Whenever I brought up the subject, he explained that he knew he could quit. As a matter of fact, he said that he had gone cold turkey for extended periods several times in his life. But he greatly enjoyed cigarettes. And he knowingly accepted the trade-offs. Several times he explained his [smoking habit] in an idiom he particularly liked:

"Let's just say that I am an informed bettor."

Herman Obermayer, *The William Rehnquist You Didn't Know*, ABA JOURNAL (Mar. 2010). But satisfying "consumer curiosity alone is not a strong enough state interest to sustain compulsion of even an accurate, factual statement . . . in a commercial context." *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996).

B. Because the Rule Does Not Concern the Disclosure of Purely Factual, Uncontroversial Information, *Zauderer* Does Not Apply.

Zauderer endorsed compelled disclaimer requirements *solely* for the purpose of counteracting potentially misleading messages included in an advertisement. But the Supreme Court has never suggested that "companies can be made into involuntary solicitors for their ideological opponents." *Cent. Ill. Light Co. v. Citizens Utility Bd.*, 827 F.2d 1169 (7th Cir. 1987). Rather, *Zauderer* allowed the state to require that advertisers "include in [their] advertising *purely factual* and *uncontroversial* information about the terms under which [their] services will be available." 471 U.S. at 651.

The Rule mandates warnings that do not even purport to convey purely factual or noncontroversial information. Rather, they ultimately communicate "a subjective and highly controversial message." *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006). "Such forced association with potentially hostile views burdens" free expression and "risks forcing [retailers] to speak where [they] would prefer to remain silent." *Pacific Gas & Elec.*, 475 U.S. at 18.

Nor can any potential health hazards posed by tobacco justify the government's invocation of *Zauderer*. The Supreme Court has repeatedly rejected assertions that there is a "vice" exception to the First Amendment. *Rubin v. Coors Brewing*, 514 U.S. 476, 482 n.2 (1995); *44 Liquormart v. Rhode Island*, 517 U.S. 484, 513-14 (1996). As Justice Stevens

explained:

> [T]he scope of any "vice exception" to the protection afforded by the First Amendment would be difficult, if not impossible, to define. Almost any product that poses some threat to public health or public morals might reasonably be characterized by a state legislature as relating to "vice activity." Such characterization, however, is anomalous when applied to products such as alcoholic beverages, lottery tickets, or playing cards, that may be lawfully purchased on the open market.

44 Liquormart , 517 U.S. at 514. So long as the purchase and sale of cigarettes continue to be lawful, there can be no basis for asserting that the health hazards posed by tobacco use justify a relaxation of normal First Amendment constraints on government action. *See United Foods, Inc.*, 533 U.S. at 410-11 ("[T]hose whose business and livelihood depend in some way upon the product involved no doubt deem First Amendment protection to be just as important for them as it is for other discrete, little noticed groups.").

For this and other reasons, the Government's suggestion that the graphic warnings imposed by the Rule are a valid regulation of commercial speech under *Zauderer* and its progeny is meritless. Rather than being "factual and uncontroversial," the question of whether or not to smoke cigarettes is far more opinion-based and controversial than a simple disclosure requirement.

II. NO CREDIBLE EMPIRICAL EVIDENCE LINKS THE RULE'S NEW GRAPHIC WARNINGS REGIME TO THE GOVERNMENT'S STATED OBJECTIVES

Even when the speech on which regulations are imposed is deemed "commercial speech"—that is, speech that does no more than "propose a commercial transaction," *Bd. of Trustees v. Fox*, 492 U.S. 469, 473 (1989)—courts have made clear that it is the regulators who bear the burden of justifying their regulations. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[T]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it."); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). The evidentiary

burden is not light; for example, the Government's burden of showing that a commercial speech regulation advances a substantial government interest "in a direct and material way . . . 'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.'" *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield*, 507 U.S. at 770-71).

In none of the cases in which the U.S. Supreme Court has addressed First Amendment challenges to regulations on commercial speech has the Court so much as suggested that it was willing to defer to a legislature's determinations regarding the need for such restrictions or their likely effectiveness. Such willingness would be inconsistent with the language quoted above; the burden of demonstrating that speech restrictions alleviate real harms to "a material degree" would amount to nothing if the government could meet that burden by simply pointing to legislative fact-finding devoid of any empirical evidence.

WLF respectfully suggests that before the FDA imposes the severe warnings and labeling regime of the sort proposed by the Rule, it ought to have solid evidence that such drastic measures will achieve their intended objectives. WLF submits that no such evidence exists. In the absence of any evidence that the new warnings will "have a significant, positive impact on public health," there can be no justification for drastically commandeering the packaging and advertising of a perfectly legal product.

WLF is aware of no credible evidence that the proposed graphic warnings would accomplish the Government's stated goal of reducing smoking rates among adults and children. Indeed, FDA's own regulatory impact analysis concluded that the estimated impact the new warnings will have on smoking rates is "not statistically distinguishable from zero." 76 Fed.

Reg. at 36,776. Notwithstanding these underwhelming findings, the FDA's regulatory impact analysis purporting to show that graphic warning labels will reduce smoking rates by even .0888 percent is highly problematic. In fact, if the years 1998 (the year the Master Settlement Agreement took effect) or 2010 (the year the FDA Act's other marketing restrictions took effect) are excluded, FDA's regulatory impact analysis would actually show an *increase* in smoking rates.

The Government purports to rely on sociological studies to support the notion that graphic warnings labels will somehow reduce the number of smokers in the United States. *See* 76 Fed. Reg. 36,628 (June 28, 2011). In particular, the Government touts studies suggesting that the labels appearing on cigarette packages and advertisements under the pre-existing warnings regime have gone largely unnoticed by smokers and non-smokers. *See, e.g.*, Fischer, et al., "Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements," *J. of the Am. Med. Assoc.*, 261: 84-89 (1989); Robinson, et al., "Do Cigarette Warning Labels Reduce Smoking: Paradoxical Effects Among Adolescents," *Archives of Pediatrics & Adolescent Med.*, 151(3): 267-72 (1997). But the studies relied on by the Government examine only whether people notice the warnings, not whether the warnings cause people to alter their behavior. In other words, none of these studies considers the likelihood that, even if consumers do take better notice of the new graphic warnings, they may not choose to alter their smoking behavior.

Nor do these studies provide any indication that the new graphic warnings are somehow likely to cause people to alter their smoking behavior. Rather, they convincingly demonstrate that "[g]reater knowledge of warning labels on advertisements was not significantly associated with either an increase or decrease in smoking." Robinson, et al., *supra*, at 271. In fact, "the observed association between warning label knowledge and subsequent increases in smoking

may suggest that even if attention and recall can be improved, cigarette warning labels *may do more harm than good*." *Id.* at 272. These studies are completely silent on whether warning labels are truly the most effective means of deterring smoking.

Many of the studies relied on by the Government do not even attempt to link the knowledge and perceived risk of health problems with an increase in a smokers' desire and resolve to quit smoking. For example, one survey concedes that "[w]hether theories of decision making and health behavior are correct that effective education about the seriousness of lung cancer and other smoking-related disease will deter people from smoking or increase smokers' efforts to quit *remains an open question*." Neil D. Weinstein, "Public Understanding of the Illness Caused by Cigarette Smoking," *Nicotine & Tobacco Research*, 6(2), 349-55, at 355 (April 2004). Simply put, none of the studies relied on by the Government can empirically attribute any greater effectiveness to graphic warning labels as opposed to increased public education and media campaigns or other less drastic approaches.

Unsurprisingly, the FDA fails altogether to reference numerous studies demonstrating the ineffectiveness of adopting graphic warnings of the type contemplated by the Rule. A recent study by David Hammond—an anti-smoking researcher on whom the Government frequently relies—reluctantly concludes: "[T]here is no way to attribute . . . declines [in smoking] to the new health warnings given that [they] are typically introduced against a backdrop of other tobacco control measures, including changes in price/taxation, mass media campaigns and smoke-free legislation." David Hammond, "Health Warning Messages On Tobacco Products: A Review," *Tobacco Control*, 20: 327-337, at 331 (August 17, 2011). *See also* Glenn Leshner, et al., "Motivated Processing of Fear Appeal and Disgust Images in Televised Anti-Tobacco Ads," 23(2) *Journal of Media Psychology*, 77-89 (2011) (concluding that the graphic ads accompanied

by threatening messages produce a defensive reaction among subjects and renders them less able to process and attend to the message, thereby reducing the likely effectiveness of the anti-smoking advocacy).

Because merely emotional responses do not translate into behavioral change, a recent 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 discernable impact on smoking behavior. *See* Heather Wardle, et al., "Final Report: Evaluating the Impact of Picture Warnings on Cigarette Packets," Public Health Research Consortium (2010) (finding "no changes in the breadth or depth of people's awareness of the health risks of smoking" after implementation in the United Kingdom of graphic health warnings).

RAND Europe's September 2010 Final Report on "Assessing the Impacts of Revising the Tobacco Products Directive" (the "RAND Report") is perhaps the most comprehensive government study to date of the impact on tobacco consumption of adopting policy measures of the type contemplated by the Rule. *See* RAND Europe, *Final Report on Assessing the Impacts of Revisiting the Tobacco Products Directive* (September 2010). Incredibly, even though it was commissioned and funded by the European Union, the RAND Report concluded that adoption of such policy measures would have virtually no impact on tobacco consumption. It concluded that the effect on tobacco consumption would be highly uncertain and would at most lead to a 0.5% reduction in smoking prevalence. Moreover, even those minimal impacts are subject to serious question in light of the extensive criticism that has been directed at the RAND Report by leading experts in the field. For example, the RAND Report included *no* quantitative econometric analysis, failed to consider whether the likely increases in counterfeiting and black market sales

would eliminate *any* reductions in smoking prevalence, and failed to consider whether the increased price competition likely to be engendered by plain packaging would have similar effects.

Ironically, following the notice and comment period, the FDA's Final Rule dismissively criticized some comments because they "referenced older studies that did not specifically address graphic warnings on cigarette packages and advertisements." *See* 76 Fed. Reg. 36,634. Yet neither the 1989 Fischer study nor the 1997 Robinson study repeatedly relied on by the FDA considered graphic warnings; both dealt solely with textual warnings. As a result, there is nothing in either study to suggest that a graphic warning will somehow receive more attention or be more effective at deterring smokers than the preexisting textual warning scheme.

In sum, there simply is no credible evidence that the regulations imposed by the Rule would accomplish the legislation's primary goal of reducing the incidence of smoking among adults and children. In the absence of such evidence, there can be little justification for proceeding with reforms that undoubtedly would have such a major adverse financial impact on legally operating businesses.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant Plaintiffs' motion for preliminary injunction.

Respectfully submitted,

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