ORAL ARGUMENT SCHEDULED FOR APRIL 10, 2012

No. 11-5332

IN THE

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

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

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia
Case No. 11-CV-1482(RJL)

BRIEF OF THE WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES, URGING AFFIRMANCE

Daniel J. Popeo
Cory L. Andrews
Richard A. Samp
WASHINGTON LEGAL
FOUNDATION
2009 Mass. Ave., N.W.
Washington, DC 20036
(202) 588-0302
Counsel for Amicus Curiae

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES AND CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Amicus curiae Washington Legal Foundation (WLF) certifies as follows:

1. Parties and Amici

All parties, intervenors, and amici appearing before the district court and in this Court are listed in the Brief for Appellants.

Pursuant to Circuit Rule 19(b), Federal Rule of Appellate Procedure 26.1, and Circuit Rule 26.1, the undersigned counsel states that *amicus curiae* Washington Legal Foundation (WLF) is a non-profit corporation organized under Section 501(c)(3) of the Internal Revenue Code; it has no parent company, issues no stock, and no publicly held company holds a 10% or greater ownership interest.

Pursuant to Circuit Rule 26.1(b), WLF describes its general nature and purpose as follows: WLF is a public interest, law and policy center that regularly appears in this Court in cases raising important First Amendment issues.

2. Ruling Below

References to the rulings below at issue appear in the Brief for Appellants.

3. Related Cases

WLF is unaware of any related cases other than those listed in the Brief for Appellants.

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GLOSSARY

APA	Administrative Procedure Act
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IOM Report	Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007)
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act of 2009
WLF	Washington Legal Foundation

INTEREST OF *AMICUS CURIAE*[1]

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 is familiar with the legal issues presented by this litigation, having twice participated as an *amicus curiae* in the district court below. WLF supports all of the arguments advanced in Appellees'

[1] Pursuant to Federal Rule of Appellate Procedure 29(c), WLF states that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties to this dispute have consented to the filing of this brief.

brief. We write separately, however, to challenge 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, as the district court rightly concluded in granting Plaintiff's request for preliminary injunction, 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* only undermines the FDA's legal position in this case.

WLF also rejects 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, much less better informing tobacco consumers about the risks of smoking. Indeed, FDA's own regulatory impact analysis has 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. Under the Rule, 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 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 and simultaneously moved for a preliminary injunction. The Government opposed Plaintiffs' motion for preliminary injunction and moved for summary judgment in its own right. On November 7, 2011, the district court granted Plaintiffs' motion for preliminary injunction. The Government now appeals from that order. WLF hereby submits this *amicus* brief in support of the Plaintiffs, urging affirmance of the district court's grant of 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 its 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* further highlights the constitutional flaw in the Government's graphic warnings regime.

In the First Amendment context, the Supreme Court has made clear that it is always the regulators who bear the burden of justifying their regulation. *See, e.g.*, *Glickman*, 521 U.S. at 492 ("The burden is on the government."); *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 actually reducing smoking rates among adults and children, much less better informing tobacco consumers about the risks of smoking. 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." 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. 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.

Finally, throughout the proceedings below, the Government presented the district court with carefully selected language from the Institute of Medicine's 2007 report as "evidence" of the need for new graphic warnings. If this Court merely scratches beneath the surface of those breezy citations, however, it will uncover a curious tendency on the part of the Government to inflate and even misstate the findings of the IOM Report's underlying sources and studies. WLF urges this Court to carefully and doggedly follow the Government's scientific claims to their ultimate authoritative source. Only then will it become clear that none of these studies support the Government's justification for imposing the Rule.

ARGUMENT

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

Plaintiffs' appellate brief convincingly demonstrates that the FDA's new Rule is subject to strict scrutiny, and moreover cannot withstand *any* version of First Amendment scrutiny. It cannot survive the strict scrutiny required in a case such as this, where the government seeks to compel

government-preferred speech. *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). Nor can it survive 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.

Throughout this litigation, the Government has sought to invoke the standard of First Amendment review associated with *Zauderer* on the basis that Plaintiffs have only a "minimal" constitutional interest in not providing the graphic warnings to their consumers. *See, e.g.*, JA at 89 (invoking the "more relaxed standard" of *Zauderer*). Contrary to the Government's claim, however, *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* only exposes the constitutional defect in the FDA's position in this case. Notwithstanding the Government's futile attempt to recast

the Rule's graphic labels as disclosures under *Zauderer*, *see* Appellant's Brief at 25-27, every Supreme Court case to consider the question has unabashedly reaffirmed that the "reasonably related" test of *Zauderer* has real teeth. In *United States v. United Foods, Inc.*, 533 U.S. 405 (2001), for example, 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, but rather contends that the Rule's primary purpose is "to convey the negative effects of smoking." JA at 92. 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).

The Government apparently takes the position that exposure to tobacco packaging causes some adult consumers to start smoking and that any such decision is by definition a "bad" decision because – regardless how much the consumers may enjoy smoking– it is likely to have long-term adverse health effects for the consumers. The Government then leaps to the conclusion that it is entitled to "protect" consumers from their foolish choices by infringing on tobacco manufacturers' First Amendment rights. But discouraging "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).

By second-guessing the personal choices of adult consumers, the FDA assumes for itself an improper role. As the Supreme Court held in *FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120, 138-39 (2000), Congress has struck a careful balance in every statute it has enacted regulating the labeling and advertisement of tobacco products, having "expressly provid[ed] that it is the policy of Congress that 'commerce and the national economy may be . . . protected to the maximum extent consistent with' consumers 'be[ing] adequately informed about any adverse health effects'"—a compromise the Court held "reveal[ed] its intent that tobacco products remain on the market." *Id*. (citing 15 U.S.C. § 1331). In direct conflict with that congressional intent, Secretary Sebelius has announced her intention that the graphic warnings will "chart[] a clear path to ending tobacco use in our country." *See* Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser. Congress, in enacting the Family Smoking Prevention and Tobacco Control Act, did not rescind that compromise, but rather reaffirmed it by retaining the compromise language in Section 1331 and including as a stated

purpose, in Section 3(7) of the Act, "to permit the sale of tobacco products to adults . . . ." The FDA, by trying to second-guess that congressional balance and override the personal choices of adults, is acting inconsistently with the statute.

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. Tellingly, the Government's brief fails even to inform the Court that *Zauderer* is limited solely to purely factual and uncontroversial information, but instead proceeds as if *Zauderer* governs all mandated disclosures, regardless of what information those disclosures contain. Likewise, at the district court below, the Government repeatedly failed to explain how the graphic warnings were either purely factual or noncontroversial. *See* JA at 92-101. Nor can it do so now.

The Rule requires cigarette manufacturers to convey the message "QUIT-NOW" to their customers. Such a message does not even purport to convey purely

factual or noncontroversial information. Rather, it ultimately communicates "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. And as the district court correctly recognized in preliminarily enjoining implementation of the Rule, notwithstanding the FDA's obvious anti-smoking advocacy, "the fact alone that some of the graphic images here appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of 'purely factual.'" JA at 28.

Even assuming, *arguendo*, that the graphic warnings are purely factual, it strains all credulity for the Government to seriously suggest that the graphic warnings are somehow noncontroversial. After all, the warnings contain highly controversial graphic images, including various images of diseased body parts and an image of a body on an autopsy table, all intended to elicit an emotional response that will shock tobacco consumers (and potential tobacco consumers). Indeed, the Secretary of Health and Human Services has publicly admitted that the warnings are part of the FDA's ongoing campaign to "encourage smokers to quit" and are intended to convey the message that "smoking is gross" and to "dispel[] the notion that somehow [tobacco use] is cool." *See* Press Briefing by Press Secretary Jay

Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), *supra*. For the Government to now insist that such blatant shock tactics are noncontroversial asks this Court to lay aside its common sense. Presumably, under the Government's interpretation of "noncontroversial," beef producers could be required to include graphic images of cattle being slaughtered on packages of beef in an effort to merely "educate consumers" about how beef is made.

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. The Rule is therefore subject to strict scrutiny, which it cannot possibly satisfy. *See Pacific Gas & Elec.*, 475 U.S. at 15 n.12.

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

Although WLF believes that the graphic warnings imposed by the Rule are impermissible compelled speech subject to strict scrutiny, the Rule also fails to satisfy the constitutional hurdles of either *Zauderer* or *Central Hudson*. First, even if *Zauderer* supplies the appropriate test, the Government may not mandate even a purely factual and uncontroversial disclosure if it is "unjustified or unduly burdensome." *Zauderer*, 471 U.S. at 651. Here, in light of the FDA's own conclusion that the Rule will have no discernible impact on smoking beliefs or behavior, it only follows that confiscating the top 50% of cigarette packaging and

the top 20% of advertising for government-mandated graphic warnings is an "unjustified" and "unduly burdensome" restriction on tobacco manufacturers' First Amendment rights.

Second, even under *Central Hudson* where 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*, 507 U.S. at 770 ("[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). This 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*, 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 770-71).

Since the U.S. Supreme Court's decision in *44 Liquormart*, commercial speech has been increasingly afforded greater First Amendment protection. Indeed, members of the Court have discussed eliminating all or part of the *Central*

Hudson test in favor of a stricter level of scrutiny. *See 44 Liquormart*, 517 U.S. at 518-20 (Thomas, J., concurring). The *Central Hudson* test remains in place, but has been applied inconsistently and sometimes improperly by lower federal courts since *44 Liquormart*. In the instant case, however, the Government urges an analysis and application of the third prong of the *Central Hudson* test that is so watered down as to render that prong virtually meaningless.

Under the third prong of *Central Hudson*, the Government bears the burden of proving that a restriction on commercial speech "directly advances the governmental interest asserted," *Cent. Hudson*, 447 U.S. at 566, and that it does so "to a material degree." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995). This prong is "critical" because, without it, the Government "could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1985) (quoting *Edenfield* , 507 U.S. at 771). Indeed, it is insufficient that a restriction "provides only ineffective or remote support for the government's purposes," or if the restriction has "little chance" of advancing the state's goal. *Edenfield*, 507 U.S. at 770-71.

Tellingly, 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 federal agency'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 or administrative fact-finding devoid of any empirical evidence.[2]

Accordingly, 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. And 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.

Simply put, the Government presented the district court with *no* credible evidence that the proposed graphic warnings would accomplish the Government's stated goal of actually reducing smoking rates among adults and children, much

[2] The Government cites *Turner Broadcasting System, Inc. v. FCC*, 520 U.S. 180 (1997), in support of the proposition that the Rule is entitled to great deference by this Court. But *Turner* deference applies only to content-neutral regulations of speech, and the Government cites to no authority that holds otherwise. *See Turner*, 520 U.S. at 185 (upholding the FCC's "must-carry rule" as a "content-neutral" restriction on speech). In any event, *Turner* gave deference only to congressional findings, not to agency findings. *See id.* at 225 (Stevens, J., concurring) ("The policy judgments made by Congress . . . are entitled to substantial deference.").

less better informing tobacco consumers of the risks of smoking. 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, even the FDA's regulatory impact analysis purporting to show that graphic warning labels will reduce smoking rates by even 0.088 percent is itself 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. *See* Michael Siegel, *FDA Analysis Shows that Graphic Cigarette Warning Labels Increased Cigarette Smoking in Canada from 2001-2008* (Aug. 30, 2011).

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 gain a better understanding of the risks of smoking. In other words, none of these studies considers the likelihood that, even if consumers do take better notice of the new graphic warnings, they will become no more likely to understand and appreciate the risks of smoking. In other words, merely measuring whether someone "notices" something does not tell us anything about whether they will better process and internalize the information presented, much less heed it.

Nor do these studies provide any indication that the new graphic warnings are somehow likely to cause people to actually 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.

In any event, the studies relied on by the Government do not even attempt to link an increased knowledge of smoking risks 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 emotional responses do not translate into greater understanding of health risks, 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 discernible impact on the "breadth or depth" of people's understanding of the health risks of smoking. *See* Heather Wardle, et al., "Final Report: Evaluating the Impact of Picture Warnings on Cigarette Packets," Public Health Research Consortium (2010) (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.

Finally, studies purporting to show that graphic warnings are somehow "salient" are completely irrelevant under the First Amendment because they advance no important or compelling government interest. As used in the FDA study, "salience" is measured primarily by the graphic warnings' ability to scare or frighten consumers. *See* 76 Fed. Reg. at 36,638-39 (reporting that the graphic warnings make viewers "depressed, discouraged, and afraid" and "arouse fear"). But "salience" tells the Court absolutely nothing about the warnings' ability to either alter consumer behavior or increase consumer knowledge of smoking risks. Graphic images may be frightening and even shocking, but the government has no valid interest in shocking consumers as an end in itself.

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

III. The Government Has Repeatedly Mischaracterized Its own Studies In This Litigation

As the previous section demonstrates, the studies relied on by the Government provide no support for the Government's claims that the Rule's new warnings will somehow reduce the incidence of smoking or otherwise improve consumers' knowledge of smoking risks. But the Government's shortcomings go much deeper. Throughout the proceedings below, the Government presented the district court with carefully selected language from the Institute of Medicine's 2007 report, *Ending the Tobacco Problem: A Blueprint for the Nation* (the "IOM Report"), as evidence of the need for new graphic warnings. If this Court merely scratches beneath the surface of those breezy citations, however, it will uncover a curious tendency on the part of the Government to inflate and even misstate the findings of the IOM Report's underlying sources and studies.

The Government assured the district court below that "there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels." United States' October 21, 2011 Memorandum of Law (Dkt. 34) at 20 (quoting 76 Fed. Reg. at 36,630). Although the Government omitted the relevant citations, this claim ultimately relies on a single study that sought to measure disparities based on income and education in an individual's awareness of health risks in Australia, Canada, the United Kingdom, and the United States. *See* Siahpush, M. et al., *Socioeconomic*

and Country Variations in Knowledge of Health Risks of Tobacco Smoking and Toxic Constituents of Smoke: Results from the 2002 International Tobacco Control (ITC) Four Country Survey, 15 Tobacco Control 65-70 (2006). Contrary to the Government's suggestion, however, the Siahpush study demonstrates just the opposite—that those countries *without* graphic warnings had the smallest disparity for every risk measured. And Canada, the only country *with* graphic warnings at the time of the study, never enjoyed the lowest disparity in any of the risks measured. Simply put, the Government's claim that "countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels" finds *no* support in the Government's own studies.

Similarly, the Government represented to the district court that graphic warnings were necessary to communicate with consumers with low levels of education. *See* United States' October 21, 2011 Memorandum of Law (Dkt. 34) at 20 ("Graphical warnings 'may be particularly important for communicating' with consumers with low levels of education, given evidence that such smokers 'are less likely to recall health information in text-based messages than people with more information.'"). This assertion, cited by the IOM Report at C-3, ultimately leads the careful reader *not* to some peer-reviewed, scientific study, but to a 1992 *letter to the editor* wherein the letter's authors purport to have analyzed the sentence length, syllables per word, and familiarity of words used in warnings on alcohol,

cigarette, and smokeless tobacco packaging (in place in 1992). *See* J. Malouff, et al., Letters to the Editor: *Readability of Health Warnings on Alcohol and Tobacco Products*, 82 Am. J. Pub. Health 464 (1992). Even if taken at face value, however, the letter provides no support for the sort of visually shocking warnings mandated by the Rule. Rather than argue that the Government should mandate graphic warnings, the letter urges only a more simplified text.

Perhaps the Government's most creative use of the IOM Report results from its claim that "[b]oth adolescent and adult smokers were more than twice as likely as nonsmokers to doubt that tobacco use, even for a period of 30 to 40 years, would cause death." United States' October 21, 2011 Memorandum of Law (Dkt. 34) at 40 (citing IOM Report at 90). This claim, lifted from the IOM Report, hinges entirely on a study that simply asked smokers and non-smokers to estimate the likelihood of dying from a lifetime of smoking. *See* Arnett, J., *Optimistic Bias in Adolescent and Adult Smokers and Nonsmokers*, 254 Addictive Behaviors, Vol. 625, 625 (2000). Contrary to the impression given by the Government, the study shows that the vast majority of consumers (both smokers and nonsmokers) actually *overestimate* the likelihood that smokers will die from smoking. Specifically, the Arnett study showed that between 74 and 86 percent of participants *agreed* that "most people who smoke all their lives" will die as a result, while 71 to 93 percent of participants believed *they* would actually die from a lifetime of smoking. But

the Government does not bother to mention that the actual risk of death from a lifetime of smoking is only between 13 and 36 percent. Thus, the Government seizes on the fact that smokers *overestimate* the personal risks of smoking only slightly less often as non-smokers to suggest that smokers are somehow disproportionately ignorant of the fact that sustained tobacco use can cause death. The Government's manipulation of the data in this manner leaves much to be desired.

Based on the Government's troubling habit of repeatedly mischaracterizing the very studies on which it relies, WLF urges this Court not to accept at face value the Government's descriptions of its own social scientific evidence. Instead, WLF urges this Court to carefully and doggedly follow the Government's scientific claims to their ultimate authoritative source. Only then will it become obvious that *none* of these studies support the Government's justification for imposing the Rule.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court affirm the well-reasoned order of the district court below.

Respectfully submitted,

/s/ Richard A. Samp
Daniel J. Popeo
Cory L. Andrews
Richard A. Samp
WASHINGTON LEGAL FOUNDATION
2009 Mass. Ave., N.W.
Washington, DC 20036
(202) 588-0302
Counsel for Amicus Curiae

CERTIFICATE OF COMPLIANCE

I certify pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) that the foregoing brief is in 14-point, proportionately spaced Times New Roman font. According to the word processing software used to prepare this brief (Microsoft Word), the word count of the brief is exactly 6,749 words, excluding the cover, corporate disclosure statement, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I certify that on January 30, 2012, I caused the foregoing brief to be filed with the Clerk of the Court through the Court's CM/ECF system. I further certify that all parties to this case are registered CM/ECF users and that service will be accomplished through the CM/ECF system.

/s/ Richard A. Samp
Richard A. Samp