

January 11, 2010

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0568 (“Required Warnings for Cigarette Packages and Advertisements”)

Dear Sir or Madam,

These comments are submitted on behalf of R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, and Commonwealth Brands, Inc. (collectively, the “Companies”). The Companies appreciate the opportunity to comment on FDA’s proposed rule implementing the warning requirements under the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act” or the “Act”). *See* 75 Fed. Reg. 69,524 (Nov. 12, 2010).¹ The Companies believe that adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases; that governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks associated with tobacco use; and that regulations should be based on objective facts and sound science. Towards these ends, the Companies are ready to work with FDA on the many important tasks and duties assigned to it under the Tobacco Control Act. As set forth herein, however, the proposed rule contains several flaws that FDA must address in order to comply with the U.S. Constitution and the Administrative Procedure Act (“APA”), 5 U.S.C. § 551 *et seq.*

The proposed rule would require that tobacco companies use the top 50% of both the front and back panels of their cigarette packages and the top 20% of advertisements to present both textual and graphic warnings of the health consequences of smoking. The graphic warnings would be printed in color, but the tobacco companies’ own advertisements would largely be limited to black and white text.² The proposed graphic images, moreover, include non-factual

¹ This letter also serves as a response to FDA’s request for comments on FDA-commissioned experimental study regarding the efficacy of the proposed warnings. *See* Experimental Study of Graphic Cigarette Warning Labels, Final Results Report, Docket. No. FDA-2010-N-0568-0006 (Dec. 2010) (“FDA Study”); 75 Fed. Reg. 75,936-37 (Dec. 7, 2010).

² The Companies and other tobacco product manufacturers and retailers have filed a lawsuit challenging the warnings and other speech restrictions mandated by the Tobacco Control Act. The United States District Court for the Western District of Kentucky held invalid the Act’s ban on color and imagery in tobacco advertising and one other provision, and upheld the new warnings and several other provisions. *Commonwealth Brands, Inc. v. United States*, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010). Both sides have appealed that set of rulings to the United States Court of Appeals for the Sixth Circuit. Attached hereto as Exhibits C-E are copies of selected pleadings from the District Court and Sixth Circuit, including (1) the complaint, (2) preliminary injunction briefs, accompanying affidavits, and hearing transcript, (3) summary judgment briefs and accompanying affidavits, and (4) the Sixth Circuit briefs. Many of the affidavits submitted in that litigation are directly relevant to the issues raised in this

cartoon images, controversial photographs that appear to have been technologically enhanced to maximize an emotional response from viewers, and, in some cases, highlight certain letters in the text of the warning in order to communicate not the statutorily mandated warning, but the additional message “I CAUSE DISEASE” or “I CAUSE CANCER.”³ In short, as FDA Commissioner Margaret A. Hamburg accurately and candidly explained when unveiling the proposed rule, the new warnings will ensure that “every single pack of cigarettes in our country will in effect become a mini billboard” for the Government’s anti-smoking message.⁴

That anti-smoking message is an ideological message. It does not simply convey information intended to enable smokers to make informed decisions about whether to smoke cigarettes. That is, the anti-smoking message is not intended to provide information that smokers and potential smokers can consider rationally in weighing the risks and perceived benefits from smoking. Rather, it plainly conveys—through graphic images and designs intended to elicit loathing, disgust, and repulsion—the Government’s viewpoint that the risks associated with smoking cigarettes outweigh the pleasure that smokers derive from them and, therefore, that no one should use these lawful products. Instead of providing new information for consumers’ risk-benefit assessments, the Government seeks to change the weights (the subjective values) that consumers apply in making such assessments. In effect, the proposed warnings convey to smokers the Government’s view that they should change in a significant way how they lead their lives. The viewpoint the Government proposes to be conveyed on the manufacturers’ packaging and advertising is thus every bit as ideological as the message at issue in *Wooley v. Maynard*, 430 U.S. 705 (1977): “Live Free or Die.” In effect, the message and viewpoint of FDA’s proposed graphic warnings is: “Live Smoke-Free or Die.”

As explained in detail herein, the proposed rule suffers from the following flaws:

First, the proposed rule fails to address the substantial constitutional problems created by confiscating the top 50% of both principal display panels of packaging and the top 20% of advertisements for graphic warnings that use nonfactual and controversial images in order to “warn” consumers of health risks that are already universally known. Even on acute poisons (*e.g.*, pesticides and toxic chemicals), the warnings are not of this size and character. It is therefore quite clear that the intended function of the proposed “warnings” is not to warn consumers about the risks from smoking, but to communicate a government message: “Don’t buy or use this product.” The message communicated by these graphic images goes far beyond remedying any consumer ignorance or misunderstanding about these products. *See infra* at 10-14.

(continued...)

letter in response to FDA’s request for comments. The arguments and information on behalf of the plaintiffs set forth in the attached documents are incorporated into this letter as if fully stated herein.

³ See Dkt. No. FDA-2010-N-0568, Proposed Required Warning Images 23-24, 31-32 (“Proposed Images”), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0568-0002.2>.

⁴ FDA, *Tobacco Control Announcement* (Nov. 10, 2010), available at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm>.

Moreover, beyond requiring manufacturers to use their property to convey the Government's messages and viewpoint, the proposed required warnings also restrict manufacturers' own speech. In plain effect, the warnings prohibit manufacturers from using the top 50% of the front and back display panels of cigarette packages (packs and cartons) and the top 20% of cigarette advertisements to convey their own messages. The proposed warnings thereby materially limit the amount of speech, and the prominence of the speech, that manufacturers can convey. Thus, the proposed warnings are properly analyzed both as mandating speech the Government wants to convey and as restricting speech that manufacturers want to convey. *See infra* at 5-18. Furthermore, by appropriating the tobacco companies' property and property interests in their trademarks, the proposed rule also violates the Fifth Amendment right of cigarette manufacturers to be free from the uncompensated taking of property. *See infra* at 18.

Second, in assessing the potential benefits of the proposed warnings, the rule relies on studies that not only are methodologically flawed, but also fail to demonstrate, even on their own terms, that the warnings will have any impact on smoking prevalence. Relatedly, the proposed rule's cost-benefit analysis contains numerous flaws that cause the Agency to overestimate the proposed rule's concededly negligible benefits while, at the same time, underestimating its costs. *See infra* at 19-23.

Third, some requirements in the proposed rule would create ambiguities or other logistical difficulties that would make compliance unnecessarily difficult. *See infra* at 12 n.12.

Finally, FDA has failed to make publicly available crucial information that informs the selection of the proposed graphics. This failure makes it impossible to fully assess the basis for the proposed rule and, unless remedied in a manner that provides an adequate opportunity for public comment prior to the issuance of a final rule, would violate the APA. *See infra* at 23-24.

These numerous flaws may reflect FDA's attempt to comply with the rigid timeline for the implementation of graphic warnings imposed by the Tobacco Control Act. Specifically, section 201(b) of the Act requires that a final rule be issued no later than 24 months after the date of enactment, *i.e.*, by June 22, 2011, and provides that such a rule shall become effective 15 months after its publication. *See* 15 U.S.C. § 1333(d) (as amended by Tobacco Control Act § 201(a), 123 Stat. at 1845); Tobacco Control Act § 201(b), 123 Stat. at 1845; 75 Fed. Reg. 69,541. Moreover, the APA in turn requires that, prior to publishing a final rule, FDA provide the public with notice of the proposed rule and a meaningful opportunity to comment. *See* 5 U.S.C. § 553(b)(3); *Hall v. EPA*, 273 F.3d 1146, 1162-63 (9th Cir. 2001) (under § 553, an agency must "provide the public with a meaningful opportunity to comment on the proposed provisions.") (internal quotation marks omitted). Thus, FDA may have believed it had insufficient time to publish a proposed rule that (a) was based on a scientifically rigorous assessment of the potential effect of the proposed warnings, (b) fully considered all potential alternatives, and (c) was sufficiently detailed to allow informed comments by the public. Nonetheless, a desire to comply with an arbitrary deadline is obviously no justification for an agency's failure to comply with its legal obligations under the Constitution and the APA.

The Companies therefore request that FDA withdraw the proposed rule and issue a new proposed rule that does not contain these flaws. In particular, FDA should order that the

Tobacco Control Act's new textual warnings be displayed in the same manner in which the Surgeon General's warnings have been displayed for years, since that format, along with other regulatory and voluntary initiatives, has contributed to the public being fully informed about the health risks from smoking. At a minimum, FDA should delay implementation of the proposed rule until the issues raised in these comments (including the attachments hereto) are resolved either administratively—by, for example, changing the rule to address these constitutional deficiencies—or through litigation. The Companies are ready and willing to work with FDA to ensure that accurate information is conveyed to consumers in a manner consistent with the requirements of federal law and manufactures' constitutional rights.

I. The Proposed Rule Violates the First Amendment, Fifth Amendment, and the APA.

Although the proposed rule undertakes no First Amendment analysis, FDA in fact has an independent obligation, under both the Constitution and the APA, to assess the constitutional implications of any proposed rule. *See Presidential Certification Regarding the Provision of Documents to the House of Representatives Under the Mexican Debt Disclosure Act of 1995* (“Presidential Certification”), 20 O.L.C. 253, 278 (1996) (“It is the duty and practice of the executive branch to avoid statutory constructions that unnecessarily raise grave doubts about the constitutionality of congressional measures. Respect for Congress, furthermore, counsels reluctance to interpret a statute so as to require the assertion of a presidential power to act contrary to the statute.”)⁵; 5 U.S.C. § 706(2)(B) (stating that a court shall hold unlawful any agency action that is “contrary to constitutional right”); *see also Munsell v. Dep’t of Agric.*, 509 F.3d 572, 589 (D.C. Cir. 2007) (noting that the APA “create[s] a mechanism for persons subject to [agency] actions to pursue challenges based on alleged constitutional violations”). When assessed under the First Amendment, the proposed rule is plainly unconstitutional.

It is well established that the Government is not free to force businesses to engage in whatever speech it deems beneficial or convenient. To the contrary, the First Amendment protects “both the right to speak freely and the right to refrain from speaking at all.” *Wooley*, 430 U.S. at 714; *see also id.* at 713 (“We are thus faced with the question of whether the State may constitutionally require an individual to participate in the dissemination of an ideological message by displaying it on his private property in a manner and for the express purpose that it be observed and read by the public. We hold that the State may not do so.”). That holding is not limited to individuals. *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion) (“For corporations as for individuals, the choice to speak includes within it the choice of what not to say.”). Thus, a law that compels speech is generally subject to the same strict scrutiny governing other content-based speech rules and is unconstitutional unless it furthers a compelling governmental interest by the least restrictive means available. *United States v. Playboy Entm’t Grp., Inc.*, 529 U.S. 803, 813 (2000); *Sable Commc’ns of Cal., Inc. v. FCC*, 492 U.S. 115, 126 (1989); *Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 646 (7th Cir. 2006).

To be sure, the Supreme Court has recognized a narrow exception to strict scrutiny for mandated commercial disclosures that are “purely factual and noncontroversial”; but that exception applies only if the disclosures are “reasonably related to [the Government’s] interest in

⁵ Available at <http://www.justice.gov/olc/cdraftfin.htm>.

preventing deception of consumers” and do not impose restrictions that are “unjustified or unduly burdensome.” *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). As explained below, the proposed rule cannot meet any of these requirements. It therefore must be evaluated under strict scrutiny—a standard it cannot satisfy. *See, e.g., Blagojevich*, 469 F.3d at 652 (concluding that a video game “warning” requirement that failed to satisfy *Zauderer* was subject to strict scrutiny). The proposed rule also imposes burdens on manufacturers’ ability to communicate their own messages, yet fails to satisfy the First Amendment’s commercial speech protections.

Finally, for similar reasons, the proposed rule violates the Takings Clause of the Fifth Amendment and the APA.

A. The Proposed Rule Is Not a Permissible Commercial Disclosure Under *Zauderer*.

The study commissioned by FDA itself to assess the efficacy of the proposed warnings demonstrates that the proposed rule would have no discernible impact on smoking beliefs or behavior. *See* Experimental Study of Graphic Cigarette Warning Labels, Final Results Report, Dkt. No. FDA-2010-N-0568-0006 (Dec. 2010) (“FDA Study”).⁶ It necessarily follows that the confiscation of the top 50% of both of the principal display panels of cigarette packaging and the top 20% of advertising for government-mandated graphic warnings is an “unjustified” and “unduly burdensome” restriction on tobacco manufacturers’ free speech rights. It also forces tobacco manufacturers to convey a message that goes well beyond the “purely factual and noncontroversial.” Accordingly, the proposed rule falls outside *Zauderer*’s narrow exception to strict scrutiny.

1. The FDA Study Confirms That the Proposed Rule Will Not Affect Risk Beliefs About Smoking or Smoking Prevalence.

As part of the current rulemaking proceeding, FDA commissioned a study to assess the efficacy of the proposed warnings. For each of the nine statutorily-mandated warnings, the study tested whether any of four graphics (which, when combined with the nine new mandated health warning statements, result in a total of 36 graphic warnings) would be effective in accomplishing any of three goals: (1) increasing awareness among adults, young adults, and youth about the health risks from smoking, including the risks from “environmental tobacco smoke” (or “second-hand smoke”); (2) increasing current adult and young adult smokers’ intention to quit; and (3) decreasing youth non-smokers’ likelihood to initiate smoking. “Overall, the results [of the study] do not support the efficacy of the graphic warning labels across any of the three measured outcomes.”⁷

In particular, even if taken at face value, the FDA Study demonstrates that the vast majority of the 36 graphic warnings had *no* statistically significant effect on beliefs about the

⁶ Available at <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0568-0008>.

⁷ *See* Exhibit A, Statement of W. Kip Viscusi 50 (“Viscusi Report”). The comments provided by Dr. Viscusi set forth in Exhibit A are incorporated into this letter as if fully stated herein.

health risks from smoking and second-hand smoke, smokers' intentions to quit, or youth initiation of smoking:

- Health Risk Beliefs. The warnings have virtually no impact on beliefs about the risks from smoking or second-hand smoke.
 - Smoking. *None* of the 36 graphic warnings led to *any* statistically significant increase in *youth* beliefs about the risks of harms to health from smoking (“risk beliefs”); indeed, 2 of the warnings were associated with a *decreased* understanding of smoking risks. Similarly, for adults, the graphics accompanying 7 of the 9 messages had no statistically significant effect on risk beliefs. Likewise, for young adults, the graphics accompanying 7 of the 9 messages failed to have any statistically significant effect on risk beliefs. Viscusi Report 70-73.
 - Second-hand Smoke. Only 1 of the 36 graphic warnings led to *any* statistically significant increase in risk beliefs across *any* warning or *any* sub-group tested. That 1 warning, moreover, dealt with addiction, *not* risks from second-hand smoke. And 5 of the 36 warnings were associated with *decreased* belief in the risks of harms to health from second-hand smoke. Viscusi Report 70-73.
- Quit Intentions. Only 1 of the 36 graphic warnings was associated with adult increased intention to quit; in contrast, 2 of the 36 graphics were associated with *decreased* intention to quit. Likewise, with young adults, only 2 of the 36 graphics were associated with increased quit intentions. Viscusi Report 70-73.
- Youth Initiation. Perhaps most significantly, on what is clearly the most important issue, the graphics accompanying 8 of the 9 warnings had *no statistically significant effect* on decreasing the likelihood that youth would begin smoking. Only 2 of the 36 graphic warnings—both of which accompanied the “Tobacco smoke can harm your children” message—were associated with decreased intentions to start smoking. On the other hand, one of the warnings—which accompanied the “Cigarettes cause cancer” message—was associated with *increased* intentions to start smoking. Viscusi Report 70-73.

In short, as Dr. Viscusi explains in detail in his attached expert report, “[a]ll but a few of the tested labels performed no better for any of the four sample variants than simply displaying the text of the new warning in the manner that warnings are currently displayed on cigarettes [and s]everal of the proposed new graphic warning statements were negatively associated with beliefs regarding the risk[s] of smoking.” Viscusi Report 61. Therefore, it is not surprising that FDA, itself, has been forced to conclude that the expected benefits from the proposed warnings “are in general not statistically distinguishable from zero.” 75 Fed. Reg. at 69,546.

The FDA Study, moreover, is riddled with serious methodological flaws designed to *overstate* the effectiveness of the graphic warnings. *See* Part II, *infra*. For example, the study selected its participants by offering individuals an opportunity to participate in a survey online,

but there is no indication that the study corrected for the selection bias that may have occurred from this design. Viscusi Report 51-52. And because the invitation to participate in the survey identified the substantive focus of the survey and stated that it was funded by FDA, “one would not expect the sample selection effects to be neutral.” *Id.* at 52. Compounding this error, the report of the study fails to address the fact that 32% of the participants quit the brief survey before completing it. *Id.* at 53. Because “[q]uitting the survey is not likely to be a random event,” and may instead be a result of “smokers who are not receptive to the graphic warnings messages dropp[ing] out of the survey,” the survey results “will overstate the likely effect of the warnings.” *Id.*

Nor should the FDA Study’s conclusion that the proposed rule will be ineffective come as a surprise. As Dr. Viscusi describes in his attached report, the factual health information in each of the proposed warnings has already been “disseminated to and absorbed by an overwhelmingly high percentage of the population” through the familiar Surgeon General’s warnings and numerous other means. *See* Viscusi Report 15. For example, in “a 1998 Gallup poll of youth aged 13-17,” “99% of surveyed youth agreed that smoking can cause lung cancer.” *Id.* That is more than “are aware that George Washington was the first U.S. President, [or] that the Earth revolves around the Sun.” *Id.* at 10. This, moreover, is true for each of the specific subjects of the proposed warnings. *Id.* at 16-31. Indeed, the public actually *overestimates* the risks from tobacco use by as much as 400%: “[T]he average perceived risk that a smoker will develop lung cancer is over 40%,” whereas the “actual risk” is “about 10% of smokers.” *Id.* at 25. Similarly, the public’s perception of the overall mortality risk from smoking “can be as much as three times higher” than the actual mortality risk, and “young people overestimate the dangers of smoking to an even greater degree” than adults. *Id.* at 28-29.

“Independent studies have demonstrated that more information about the risks of smoking does not influence smoking rates or consumer behavior.” *Id.* at 21. Even the Surgeon General’s 1994 report acknowledges the inaccuracy of the “assumption . . . [that] young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke.” *Id.* at 68. It specifically notes that “comprehensive reviews [have] concluded that smoking-prevention programs based on the information deficit approach were not effective.” *Id.* As Dr. Viscusi further explains, “[w]arnings that . . . attempt to simply browbeat individuals into changing their behavior will not be successful.” *Id.* at 49.

2. The Proposed Rule Is “Unjustified” and “Unduly Burdensome.”

In light of the FDA Study’s conclusion that the proposed rule will have no discernible impact on smoking beliefs or behavior, it necessarily follows that the confiscation of the top 50% of both principal display panels of cigarette packaging and the top 20% of advertising for government-mandated graphic warnings is an “unjustified” and “unduly burdensome” restriction on tobacco manufacturers’ free speech rights.

Under the *Zauderer* standard, FDA must weigh the benefits of the proposed rule against the burdens it imposes on cigarette manufacturers and others. Courts have found that disclosure requirements are not unjustified or unduly burdensome when they impose straightforward textual warnings and address a substantial and non-speculative risk of consumer confusion. For

example, in *Zauderer*, itself, the Court upheld an attorney-disciplinary rule that required contingency-fee advertisements to disclose that contingent-fee clients “would be liable for costs (as opposed to legal fees) even if their claims were unsuccessful.” 471 U.S. at 633. This requirement was permissible, the Court reasoned, because the attorney’s interest in not providing this factual information was “minimal,” *id.* at 651, and because, given the likelihood that a layman would conflate legal “fees” with other litigation “costs,” the possibility that “substantial numbers of potential clients would be . . . misled [was] hardly a speculative one,” *id.* at 652. *See also Borgner v. Brooks*, 284 F.3d 1204, 1212, 1215 (11th Cir. 2002) (upholding a requirement that dentists advertising a board certification disclose that the certification was not state sanctioned, and reasoning that the disclosure requirement would “not be especially long or burdensome” and that multiple surveys had “suggest[ed] that a majority of consumers are misled into thinking that a dentist who advertises [a board certification is] somehow sanctioned by the State of Florida”).

In contrast, courts have found that disclosure requirements are unjustified and unduly burdensome where they limit the ability of a business to convey its own message(s) or where the possibility that the disclosures will prevent consumer confusion is only speculative. Thus, in *Ibanez v. Florida Department of Business & Professional Regulation*, 512 U.S. 136 (1994), the Court invalidated a requirement that any use of a designation as an accounting specialist be accompanied by a comprehensive disclaimer. The Court reasoned that the length of the disclaimer “effectively rule[d] out notation of the ‘specialist’ designation on a business card or letterhead, or in a yellow pages listing”; and the state had failed to identify “any harm that is potentially real, not purely hypothetical.” *Id.* at 146-47. Likewise, in *International Dairy Foods Ass’n v. Boggs*, 622 F.3d 628 (6th Cir. 2010), the court invalidated an Ohio law that required milk processors who advertise that their milk comes from cows not supplemented with rbST to include a contiguous additional statement that “[t]he FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.” *Id.* at 634. The court reasoned that, although the risk of consumer confusion addressed by the disclosure requirement *in general* “[wa]s not speculative,” the state had identified nothing more than an agency director’s “anecdotal experience” to suggest that the disclosure had to be contiguous with the initial statement regarding rbST-free production in order to prevent such confusion. *Id.* at 642-43. *See also Entm’t Software Ass’n v. Blagojevich*, 404 F. Supp. 2d 1051, 1081-82 & n.12 (N.D. Ill. 2005) (invalidating video game warning requirements because the state “offered no evidence that there is any actual confusion or deception of parents or children” and because the disclosure requirements were “far more extensive than the Ohio Disciplinary Rule considered in *Zauderer*”), *aff’d*, 469 F.3d 641 (7th Cir. 2006).

The proposed rule plainly fails *Zauderer*’s “unjustified or unduly burdensome” standard. As noted above, the FDA Study found no “efficacy of the graphic warning labels across any of the three measured outcomes,” Viscusi Report 50; and, as a result, FDA, itself, concluded that the benefits of the proposed rule “are in general not statistically distinguishable from zero.” 75 Fed. Reg. at 69,546. Consequently, the proposed rule cannot possibly be justified by any asserted interest in redressing consumer ignorance or misunderstanding. It is therefore “unjustified” under *Zauderer*. *See Zauderer*, 471 U.S. at 651; *Ibanez*, 512 U.S. at 146.

On the other side of the balance, the proposed rule compels cigarette manufacturers to engage in highly burdensome speech that goes far beyond adequate warning information. The Government's new color-graphic warnings would drown out the tobacco companies' own legitimate speech by occupying the top 50% of both principal display panels of cigarette packaging and at least the top 20% of all advertisements.⁸ Consequently, tobacco companies' own branding and marketing messages on cigarette packaging would be relegated to the bottom portions. For most cigarettes displays, the top portion of the cigarette packaging is most visible to the consumer at retail. Moreover, tobacco products generally must be displayed several feet behind a sales counter in order to comply with other federal and state laws, *see, e.g.*, 21 C.F.R. § 1140.16(c). By requiring the warning on the top portion of the pack, FDA has seized this primary position for its ideological message and relegated the manufacturers' presentation of their brand names to an inferior position that would render their own speech on cigarette packaging wholly ineffective.⁹ Indeed, the Government's images and messages monopolize all the prominent space on cigarette packages, and thereby make it impossible for manufacturers to communicate their own messages and their own viewpoints prominently in packaging.¹⁰ Such effective exclusion of points of view contrary to the Government's is, by itself, plainly a substantial burden that violates the First Amendment. *See Blagojevich*, 469 F.3d at 652 (7th Cir. 2006) ("Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning."). *Cf. Texas v. Johnson*, 491 U.S. 397, 415 (1989) ("[N]othing in our precedents suggests that a State may foster its own view of the flag by prohibiting expressive conduct relating to it.").

Likewise, the new warnings on the top fifth of advertisements overwhelm the portion remaining for the manufacturers' speech, which, in contrast to the color-graphic warnings, would (subject to narrow exceptions, *see* 21 C.F.R. § 1140.32(a)(1)-(2)), be limited to black and white

⁸ In actuality, the proposed rule likely will confiscate significantly more than 20% of many advertisements. The rule would require that the warnings appear in the top fifth of advertisements and comprise at 20% of the available space. *See* 75 Fed. Reg. at 69,564 (citing 15 U.S.C. § 1333(b)(2) (as amended by Tobacco Control Act § 201(a), 123 Stat. at 1845)). The rule further would require that the warning be placed in a rectangular box, and the box may not be altered (*e.g.*, stretched or elongated) in any way. *Id.* FDA's website provides an example of such a warning, placing the warning in the top right portion of the hypothetical advertisement. *See* <http://www.fda.gov/TobaccoProducts/Labeling/CigaretteProductWarningLabels/ucm231416.htm>. For many commonly used advertisements, particularly at point of sale, this placement will create a dead space that will be essentially useless from a messaging or branding perspective. Thus, for many advertisements, the way FDA has implemented the requirement will result in far more than 20% of the advertisement being coopted.

⁹ *See* Exhibit D, Declaration of Robert H. Dunham ("Dunham Decl.") ¶ 29 ("Merchandising fixtures are typically several feet behind a sales counter, and if our packaging has 50% less space for conveying messages, and [is] thus viewed from several feet away, words quickly becomes illegible . . ."); Exhibit D, Declaration of Timothy Jones ("Jones Decl.") ¶ 31 ("[U]nder the new restrictions imposed by the Act, adult consumers will not be able to see the information on our packaging at retail. . . . [The Act's] new restrictions will, as a practical matter, mean that all of the information that distinguishes our products from our competitors' products will not be visible to the adult consumer before he or she makes a purchase.").

¹⁰ For example, the back of a package of *Camel* filter cigarettes currently states that "[a] master-crafted blend of only the finest hand-picked Samsun & Izmir Turkish tobaccos with robust domestic tobacco blend creates Camel's distinctive flavor and world-class smoothness." Dunham Decl. ¶ 28. If 50% of both principal display panels of packaging must be dedicated to the new warning, then, "[a]s a practical matter, that same message cannot be conveyed . . . because the type face would have to be made much smaller." *Id.* This is vividly demonstrated in the images reproduced in paragraph 28 of the Dunham Declaration.

text, *see* 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.32(a). Collectively, these restrictions ensure that tobacco companies' speech would be dominated by the mandated warnings, which would "effectively rule[] out" tobacco companies' own attempts to convey substantive or other marketing information about their products, *Ibanez*, 512 U.S. at 146-47. *See* Dunham Decl. ¶ 29; Jones Decl. ¶ 31.

The burden imposed by eliminating cigarette packaging as a viable means of branding and marketing is particularly heavy given the pre-existing limitations on the speech of tobacco product manufacturers. Federal law already bans cigarette advertising on radio and television. 15 U.S.C. § 1335. And FDA regulations pursuant to the Tobacco Control Act and the Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, impose numerous additional restrictions. *See, e.g.*, 21 C.F.R. § 1140.16 (d)(1) (ban on distribution of cigarette samples); 21 C.F.R. § 1140.34(a) (ban on branded non-tobacco products); 21 C.F.R. § 1140.34(b) (ban on continuity programs); 21 C.F.R. § 1140.34(c) (ban on sponsorship of social or cultural events).¹¹ *See also* 21 U.S.C. § 321(rr)(4) (ban on joint product marketing of a tobacco product "in combination with any other article or product" regulated by FDA); 75 Fed. Reg. 13,241 (Mar. 19, 2010) (issuing an advance notice of proposed rulemaking to restrict "outdoor" advertising for tobacco products). Thus, cigarette packaging is one of the few remaining forums in which cigarette manufacturers can disseminate their marketing message to adult smokers. By confiscating the most important part of the cigarette package with a graphic government message that would overwhelm any speech by cigarette manufacturers, the proposed rule would thus eliminate one of the most important remaining avenues for tobacco companies' own speech. *See Reilly*, 533 U.S. at 564-65 (noting that where "retailers . . . use few avenues of communication, then . . . outdoor advertising regulations potentially place a greater, not lesser, burden on those retailers' speech"); *Linmark Assocs. v. Twp. of Willingsboro*, 431 U.S. 85, 93 (1977) (invalidating ban on house "for sale" signs where the alternative avenues of speech existed only "in theory").

In sum, the proposed rule fails to offer any benefit "that is potentially real, not purely hypothetical," and at the same time, imposes severe restraints on manufacturers' free speech rights by "effectively rule[ing] out" a crucial avenue for tobacco product manufacturers' own speech, *Ibanez*, 512 U.S. at 146. It is, therefore, the epitome of an "unjustified or unduly burdensome" restriction on free speech, *Zauderer*, 471 U.S. at 651. Indeed, if this rule does not exceed the limitations of *Zauderer*, then it is difficult to imagine what types of tobacco-product warnings would.

3. The Proposed Rule Does Not Convey "Purely Factual and Uncontroversial" Information.

Finally, the proposed warnings are not even arguably "purely factual and uncontroversial." *Zauderer*, 471 U.S. at 651. To be sure, the proposed textual warnings and some of the graphic images depict potential health consequences of smoking; yet the size and

¹¹ Moreover, most major tobacco product manufacturers are also subject to the Master Settlement Agreement ("MSA") with the states, which imposes numerous marketing restrictions that both overlap with and exceed restrictions under federal law, including, for example, bans on outdoor and transit advertising, the acquisition of stadium or arena naming rights, or the purchase of product placement in media. *See* MSA § III, *available at* <http://www.rjrt.com/MSAFullText.aspx>.

design of the warnings, understood in context, make it impossible to conclude that the warnings communicate a primarily factual, let alone a “purely factual and uncontroversial” message. *Id.* (emphasis added).

The size of the warnings belies any suggestion that they are intended simply to convey factual information. Indeed, in 1996 FDA rejected comments suggesting that the current Surgeon General’s warnings occupy a larger percentage of cigarette packaging or be augmented with “graphic enhancements to make the information in the brief statement more noticeable”; such expanded warnings were not necessary, FDA determined, because “the current Surgeon General’s warnings are sufficient” as a means of conveying the “relevant warnings, precautions, side effects, and contraindications” of cigarettes. 61 Fed. Reg. at 44,521 (Aug 28, 1996) (quoting 21 U.S.C. § 352(r)). And although the agency *now* suggests that the Surgeon General’s warnings “fail to convey relevant information in an effective way,” 75 Fed. Reg. at 69,525, it provides no reasoned or scientific basis for this change in position. The dramatically expanded warnings now proposed by FDA can hardly be justified as necessary to render the factual information readable. Nor can it be argued that larger warnings are necessary to grab the attention of consumers who would benefit from the warnings but do not notice them. Although such a method might be rational in other contexts, it is clear that the public (including adolescents) has an extraordinarily high degree of understanding of the health consequences of smoking. *See* Viscusi Report 17-32. Therefore, as the FDA Study demonstrates, the massive warnings contained in the proposed rule would not bring new information to any meaningful number of consumers, beyond what the current warnings already provide. *Id.* at 72-75. Instead, by effectively shouting well-understood information to consumers, FDA is communicating an ideological message, a point of view on how people should live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking.

To the extent there is any doubt that the proposed warnings convey an ideological message rather than purely factual information, it is removed by FDA’s proposed graphic images. Many of these images use non-factual cartoon drawings to convey highly disturbing and controversial ideas—*e.g.*, drawings of an individual jamming a cigarette into his arm as if it were a heroin needle, and a mother blowing smoke into her baby’s mouth. Proposed Images at 3-4, 13-14. Others appear to use technologically-enhanced photographs to emphasize the effects of sickness and disease. *Id.* at 1-2, 29-34, 39-40, 43-44, 49-50, 53-54. And some even go so far as to highlight specific letters in the text of a warning so that it conveys, not just the statutorily-mandated warning, but the message, “I CAUSE DISEASE” or “I CAUSE CANCER.” *Id.* at 23-24, 31-32. Indeed, none of FDA’s proposed images is “purely factual and uncontroversial,” *Zauderer*, 471 U.S. at 651—not standing alone, and certainly not when plastered on the top half of both principal display panels of packages and the top fifth of advertisements. Rather, the images are self-evidently designed to evoke an emotional response—one of loathing, disgust, and repulsion—in service of the Government’s viewpoint about how people should weigh the pleasures against the well-known health risks associated with smoking cigarettes.

Such fear-based tactics are no closer to mere informational disclosures than any of the “shock and awe” advocacy used in numerous ideological debates, such as when anti-abortion protesters display photographs of aborted fetuses or animal-rights activists display photographs of mutilated animals. Although such images illustrate actual effects of abortions and actual

animal treatment, no one would contend that they are “purely factual and uncontroversial.” *Id.* Thus, no one would contend that the Government could force health clinics or grocery stores to display “warnings” containing such photographic images. To the contrary, such images are, by design, intended to convey a non-factual and controversial message that the targeted practice is socially unacceptable, and is intended to “shock” others into accepting that message. There is, however, no constitutional difference between these images and the graphic images in the proposed rule.

Likewise, § 1141.16(a) of the proposed rule would require that cigarette packaging and advertising include a “reference to a smoking cessation assistance resource in accordance with, and as specified in, ‘Cigarette Required Warnings—English and Spanish’ (incorporated by reference at § 1141.12) or ‘Cigarette Required Warnings—Other Foreign Language Advertisements’ (incorporated by reference at § 1141.12), whichever is applicable.” 75 Fed. Reg. at 69,564. It cannot, however, be maintained that the Government imposes a purely factual disclosure when it requires tobacco companies to “disclose” a smoking-cessation resource, *id.* Such “disclosure” conveys no factual information about the product that tobacco companies are selling and, indeed, effectively forces the companies to communicate the subjective policy message to consumers, “don’t buy or use this product.” Consequently, like the other parts of the graphic warnings, the required inclusion of information about a smoking-cessation resource violates the First Amendment.¹²

The non-factual nature of the new warnings is further highlighted by the manner in which the FDA Study assesses them. The study is designed ostensibly to assess the ability of the warning labels to “convey[] information about various health risks of smoking.” FDA Study 1-1. The study’s “control group,” however, was already exposed to the new textual warnings—that is, the “control group” consisted of individuals who viewed the *new textual* warnings as they appeared on the side of the package. Any changes caused by exposure to the graphics, therefore, cannot be attributed to any new *information* that appears in the *new text* of the warnings. Instead, exposure to the new warnings measured only the effect of “[e]liciting strong emotional and

¹² This provision also creates ambiguities and logistical difficulties that would make compliance unnecessarily difficult. Although § 1141.16 details some requirements of a qualified “smoking cessation resource,” it employs vague terminology such as “evidence-based [and] unbiased” support and “non-evidence-based smoking cessation practices,” which are susceptible of conflicting interpretations. Further, § 1141.16 does not identify a specific qualified resource or provide for the possibility that no such resource is (or will be) available. This omission makes it impossible for cigarette manufacturers to be sure that they are complying with the proposed regulation. Moreover, to the extent a qualified “smoking cessation resource” is identified only in a final rule, manufacturers will be deprived, in violation of the APA, of an adequate opportunity to assess and comment on the impact of the “cessation disclosure” requirement in violation of the APA. *See* 5 U.S.C. § 553(b)(3); *Hall*, 273 F.3d at 1162 (under § 553, an agency must “provide the public with a meaningful opportunity to comment on [the proposed] provisions.”) (internal quotation marks omitted). Accordingly, this aspect of the proposed rule should not be finalized. To the extent that FDA seeks to require the inclusion of a cessation resource on cigarette packs or advertising, it should identify a list of such approved resources in a separate proposed rule and allow for public comment on the list and on the requirement to include a cessation resource on all cigarette packages and advertising. Further, any rule imposing such a requirement must make clear that FDA will not enforce the requirement until it has provided a list of cessation resources that comply with the rule.

Separate letters submitted by Philip Morris USA Inc. and Lorillard describe additional ambiguities, logistical difficulties, and implementation issues created by the proposed rule, and are incorporated into this letter as if fully stated herein.

cognitive reactions to the graphic cigarette warning label.” *Id.* at 1-2. Thus, the FDA Study, itself, confirms that the graphic warnings were intended by FDA not to inform consumers with “purely factual and uncontroversial” information, but, rather, to “shock” them into adopting the Government’s preferred course of conduct with respect to a lawful product.

In sum, although the Government does, under *Zauderer*, have a limited right to force commercial actors to disclose factual information about their products so that consumers can make rational purchasing decisions, it has no right to force manufacturers to convey messages not addressed to consumers’ intellects, but to their emotions. For when the Government does the latter, it converts manufacturers into a vehicle not for disseminating facts, but for conveying the Government’s subjective and ideological view of how consumers should live their lives. The Government may, of course, convey that ideological message using its own voice; but, under the First Amendment, it cannot force manufacturers to be the Government’s unwilling mouthpiece without “violat[ing] the fundamental rule of protection under the First Amendment, that a speaker has the autonomy to choose the content of his own message.” *Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995). As the Supreme Court explained in *Hurley*,

Since *all* speech inherently involves choices of what to say and what to leave unsaid, one important manifestation of the principle of free speech is that one who chooses to speak may also decide what not to say. Although the State may at times prescribe what shall be orthodox in commercial advertising by requiring the dissemination of purely factual and uncontroversial information, outside that context it may not compel affirmance of a belief with which the speaker disagrees. Indeed this general rule, that the speaker has the right to tailor the speech, applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid, subject, perhaps, to the permissive law of defamation. Nor is the rule’s benefit restricted to the press, being enjoyed by business corporations generally and by ordinary people engaged in unsophisticated expression as well as by professional publishers. Its point is simply the point of all speech protection, which is to shield just those choices of content that in someone’s eyes are misguided, or even hurtful.

Id. (internal citations and quotation marks omitted). By promulgating a rule that, in the words of FDA Commissioner Hamburg, is designed to ensure that “every single pack of cigarettes in our country will in effect become a mini billboard” for the Government’s anti-smoking message,¹³ FDA has impermissibly conscripted private property “as a ‘mobile billboard’ for [its] ideological message,” *Wooley*, 430 U.S. at 715. That, however, it may not do—at least not without first satisfying strict scrutiny.

Accordingly, the proposed warnings do not fit within the narrow *Zauderer* exception for “purely factual and uncontroversial” commercial disclosures that are not “unjustified or unduly burdensome.” *Zauderer*, 471 U.S. at 651. *See also Blagojevich*, 469 F.3d at 652 (invalidating a video game “warning” label under strict scrutiny because the label “ultimately communicate[d] a

¹³ FDA, *Tobacco Control Announcement*, (Nov. 10, 2010), <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm>.

subjective and highly controversial message” rather than merely disclosing uncontroversial factual information).

B. The Proposed Rule Must Be Assessed Under Strict Scrutiny, Which It Cannot Survive.

Because the proposed rule does not fall within *Zauderer*'s narrow exception, it is subject to strict scrutiny, pursuant to which FDA bears the burden of demonstrating that it furthers a compelling governmental interest by the least restrictive means available. *Playboy Entm't Grp.*, 529 U.S. at 813; *Sable Comm'ns*, 492 U.S. at 126; *Blagojevich*, 469 F.3d at 646. Strict scrutiny is the Supreme Court's "most rigorous and exacting standard of constitutional review." *Miller v. Johnson*, 515 U.S. 900, 920 (1995). Under this demanding standard, the interest served must be truly compelling and, even then, a restriction of speech is not permitted where it is "plausible" that the same interest can be furthered by a lesser imposition on speech. *Playboy Entm't Grp.*, 529 U.S. at 813-14. Indeed, "[o]nly rarely are statutes sustained in the face of strict scrutiny. . . . [S]trict-scrutiny review is strict in theory but usually fatal in fact." *Bernal v. Fainter*, 467 U.S. 216, 219 n.6 (1984) (internal quotation marks omitted).

The proposed rule is particularly suspect because it imposes a form of viewpoint discrimination. In particular, it forces manufacturers' packaging and advertising to transmit *the Government's* viewpoint regarding cigarette use while, simultaneously, undermining the ability of manufacturers to communicate their *own* viewpoints. Such viewpoint discrimination is "censorship in a most odious form," *Police Dept. of Chi. v. Mosley*, 408 U.S. 92, 98 (1972) (quoting *Cox v. Louisiana*, 379 U.S. 536, 581 (1965) (Black, J., concurring)). As such, the proposed rule is "presumptively unconstitutional." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 830 (1995).

Here, the governmental interest in the proposed warnings is presumably to inform the public of the health effects of smoking and reducing youth tobacco use. The proposed rule, however, does not further these interests and, in any event, is not even arguably the least restrictive means of achieving them. The proposed rule, therefore, cannot possibly survive strict scrutiny.

First, as the FDA Study acknowledges, the proposed rule does not, in fact, further any of the governmental interests it is supposed to serve: the expected benefits from the proposed warnings "are in general not statistically distinguishable from zero" because they will have no effect on consumers' risk beliefs or on whether they smoke or not 75 Fed. Reg. at 69,546. Moreover, the proposed rule is not needed to further any governmental interest in informing the public or reducing youth tobacco use. Rather, as described above, the proposed warnings provide no new factual information to consumers. Therefore, by FDA's own admission, there is an inadequate factual basis for concluding that the rule materially advances any legitimate governmental interest.

Second, the proposed rule is not even arguably the *least restrictive* means available for communicating FDA's "public health" message. To the contrary, a host of alternative methods offer plausible avenues for disseminating this message, none of which would infringe on manufacturers' free speech rights at all.

Most obviously, the Government could disseminate its anti-smoking message itself. It could, for example, increase funding for anti-smoking advertisements on television and radio and in other media. It could also issue additional statements in press conferences, press releases, websites, government reports, and public hearings, urging consumers to quit smoking and avoid cigarettes. To be sure, the Government may find it more convenient and less expensive to conscript cigarette manufacturers' property to disseminate the Government's anti-smoking viewpoint, but such interests are hardly sufficient under strict scrutiny. *See Palmer v. Thompson*, 403 U.S. 217, 226 (1971) ("Citizens may not be compelled to forgo their constitutional rights because officials . . . desire to save money.").

Nor is this the only less-restrictive-alternative available to the Government. To the contrary, as explained in detail in the attached declarations of Dr. Cecil Reynolds and Dr. Viscusi:

- The MSA provides to the states annually billions of dollars that are intended for tobacco-control programs but are instead spent by the states for unrelated purposes. The Government's own agencies have stated that requiring the states to increase the allocation of MSA funds to youth tobacco prevention—from the meager 3.5% recently employed to the still-modest CDC-recommended 15%—would be effective in reducing youth tobacco use. *See* Exhibit D, Declaration of Cecil Reynolds ("C. Reynolds Decl.") ¶¶ 54-57. The Government could condition receipt of federal funds on states' allocation of MSA funds in accordance with CDC recommendations.
- There are dozens of non-speech-restrictive strategies that the Government's own agencies and the public-health community believe would reduce youth tobacco use, because they address the social factors that directly influence such use. *See* C. Reynolds Decl. ¶¶ 28-30, 50-66. The existing (though thus far limited) deployment of these strategies has already proven effective in reducing youth tobacco use. *See id.* ¶¶ 6-8, 20, 23.
- To the extent the proposed warnings are intended to deter youth smoking, the Government could improve efforts to prevent the unlawful sales of tobacco products to minors. Previous efforts in this regard have, not surprisingly, proven to be an effective means of reducing youth tobacco use and the federal Synar Amendment, which requires states to enact and enforce laws prohibiting such sales and to achieve a retail violation rate of less than 20%, 42 U.S.C. § 300x-26, has proved extraordinarily effective. *See* C. Reynolds Decl. ¶¶ 52, 61.
- Nor did the Government consider whether increased cigarette taxes, which have been shown to reduce cigarette consumption, *see* Viscusi Report 33, would be at least as effective as the proposed warnings.

At a minimum, the Government could modify the health warnings to make them less burdensome. It could, for example, (1) reduce the packaging and advertising space occupied by the proposed warnings to no more than 20 percent of cigarette packaging and 10 percent of an advertisement; (2) require warnings on only the front *or* back of packaging but not both; (3) allow warnings to be placed on the bottom, rather than the top, portion of packaging and

advertising; and (4) select graphics that convey purely factual information as opposed to the emotionally charged ones contained in the proposed rule. In addition, as it has done with prescription drugs and devices, the Government could provide an exemption from the graphic warnings requirement for “reminder” advertising and labeling. Reminder advertising and labeling is a well-established category for several FDA-regulated products. Reminder pieces may call attention to the name of a product and provide certain other information, such as price, but may not contain express or implied claims. *See, e.g.*, 21 C.F.R. § 201.100(f) (exempting promotional labeling that “calls attention to the name of the drug product” and certain other information, from the requirement to include warnings, precautions, and other similar information); 801.109(d) (same for prescription medical devices). A similar exemption would be warranted here.

Any such revised requirements might still violate the First Amendment, but the fact that the Government ignored a less burdensome warning in favor of the proposed rule easily demonstrates that the proposed rule is not even arguably the *least* speech-restrictive means of satisfying any legitimate governmental interest. *See Blagojevich*, 469 F.3d at 652 (invalidating a warning label on video games because “at four square inches, the ‘18’ sticker *literally* fails to be narrowly tailored—the sticker covers a substantial portion of the box. The State has failed to even explain why a smaller sticker would not suffice. Certainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's unjustified requirement of the four square-inch ‘18’ sticker.”).

These are but a few of the many alternatives to the proposed rule. Yet it appears that the Government made no effort to even consider these or other alternatives, much less demonstrate that they would not be as effective as the proposed rule. Accordingly, because the proposed rule neither furthers the Government's interests nor employs the least speech-restrictive means in pursuit thereof, the rule cannot satisfy strict scrutiny and, therefore, violates the First Amendment.

C. The Proposed Rule Also Cannot Be Justified Under *Central Hudson*.

As explained above, the proposed warnings compel tobacco manufacturers to disseminate a government-drafted anti-smoking message; because such compelled speech does not fit within the narrow *Zauderer* exception, the proposed warnings are subject to strict scrutiny. *See, e.g., Blagojevich*, 469 F.3d at 652 (concluding that a video game “warning” requirement that failed to satisfy *Zauderer* was subject to strict scrutiny). In addition, the proposed rule burdens tobacco manufacturers' own speech by prohibiting them from using the top 50% of their packages and the top 20% of their advertisements to disseminate their own commercial messages. In this regard, the proposed rule is comparable to, but more burdensome than, a requirement that the top half of packages and top fifth of advertisements be left blank. Therefore, the proposed rule also must satisfy the First Amendment test governing restrictions on commercial speech set out in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), pursuant to which the Government must prove (among other things) that a speech restriction “directly and materially advance[s]” a substantial governmental interest, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995), and that the restriction “is not more extensive than necessary to

serve that interest,” *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002) (internal citation omitted). The proposed rule, however, also fails under *Central Hudson*.

First, the proposed rule does not “directly and materially advance” any governmental interest in redressing consumer ignorance or misunderstanding or reducing tobacco use. *Cf. Rubin*, 514 U.S. at 488. To satisfy this component of *Central Hudson*, the Government must “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a *material degree*.” *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (emphasis added). “Consequently, the regulation may not be sustained if it provides only ineffective or remote support for the government’s purpose.” *Greater New Orleans Broad. Ass’n. v. United States*, 527 U.S. 173, 188 (1999). *See also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506 (1996) (plurality op.) (“[T]he State has presented no evidence to suggest that its speech prohibition will *significantly* reduce marketwide consumption.”) (emphasis in original). The Supreme Court “ha[s] never accepted mere conjecture as adequate to carry a First Amendment burden . . .” *Nixon v. Shrink Mo. Gov’t PAC*, 528 U.S. 377, 392 (2000). Here, however, as explained above, the proposed rule would have no material affect on risk beliefs or smoking behavior.

Second, the proposed rule is “more extensive than necessary to serve” any asserted governmental interest, *Thompson*, 535 U.S. at 367. Under this component of *Central Hudson*, “if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so.” *Id.* at 371. Thus, in *Thompson*, the Court invalidated a federal law restricting speech because “[s]everal non-speech-related means of drawing [the] line [Congress intended] might [have] be[en] possible,” yet the Government had failed to explain “why these possibilities, alone or in combination, would be insufficient.” *Id.* at 372-73. Likewise, in *BellSouth Telecommunications, Inc. v. Farris*, 542 F.3d 499 (6th Cir. 2008), the court invalidated a state-law speech restriction designed to prevent consumer confusion because the state had ignored a “full arsenal of options short of restricting speech.” *Id.* at 508-09. Here, as in *Thompson* and *BellSouth*, the Government has failed to employ—or even consider—the numerous obvious alternatives described above, *see supra* at 14-16, which would be at least as effective as the proposed warnings in accomplishing their asserted goals.

Indeed, there is no evidence that, in enacting sections 201 and 202 of the Tobacco Control Act, Congress considered any of these less restrictive alternatives or that, in issuing the proposed rule, FDA did so. In the Tobacco Control Act, Congress made 46 separate findings. *See Tobacco Control Act* § 2, 123 Stat. at 1776-81. None of them reflects any consideration of alternatives to the graphic warnings required by sections 201 and 202 of the Act. *Cf. Bartnicki v. Vopper*, 532 U.S. 514, 531 n.17 (2001) (“the relevant factual foundation is not to be found in the legislative record”). Under the First Amendment, those failures to consider alternatives are fatal. *See Greater New Orleans*, 527 U.S. at 188 (“The Government . . . must demonstrate narrow tailoring of the challenged regulation to the asserted interest”; “the challenged regulation should indicate that its proponent “‘carefully calculated’ the costs and benefits associated with the burden on speech imposed by its prohibition” (quoting *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993) (quoting *Bd. of Trustees of the State Univ. of NY v. Fox*, 492 U.S. 469, 480 (1989))).

The alternatives mentioned above plainly would serve the Government's legitimate interests here at least as effectively as would the proposed rule, but without restricting speech (or as much speech as the proposed rule). *Cf., e.g., 44 Liquormart*, 517 U.S. at 507 (plurality op.) ("It is perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal . . ."); *Rubin*, 514 U.S. at 490-91 (accepting challenger's proposed alternatives as showing that the restriction was more extensive than necessary); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 563 (2001) ("the range of communications restricted seems unduly broad"). Consequently, the proposed rule plainly is "more extensive than necessary to serve [the Government's] interest[s]." *Thompson*, 535 U.S. at 367.

Accordingly, in addition to unconstitutionally compelling tobacco manufacturers to disseminate the government's anti-smoking message, the proposed rule also unconstitutionally restricts cigarette manufacturers' right to disseminate their own commercial speech.

D. The Proposed Rule Violates the Takings Clause of the Fifth Amendment.

The new label requirements, by appropriating the tobacco companies' property and property interests in their trademarks, also violate their Fifth Amendment right to be free from the uncompensated taking of property. The Takings Clause of the Fifth Amendment mandates that private property shall not be taken for public use without just compensation. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 536 (2005). When the government directly appropriates or physically invades property, it is the most obvious example of a taking. *Id.* at 537. In addition, government regulation of private property may also be so onerous that "its effect is tantamount to a direct appropriation or ouster." *Id.* The new labeling requirements constitute both a per se physical taking of the tobacco companies' packaging and advertising space as well as a regulatory taking of their interests in their intellectual property.

The requirement that the label statement "shall comprise the top 50 percent of the front and rear panels of the [cigarette] package" (§ 201(a)) constitutes a "direct government appropriation or physical invasion of personal property." *Lingle*, 544 U.S. at 537; *see Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982). That requirement thus effects a "classic taking" in which "the government directly appropriates private property for its own use." *Tahoe Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency*, 535 U.S. 302, 324 (2002). The proposed labeling requirements also effect a regulatory taking of the tobacco companies' intellectual property, packaging, and advertising. *See Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 44-46 (1st Cir. 2002) (en banc). The statutory and common law protections provided to trademarks and trade dress provide a "reasonable expectation" that the Companies' intellectual property rights will be protected. *Philip Morris, Inc. v. Harshbarger*, 159 F.3d 670, 678 (1st Cir. 1998) (citing *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1011 (1984)).

E. The Proposed Rule Violates the APA.

FDA's failure to consider the alternative methods described above, *supra* at 14-16, also violates the APA, which requires FDA to consider alternative regulatory approaches that are "neither frivolous nor out of bounds." *Chamber of Commerce v. SEC*, 412 F.3d 133, 144-45 (D.C. Cir. 2005) (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S.

29, 54 (1983); *SEC v. Chenery Corp.*, 332 U.S. 194, 196-97 (1947)). The duty to consider valid alternatives is particularly relevant here because the Tobacco Control Act repeatedly provides FDA with authority to adjust the proposed label requirements. See 15 U.S.C. § 1333(b)(2), (b)(4), (d), (e), as amended by the Tobacco Control Act § 201(a), 202, 123 Stat. at 1842. See also *Presidential Certification*, 20 O.L.C. at 278¹⁴; *Limitations on the Detention Authority of the Immigration and Naturalization Service*, Op. Off. Legal Counsel (2003)¹⁵; U.S. Const. art. II, § 3, cl. 4 (the President “shall take Care that the Laws be faithfully executed”). Indeed, it appears that FDA did adjust the size and placement of the warnings for cigarette cartons. See 75 Fed. Reg. at 69,537 (modifying the requirement that the warnings appear in the top 50 percent of cigarette cartons to avoid “distortion” of images). Given FDA’s conclusion that it had sufficient authority to adjust the size and placement of such warnings, the agency likewise has authority to adjust the warnings to avoid the numerous constitutional infirmities identified in these comments.

II. The Evidence Cited by the Proposed Rule Does Not Demonstrate That the Proposed Warnings Will Reduce Smoking Prevalence.

In view of the burdens and restrictions that would be imposed by the proposed warnings on packaging and in advertising, the APA (i.e., rational policymaking) and the First Amendment independently require some demonstration by FDA that the proposed warnings, as opposed to the alternatives mentioned above, are necessary to bring about the intended regulatory benefits. As to the APA, see, e.g., *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). As to the First Amendment, see, e.g., cases cited at Part I, *supra*.

The proposed rule, however, identifies no evidence, gathered by either Congress or FDA, that the proposed warnings will have a statistically significant effect in increasing consumer awareness and reducing smoking prevalence or will be superior to the alternatives mentioned above. Such imposition of substantial burdens and restrictions on free speech and other costs without any demonstration of significant benefits or of superiority to readily available less-restrictive alternatives constitutes arbitrary and capricious agency action in violation of the APA and also violates the First Amendment.

A. The Studies Cited by FDA, Even Taken at Face Value, Do Not Support the Proposed Rule.

The studies cited by the proposed rule, even if taken on their own terms, demonstrate only the unsurprising proposition that graphic warnings of the risks associated with smoking increase the salience (or prominence) of those warnings. These studies, however, do *not* demonstrate, or even suggest, that reminding consumers of risks they already know—and indeed overestimate—will have any effect on smoking prevalence. To the contrary, as explained above, “[i]ndependent studies have demonstrated that more information about the risks of smoking does

¹⁴ Available at <http://www.justice.gov/olc/cdraftfin.htm>.

¹⁵ Available at <http://www.usdoj.gov/olc/INSDetention.htm>.

not influence smoking rates or consumer behavior,” Viscusi Report 21; and even the Surgeon General has rejected the “‘assumption . . . [that] young people had a deficit of information that could be addressed by presenting them with health messages in a manner that caught their attention and provided them with sufficient justification not to smoke,’” *id.* at 24.

Nor can the proposed warnings be justified as an emotional appeal to encourage consumers to avoid cigarettes. As already described, the First Amendment does not allow the Government to force businesses to convey the Government’s own ideological message. *See supra* at 10-14. However, even if such a purpose were constitutionally permissible, the proposed rule would fail because there is no evidence that the warnings mandated by the Act will “result in a statistically significant reduction in smoking initiation among youth or the overall prevalence of cigarette smoking.” Viscusi Report at 2. As described above, the FDA Study itself proves this point, confirming that the graphic warnings will have virtually *no* effect on smoking intentions, let alone behavior. *See* Viscusi Report 70-73. Indeed, the graphics accompanying 8 of the 9 warnings had *no statistically significant effect* on preventing youth initiation of smoking, and one of the graphic warnings was actually associated with *increased* youth intention to start smoking. *Id.* Likewise, 35 out of 36 warnings had no statistically significant effect on adult intentions to quit, 34 of 36 had no effect on young adult intentions to quit, and 1 of the graphic warnings was actually associated with *decreased* quit intentions. *Id.*

This point is also demonstrated by the experiences of Canada, Australia, and the United Kingdom. As Dr. Viscusi explains, “[d]espite the presence of these large text warnings and/or large text and graphic warnings on cigarette packaging in Canada, the U.K., and Australia, there is no evidence that . . . [they] produced a reduction in smoking among adults or youth in those countries based on analysis of smoking prevalence in each country.” Viscusi Report 78. Take, for example, Canada’s nearly identical warnings. “The appropriate test for [the] [e]ffect of the new warnings is whether there is a break in the smoking prevalence trend.” *Id.* In other words, although “[t]here has been a steady decline in smoking prevalence rates over time, . . . has th[e] rate of decline increased as a result of the new warnings?” *Id.* As Dr. Viscusi demonstrates, “despite having seven years of data on smoking prevalence following their introduction,” the Canadian warnings have had “no apparent impact at all on the trend in smoking prevalence,” thus “vividly demonstrat[ing] [that] simply assuming, on the basis of ‘common sense’ or otherwise, that such warnings will reduce smoking, is unjustified based on real world experience.” *Id.* at 80.

In light of the results in FDA’s own study and the lack of a demonstrated effect of similar graphic warnings in other countries, FDA is entirely correct to conclude that the expected benefits of the proposed warnings are “not statistically distinguishable from zero.” 75 Fed. Reg. at 69,546. Imposing a burdensome and speech-restrictive rule whose benefits are “not statistically distinguishable from zero” violates the First Amendment and the APA’s requirement of reasoned decision-making.

B. The FDA Study Suffers From Serious Methodological Flaws.

In addition, as Dr. Viscusi further explains, the FDA Study suffers from numerous additional critical methodological flaws, which render even the limited positive conclusions of the FDA Study unreliable. *See generally* Viscusi Report 37-48. For example:

- By relying on a survey of stated quit intentions rather than undertaking a longitudinal assessment of actual behavior, the study, like many other studies in this area, cannot demonstrate any *actual impact* of the warnings on smoking prevalence. *Id.* at 46-47.
- The study, in apparent disregard of prior comments by Dr. Viscusi, failed to address the risk that youth respondents would alter their survey responses due to “a concern on their part that their parents would or could become aware of their participation in the survey.” Viscusi Report 41.¹⁶ Rather, the FDA Study appears to have compounded this risk by deriving its youth sample from families with parents who also participated in the study. *Id.*
- The study failed to evaluate the extent to which certain of the warnings (in particular, the addiction warning) may actually discourage quitting by suggesting to smokers that they cannot quit smoking on their own. *Id.* at 48.
- In assessing the cognitive and emotional reactions to the warning labels, the study weighted the responses to multiple questions; yet the study report fails to disclose the weights used and the justifications for those weights. *Id.* at 51. Without this information, it is not possible to assess whether any bias was introduced through such weighting. *Id.*
- It appears that the study failed repeatedly to ensure a representative sample of the national population and failed to do so in a manner that may have biased the study results. Specifically, the report of the study “fails to disclose the most basic sampling information,” *id.* at 52; and there is no indication that those conducting the study adjusted for the effect of choosing study participants by soliciting volunteers. *Id.* This failure is significant because “the mix of respondents who take the survey may not reflect the population of interest, [and that lack of match] potentially bias[es] the statistical estimates.” *Id.*
- Even more troubling, the study shows no signs of having been adjusted for the substantial number of participants who failed to complete the study: “After having begun th[e] relatively brief survey, 32% of those who passed the initial screen to take the survey quit the survey before completing it.” *Id.* at 54-55. Such a poor completion rate is troubling because “[q]uitting the survey is not likely to be a random event. [Rather, o]ne possibility is that smokers who are not receptive to the graphic warning messages dropped out of the survey as a protest against this policy effort, in which case the survey results will overstate the likely effect of the warnings.” *Id.*
- The FDA Study’s analysis of cognitive reactions to the warnings inexplicably omits responses to whether the warnings looked “cool.” *Id.* at 55. Of course, if a substantial number of consumers view the proposed warnings as “cool” rather than either informative or disturbing, those warnings are unlikely to have their intended effect. *Id.*

¹⁶ Dr. Viscusi provided a number of comments in response to FDA’s earlier request for comments regarding the methodology for testing the proposed warnings. *See* Viscusi Report at 38. To date, however, it appears that the Agency has not responded to those comments, or to any others that it received, but, instead, conducted its study without any regard to the comments it had previously solicited and received.

Again, the omitted information does not appear to have been neutral; rather, “regression results indicate that the belief that the warnings look ‘cool’ is one of the strongest estimated effects in the study, and goes in the opposite of the intended direction.” *Id.*

- The study measured risk awareness and smoking intentions on a scale. This is not only “an inappropriate approach in survey methodology for testing awareness of a fact” but also resulted in the study’s authors making subjective (and undisclosed) decisions regarding how to weight these values. *Id.* at 56.

These multiple critical methodological defects in FDA’s study make any positive conclusions from it wholly unreliable. Due to these defects, the study cannot be used to satisfy any constitutional burden on the Government in defending its restriction on manufacturers’ speech, and cannot be used to satisfy the Government’s burden under the APA to show that the proposed rule is not arbitrary and capricious. To the contrary, the study confirms that the Government cannot possibly meet these burdens.

C. FDA’s Cost-Benefit Analysis Overestimates the Proposed Rule’s Benefits While Underestimating Its Costs.

Finally, the proposed rule’s Regulatory Impact Analysis sets forth FDA’s cost-benefit analysis of the rule. Ultimately, this analysis concedes that the expected benefits from the proposed warnings “are in general not statistically distinguishable from zero.” 75 Fed. Reg. at 69,546. But even here, as described in more detail by Dr. Viscusi and Dr. Robert Maness,¹⁷ FDA’s cost-benefit analysis contains numerous flaws that cause the Agency to overestimate the proposed rule’s concededly negligible benefits while, at the same time, underestimating its costs. For example:

- FDA overestimates the potential benefits of smoking cessation by counting all conceivable savings that could be achieved if the prevalence of smoking declined (*e.g.*, savings with respect to medical care, fires, etc.), but ignores all of the debits that would be incurred in such a scenario (*e.g.* increased costs for nursing home care, pensions, Social Security, etc.). Viscusi Report 88; Maness Report 20-21. Although the costs associated with longer lives may be desirable, they are nonetheless costs.
- FDA’s estimate of benefits assumed that a change occurred in the trend in smoking prevalence in Canada, that such a change was attributable to the introduction of graphic warnings, and that a comparable change can be expected if graphic warnings are introduced in the United States. Maness Report 7. However, the introduction of graphic warnings in Canada had no demonstrable effect on smoking rates in that country. *Id.* at 8; *See also* Viscusi Report 80 (“In the case of Canada, which uses both large text, placed on the front and back of the pack, and graphic imagery regarding health effects of smoking, there is no apparent impact at all on the trend in smoking prevalence.”). In any event, FDA concedes that it failed account for significant factors such as increasing cigarette

¹⁷ *See generally*, Viscusi Report 86-90 ; Exhibit B, Statement of Robert S. Maness 6-26 (“Maness Report”). The comments provided by Dr. Maness set forth in Exhibit B are incorporated into this letter as if fully stated herein.

prices, new restrictions on public smoking, and other anti-tobacco initiatives in Canada, which preclude an assumption of similar results in the United States. Maness Report at 8-20.

- FDA’s analysis fails to account for the likelihood that graphic warnings will alter the competitive equilibrium between premium branded cigarettes and generic cigarettes. By confiscating the top 50% of both primary display panels on cigarette packaging, the proposed rule would make cigarette packages look more homogeneous and reduce consumers’ ability to distinguish between branded and generic cigarettes. *Id.* at 24. “In such circumstances, economic theory predicts that premiums for branded cigarettes would decrease and price competition would intensify.” *Id.* Such a reduction in price “would likely lead to an increase in cigarette usage that could more than offset the small and statistically insignificant reductions in smoking rates estimated by the FDA.” *Id.*
- The proposed rule notes that reduced cigarette consumption will lead to private costs such as lost income for tobacco growers, lost jobs in cigarette manufacturing, and lost profits for retailers. FDA dismisses these costs, however, as mere “distributional effects”; that is, FDA assumes that tobacco-related businesses and their employees will simply divert their energies to alternative and equally profitable economic activity. *Id.* at 27-31. Such assumptions are inconsistent with basic economic theory, which predicts that businesses and employees will devote their activities to their highest valued use. *Id.* at 29. There is thus no basis to assume that land currently planted in tobacco “can be easily shifted to other crops with no net loss,” that “losses in the tobacco industry would be offset by job gains in non-tobacco [sectors],” or that retailers can simply “shift shelf space and promotional activities to non-tobacco products” without reducing profits. *Id.* at 27-31.

In sum, the methodological flaws in the studies relied upon by FDA and in FDA’s own cost-benefit analysis separately render the proposed rule unconstitutional under the First Amendment and arbitrary and capricious under the APA.

III. FDA’s Failure To Release Important Data Underlying Its Selection of the Proposed Graphics Deprives the Public of an Opportunity To Assess the Proposed Rule Fully and, Unless Such an Opportunity Is Provided Before Issuance of the Final Rule, Violates the APA.

Finally, as Dr. Viscusi explains, other aspects of the proposed rule are also based on unspecified or unidentified information. FDA’s failure to identify that information and make it available to the public deprives the public (including cigarette manufacturers) of “a meaningful opportunity to comment on the proposed provisions.” *Hall*, 273 F.3d at 1162 (internal quotation marks omitted). Specifically, despite previous comments by Dr. Viscusi noting the importance of disclosing FDA’s process for selecting warning text and graphics, the FDA Study “has neglected to describe those processes in meaningful detail.” Viscusi Report at 37. “The lack of this documentation undermines the ability to offer comments on those judgments and processes.” *Id.* See also Maness Report at 5 (“The absence of full disclosure of assumptions and computations impedes the independent analysis and review of the FDA’s conclusions.”); *supra*

at 12 n.12 (objecting to the proposed rule’s failure to identify the “smoking cessation resource” that must be included in the warnings).

Because an “integral” component of notice-and-comment rulemaking is “the agency’s duty to identify and make available technical studies and data that it has employed in reaching decisions to propose particular rules,” this failure to disclose “the technical basis for [FDA’s] proposed rule in time to allow for meaningful commentary” constitutes “serious procedural error,” *Owner-Operator Ind. Drivers Ass’n. v. Public Citizen*, 494 F.3d 188, 201 (D.C. Cir. 2007) (holding that because the agency’s operator-fatigue model was “unquestionably among the most critical factual material that was used to support the agency’s position,” the agency’s “failure to provide an opportunity for comment on the model’s methodology therefore constitute[d] a violation of the APA’s notice-and-comment requirements”).

* * *

For the foregoing reasons, the proposed rule violates the APA and the First Amendment. It imposes major burdens on protected speech without adequate justification; it does not adequately consider less burdensome alternatives that would advance the Government’s legitimate interests at least as much as would the proposed rule; it relies on studies that are permeated with methodological flaws; it contains imprecise and ambiguous requirements; and it fails to disclose fully the studies and data on which it is based. The proposed rule therefore does not reflect the reasoned decision-making required by the APA and violates the First Amendment.

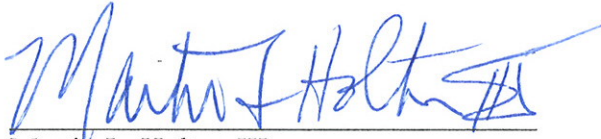
It is “the duty and practice of the executive branch to avoid statutory constructions that unnecessarily raise grave doubts about the constitutionality of congressional measures. Respect for Congress, furthermore, counsels reluctance to interpret a statute so as to require the assertion of a presidential power to act contrary to the statute.” *Presidential Certification*, 20 Op. Off. Legal Counsel at 278¹⁸; *see also Limitations on the Detention Authority of the Immigration and Naturalization Service*, Op. Off. Legal Counsel (2003) (“It is settled, of course, that where there are two or more plausible constructions of a statute, a construction that raises serious constitutional concerns should be avoided.”)¹⁹ Thus, even though some of the unconstitutional features of the proposed rule are contained in the Tobacco Control Act, FDA should exercise the wide discretion it has in implementing the Act, both under the Act itself, *see, e.g.*, 15 U.S.C. §§ 1333(b)(4), (d), (e), as amended by 123 Stat. 1842-46, and the U.S. Constitution, *see* U.S. Const. art. II, § 3, cl. 4 U.S. Const. art. II, § 3, cl. 4 (the President “shall take Care that the Laws be faithfully executed”), to eliminate the constitutional and other infirmities described herein. In particular, it should promulgate a revised proposed rule that requires the Tobacco Control Act’s new textual warnings to be displayed in the same manner in which the Surgeon General’s warnings have successfully been displayed for decades and that does not unconstitutionally force tobacco manufacturers to direct adult customers to a smoking cessation resource. At a minimum, FDA should delay implementation of the proposed rule until these issues are resolved either administratively—by, for example, changing the proposed rule to address these constitutional deficiencies—or through litigation.

¹⁸ Available at <http://www.justice.gov/olc/cdraftfin.htm>.

¹⁹ Available at <http://www.usdoj.gov/olc/INSDetention.htm>.

Thank you for your consideration of these important concerns.

Sincerely,



Martin L. Holton III
Executive Vice President and General Counsel
R. J. Reynolds Tobacco Company

Ron Milstein
General Counsel
Lorillard Tobacco Company

Rob Wilkey
Senior Legal Counsel
Commonwealth Brands, Inc.

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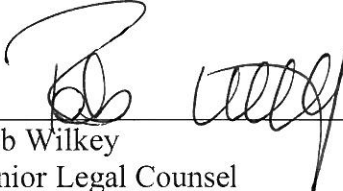
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