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***VIA FACSIMILE: (301) 827-6870***

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

**Re:** ***21 CFR Part 1141***
***Required Warnings for Cigarette Packages and Advertisements***
**Docket No. FDA-2010-N-0568, RIN No. 0910-AG41**

Dear Sir or Madam:

The Association of National Advertisers, Inc. ("ANA") and American Advertising Federation ("AAF") (the "Advertising Associations") hereby comment on the proposed requirements that tobacco product packaging and advertising contain color graphics depicting negative health consequences of smoking. The FDA released options for the illustrated warnings that would be required under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") and asked interested parties to comment. [1] The Advertising Associations submit these comments because the Tobacco Control Act's marketing provisions ignore constitutional protections afforded advertising and product packaging, at the expense of core First Amendment principles.

## *Introduction*

The ANA leads the marketing community by providing insights, collaboration and advocacy to a membership of 400 companies with 9,000 brands that collectively spend over $250 billion annually in U.S. marketing communications and advertising. The ANA strives to communicate marketing best practices, lead industry initiatives, influence industry practices, manage industry affairs, and advance, promote, and protect advertisers and marketers. The AAF is the Washington, D.C. trade association that represents 50,000 professionals in the advertising industry, with 130 corporate members that are advertisers, agencies, and media companies repre-

[1] *Required Warnings for Cigarette Packages and Advertisements; Proposed Rule*, Docket No. FDA-2010-N-0568, RIN No. 0910-AG41, 75 Fed. Reg. 69524 (2010) ("*Notice*").

senting the nation's leading brands and corporations. The Advertising Associations participated as *amici* in litigation challenging certain of the marketing provisions in the Tobacco Control Act that repudiate core principles of commercial speech doctrine developed over several decades. [2]

Although the particular warnings and proposed requirements raised in this *Notice* relate to the marketing of tobacco, the constitutional focus of our comments is not cigarettes or tobacco products. Rather, the Advertising Associations' concerns involve our nation's commitment to the First Amendment and, particularly, the commercial speech doctrine. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). The Supreme Court has made clear the applicable principles are the same regardless of whether the issue involves speech about tobacco, or any other product. It stressed that "speech regulation cannot unduly impinge on the speaker's ability to propose a commercial transaction and the adult listener's opportunity to obtain information," and that this applies with no less force when the object of regulation is tobacco. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001). There is no First Amendment "vice exception," and "so long as the sale and use of tobacco is lawful for adults," *id.* at 571, government may not target speech about it on grounds it "pertains to a 'vice' activity." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1986); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995).

As one court recently held in invalidating government-mandated signs with "gruesome images ... accompanied by corresponding information about the dangers of smoking," tobacco purveyors are "entitled to the full protection of the law, for our sake as well as theirs." *23-34 94th St. Grocery Corp. v. New York City Bd. of Health*, 2010 WL 5392876 *1 (Dec. 29, 2010). The Tobacco Control Act's marketing provisions lose sight of that principle. The disturbing graphic images the FDA proposes here, that tobacco companies will be forced by rule to affix to their ads and product packaging, exemplify and exacerbate that affront to the First Amendment.

***Discussion***

The Tobacco Control Act's marketing provisions in general, and the graphic warnings the FDA proposes here specifically, ignore core limits on government authority to regulate commercial speech. These include the principles that "the power to prohibit or to regulate particular conduct does not necessarily include the power to ... regulate speech" about it, *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 193 (1999), and that when government seeks to further interests in the commercial arena, "regulating speech must be a last – not first – resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). Accordingly, if the FDA seeks to affect lawful choices of adults, it must first seek to regulate *conduct* rather than restricting or compelling speech about it. *E.g.*, *44 Liquormart*, 517 U.S. at 503. *See W. States*

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[2] *See* Brief of *Amici Curiae* ANA *et al.*, *Commonwealth Brands, Inc. v. United States*, 678 F.Supp.2d 512 (W.D. Ky. 2010) (No. 1:09-cv-117, filed Nov. 30, 2009); Brief of *Amici Curiae* ANA *et al.*, *Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir. filed June 4, 2010).

*Med. Ctr.*, 535 U.S. at 374. Pursuing such goals by regulating speech is "paternalistic," and generally unconstitutional. *See, e.g.*, *44 Liquormart*, 517 U.S. at 510, 516.

The district court's initial holding in *Commonwealth Brands* is not to the contrary. That court found that parts of the Tobacco Control Act are unconstitutional, although it did not agree that the new warning-label requirements necessarily violate the First Amendment. [3] However, this does not mean the FDA can proceed with the proposed graphics without more fully analyzing their First Amendment implications. As a threshold matter, the case is now on review in the Sixth Circuit. *See supra* note 2. More importantly, the district court had before it only an abstract statutory command that *some* kind of graphics would accompany new textual warnings – it did not consider the specific images now at issue. [4] The FDA bears the burden of demonstrating the graphic warnings it now proposes satisfy constitutional limits, *see*, *e.g.*, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985), yet the *Notice* fails to even mention the issue.

***The Graphic Images are Excessive.*** The proposed options for graphics combined with the new cigarette warnings are expressly designed to be propagandistic rather than informative. For example, one disturbing image proposed for the "cigarettes are addictive" warning shows a man smoking through what appears to be his tracheostomy opening, leading researchers to label it the "hole in throat" graphic. [5] Another image, for the "tobacco can harm your children" warning, shows a pale youth with sunken eyes using an oxygen mask (thus, the "girl in oxygen mask" appellation). *Experimental Study Report* at 3-6. For "cigarettes cause fatal lung disease," the *Notice* proposes a picture of the feet of a cadaver on an autopsy table (the "toe tag" graphic) and pictures of traumatized lungs ("healthy/diseased lungs" and "lungs full of cigarettes" graphics). *Id.* at 3-10. Similar labels identify other graphics, such as the "deathly ill woman" and "lesion on lip" photos for the "cigarettes cause cancer" warning, *id.* at 3-14, and an image of a crying "baby in incubator" for "smoking during pregnancy." *Id.* at 3-22. And for the "smoking can kill you" warning, there are more cadavers, a "man in casket," and one "with chest staples." *Id.* at 3-26. *See id.* at 3-18 ("oxygen mask on [ ] face" and "man in pain with hand on chest" for "strokes and heart disease" warning); *id.* at 3-34 ("cigarettes in toilet bowl" for "quitting smoking now").

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[3] *See* 678 F.Supp.2d at 525-26, 528-32, 534-35.

[4] *See Notice*, 75 Fed. Reg. at 69524-25. *Compare Commonwealth Brands*, 678 F.Supp.2d at 532 ("Court does not believe … addition of a graphic image will alter the substance of such messages, at least as a general rule.").

[5] *Experimental Study of Graphic Cigarette Warning Labels, Final Results Report*, Prepared for Center for Tobacco Products, FDA, by RTI International, Dec. 2010, at 3-2 ("*Experimental Study Report*"), added to record for public comment in *Required Warnings for Cigarette Packages and Advertisements*, Docket No. FDA-2010-N-0568, RIN No. 0910-AG41, 75 Fed. Reg. 75936 (2010). *See also Notice*, 75 Fed. Reg. at 69535 (describing research underway to study the efficacy of the proposed graphics vis-à-vis consumer attitudes, beliefs and intended behaviors related to smoking, including encouraging cessation and discouraging initiation, the relative ability of the images to convey information, and whether responses differ across groups demographically and/or based on smoking status).

These graphics are to appear on "all advertisements, regardless of form – which could include ... magazine and newspaper ads, pamphlets, leaflets, brochures, point of sale displays, ... posters, billboards, direct mailers, and internet advertising." *Notice*, 75 Fed. Reg. at 69537. The images are not designed to convey information, but instead are calculated to make people avert their eyes from legal products and advertisements, and to change their behavior. It appears the real goal is not to convey factual information but to engender revulsion by those who see the images, and to force tobacco companies to stigmatize their own products. In fact, one reaction the *Experimental Study* measured for many of the graphics was how strongly they elicited a response that "the pack was difficult to look at." *Experimental Study Report* § 3, *passim*.

Such a regulatory goal undermines any claim that communicating health information is the intended purpose. It is also belied by the fact that there is no serious doubt tobacco users already know smoking poses serious health risks, despite suggestions to the contrary. [6] Indeed, as one academic in the forefront of tobacco cessation has noted, "[i]n recent years, public opinion polls have consistently indicated that the public, including the smoking public, is well aware of the health risks of smoking." Robert L. Rabin, *Tobacco Control Strategies: Efficacy and Future Promise*, 41 LOYOLA L. REV. 1721, 1748 & nn.a1 & 106 (Summer 2008); *id.* at 1726. *See also* Robert L. Rabin, *The Tobacco Litigation: A Tentative Assessment*, 51 DEPAUL L. REV. 331, 352 (Winter 2001) (same). *Cf.*, *e.g.*, *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 350-51 (6th Cir. 2000) (collecting tobacco cases applying "common knowledge" doctrine). The extent to which the government has gone out of its way to disgust rather than inform, and even then to convey information that is already generally known, is a serious constitutional problem.

***The Graphic Images Unconstitutionally Compel Speech.*** The proposed graphic images (and their accompanying warnings) compel speech by cigarette producers on their packaging and in ads in violation of the First Amendment, which secures "both the right to speak [ ] and ... to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). Except for purely factual and non-controversial disclosures as noted below, the government may not compel private entities to bear on their own property non-factual messages selected or dictated by the government. *Id.* at 715. This is because where statutes "[m]andat[e] speech that a speaker would not otherwise make," they "necessarily alter[ ] the content of the speech." *Riley v. National Fed'n of the Blind of N.C., Inc.,* 487 U.S. 781, 795 (1988). As the Supreme Court has observed, some of its "leading First Amendment precedents have established ... that freedom of speech prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006). This is as true for "corporations as for individuals," [7] and that includes tobacco purveyors as much as any other advertiser or other company. *Lorillard*, 533 U.S. at 571.

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[6] *E.g.*, *Notice*, 75 Fed. Reg. at 69525, 69529-30, 69533.

[7] *Pacific Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (pl. op.); *Citizens United v. FEC*, 130 S. Ct. 876, 899 (2010).

The lurid images the *Notice* proposes cannot be justified under the narrow constitutional exception permitting disclosure requirements for non-controversial information. Under *Zauderer* and its progeny, compelled disclosure may be permissible to convey "purely factual" information. 471 U.S. at 651. *E.g.*, *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 556 F.3d 114, 131-34 (2d Cir. 2009); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113-14 (2d Cir. 2001). However, such disclosures may be required only if they are "uncontroversial" and apply to commercial messages that may otherwise mislead or deceive. *E.g.*, *Zauderer*, 471 U.S. at 651. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339-40 (2010). If government seeks to compel overly burdensome disclosures or to co-opt a speaker's message, its regulation is unconstitutional, and courts consistently reject efforts to compel private entities to sponsor government propaganda. *E.g.*, *Wooley*, 430 U.S. at 714; *PG&E*, 475 U.S. at 15.

The decision in *Entertainment Software Association v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), well illustrates this point. In that case, the Seventh Circuit invalidated mandatory stickers on "violent" and "sexually explicit" video games – even though they comprised no more than a four-inch square sticker with number "18," indicating that the games could not be sold to minors. The court explained that the mandatory labeling requirement could not be upheld for the same reason "we would not condone a health [ ] requirement that half of the space on a restaurant menu be consumed by [a] raw shellfish warning." *Id.* at 652. If a stark numeral 18 could not clear the hurdle of being "uncontroversial," it is impossible to see how the lurid imagery the FDA now proposes could survive constitutional scrutiny.

The graphics proposed here far exceed current, eminently noticeable textual warnings, which also are proposed to become more prominent and emphatic. Taken together, purposefully disturbing imagery combined with bolstered text warnings will turn cigarette packs into "mobile billboards" for the government's "ideological messages" about smoking. *Maynard*, 430 U.S. at 715. The graphics are *intended* to be "controversial" to draw attention, and carry also the undue burden of being designed to repel consumers from a legal product. The proposed warnings far exceed the court's assumption in *Commonwealth Brands*, that the graphics do not "alter the substance of the message," and that the warnings are "objective" and "have not been controversial for decades." 678 F.Supp.2d at 531-32. However, the court reached its conclusion without seeing the images in question, as the FDA had yet to unveil them. Now that they have been revealed, images like "hole in throat," "deathly ill woman," "toe tag," and "cigarettes in toilet bowl" can hardly be called purely "informational" or "uncontroversial."

This is precisely the kind of paternalism that the First Amendment does not permit. In addition to the graphic warnings proposed in this *Notice*, the Tobacco Control Act imposes strict limits on advertising and promotion of tobacco products. However, Congress "has no [ ] authority to license one side of a debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules." *R.A.V.*, 505 at 392. Ultimately, given the purposefully shocking and controversial nature of the graphics the FDA has selected, the obligation to carry them in ads

and on cigarette packages is a content-based regulation that is presumptively invalid, *see id.* at 382, and unlikely to withstand constitutional review.

***The Graphic Images Cannot Directly and Materially Advance Any Interest.*** Even under an intermediate standard of constitutional scrutiny, the proposed mandatory graphics must directly and materially serve important government interests without restricting speech more extensively than necessary. *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 565-66. The *Notice* states that the interest to be served is "reducing the number of Americans … who use cigarettes," by "discourag[ing] nonsmokers … from initiating [ ] use and [ ] encourag[ing] current smokers to consider cessation." 75 Fed. Reg. at 69525-26 (citing Pub. L. 111-31 § 2(31)). However, evidence cited in or submitted under the *Notice* essentially admits the graphic warnings will not advance these objectives.

Evidence cited in the *Notice* regarding similar warnings in other countries shows a negligible effect on smoking rates. *Id.* at 69532. Putting aside that the countries do not enjoy the free speech protections of our First Amendment, international experience with these kinds of graphically enhanced warnings indicates that any impact on smoking rates will be nominal, at best. The *Notice* states that graphic warnings are more noticeable or easily recalled, or that those who see them may be more likely to "think about" the health impact of smoking. *Id.* But measuring such things as "thought[s] about quitting" fall far short of actual changes in smoking behavior.

For example, the *Notice* cites experience in Canada that smoking prevalence dropped by two percentage points in one year after the advent of graphic cigarette warnings, and an additional percentage point after the next year. *Id.* However, the *Notice* admits "[i]t is not possible to draw a direct causal connection between the graphic warnings and [the impact on smoking] because other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking also occurred during the same period." *Id.* Such a showing fails to meet *Central Hudson*'s requirement that the government must prove its restrictions directly and materially achieve its stated purpose. *Central Hudson Gas & Elec.*, 447 U.S. at 568-70.

The *Experimental Study Report* anticipated in the *Notice* further confirms the proposed graphic warnings fail to satisfy the *Central Hudson* test. The *Report* acknowledges there is no way to predict – let alone prove – that putting them on labels and in ads will have any lasting effect. In discussing actual change in smoking behavior, the *Report* states "[t]he scale on which … change [ ] occurs is largely unknown in the context of … exposure to the graphic[s]." *Experimental Study Report* at 1-2. Moreover, there is "much uncertainty about how [ ] shorter-term outcomes are related to the longer-term outcomes that are of most interest." *Id.* § 4.5. Significantly, the study "did <u>not</u> find strong evidence that the warning labels ... had much of an impact on [the] measure of cessation," based on the question "How likely do you think it is that you will try to quit in the next month." *Id.* § 4.4 (emphasis added). The same was true of the metric (used with youth) of how likely respondents felt they were to be smoking a year later. *Id.* As the

*Report* bluntly put it, the graphics "did not elicit strong responses in terms of intentions related to cessation or initiation." *Id.*

It is not enough for government to claim that such speech regulations "*may* increase quit attempts," "*may* induce [ ] smokers to reduce consumption," or "*may* reduce smoking rates." *Notice*, 75 Fed. Reg. at 69532 (emphases added). The FDA cannot satisfy its burden merely with speculation or conjecture, but must demonstrate its regulation will alleviate the targeted harms to a material degree. *E.g.*, *Greater New Orleans*, 527 U.S. at 188. Even courts noting the ongoing incidence of smoking may reflect in part the "addictive quality of nicotine" note as well that it "also reflects choices made in response to competing information." *23-34 94th St. Grocery*, *supra*, at *2. The fact that the government may not like these choices by some adult users of a legal product does not allow it to adopt regulations on commercial speech that cannot be shown to have any meaningful effect.

***The Graphic Images Bypass Alternatives Less Restrictive than Compelled Speech.*** Regulations on commercial speech are unlawful if they are "more extensive than is necessary to serve" the government's interests. *W. States*, 535 U.S. at 374 (*quoting Central Hudson,* 447 U.S. at 566). Accordingly, if the FDA can achieve its objectives without "restrict[ing] speech, or [by] restrict[ing] less speech, [it] *must* do so." *Id.* at 371 (emphasis added). The existence of "numerous and obvious less-burdensome alternatives" is certainly relevant "in determining whether the 'fit' between the ends and means is reasonable." *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993). In applying this rule, the Court does not require that less restrictive alternatives are in fact available or would work – it is sufficient if non-speech-related means "might be possible." *Id.* at 372.

Here, counter-advertising that does not usurp a product provider's own advertising and packaging would be at least as effective as requiring the graphic warnings the *Notice* proposes. The FDA, or any other arm of the federal government, remains free to communicate via property it owns or through other communication channels the messages it believes are conveyed by the graphic warnings – even using the "hole in throat," "toe tag," "cigarettes in toilet" or similar visuals, if so desired. *See*, *e.g.*, *Riley*, 487 U.S. at 800 (noting state could "itself publish the … disclosure[s] it require[d of] professional fundraisers"). Indeed, nothing prevents the government from purchasing ad space, even right alongside tobacco ads, or air time, to present the very graphics at issue.

Further, there are all sorts of other things the government can – and must – do rather than forcing tobacco companies to put large, disturbing graphics demonizing their own products in their own ads and on their own packaging. *Cf. PG&E*, 475 U.S. at 7, 15 n.12. In the *Commonwealth Brands* decision now on appeal, the district court listed several alternatives to regulating

tobacco marketing, including enforcing laws against tobacco purchases or use by minors. [8] Similarly, a 2008 report by HHS recommended "comprehensive" tobacco control programs that include "community programs to reduce tobacco use, chronic disease programs … , school programs, … counter-marketing, cessation programs, surveillance and evaluation, administration and management, and enforcement." [9]

The fact that comprehensive control programs such as those the *Synar Report* recommended have not been given fair opportunity to work makes requiring the graphic warnings more extensive than necessary. As the American Lung Association explains, there remains a "clearly articulate[d] need … to fully fund tobacco prevention and cessation programs, increase state cigarette taxes and pass comprehensive smokefree laws," [10] all of which are alternatives to regulating tobacco ads.

By the government's own admission, the effectiveness of comprehensive control programs as compared to regulating marketing – if ever tried in earnest – is undeniable. The Centers for Disease Control ("CDC") affirms that "the more states spend … the greater the reductions in smoking." [11] As CDC forcefully concluded: "We know what works, and if we were to fully implement the proven strategies, we could prevent the … toll that tobacco takes." *Id.* at 15. The First Amendment *requires* the government to take these non-speech-related steps before forcing companies to demonize their own product packaging and advertisements with disturbing, government-mandated visuals.

Finally, not only do the above alternatives illustrate that regulating tobacco purveyors' speech is more extensive than necessary, *Coors*, 514 U.S. at 490-91, the graphic warnings also "literally fail" narrow tailoring. *See Entm't Software*, 469 F.3d at 652. The Seventh Circuit held "18" labels on video games flunked this requirement because they "cover[ed] a substantial portion of the box," even though, all told, they occupied only about five percent of the total front and back panels. *Id.* Here, the Tobacco Control Act requires the graphic warnings proposed in the *Notice* to occupy the top 20 percent of ad space and the uppermost, most prominent,

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[8] 678 F.Supp.2d at 538. The initial district court ruling erroneously rejected such measures, accepting government arguments that it would not be "'less burdensome' to increase penalties on minors falling victim to 'the industry's advertising techniques' rather than directly curtailing those techniques." *Id.* at 538 (citation omitted). That holding now is on appeal, and the relevant constitutional inquiry is whether the government is seeking to impose undue burdens *on speech*, as the proposed graphics clearly do. *Greater New Orleans*, 527 U.S. at 192.

[9] *Synar Reports Youth Tobacco Sales*, at 7 (http://prevention.samhsa.gov/tobacco/synarreportfy2008.pdf).

[10] American Lung Association, *State of Tobacco Control 2008* at 5 (*available at* http://www.stateoftobaccocontrol.org/2008/ALA_SOTC_08.pdf).

[11] Centers for Disease Control and Prevention, *Best Practices for Comprehensive Tobacco Control Programs* (Oct. 2007) at 9 (*available at* http://www.cdc.gov/tobacco/tobacco_control_programs/stateandcommunity/best_practices/).

50 percent of packaging. This clearly fails the commercial speech doctrine's tailoring requirements.

***Conclusion***

The *Notice* proposes vivid and shocking anti-smoking graphics to accompany new textual warnings for cigarette ads and packages without any consideration of whether they pass constitutional muster. More significantly, requiring such pictorial "warnings" is entirely unprecedented. The proposed images confirm that the goal of Tobacco Control Act §§ 201-202 is not merely to require non-controversial disclosure to consumers of information of which they may be unaware. Rather, the new text and graphics requirements would convert product packages and marketing into platforms for the government's viewpoint. The FDA should not be in the business of making lawful products and advertising "difficult to look at." Even were that an appropriate objective, the First Amendment and the commercial speech doctrine preclude such a drastic approach.

Very truly yours,

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