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No. 11-5332

In the

United States Court of Appeals for the District of Columbia Circuit

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

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants-Appellants,

AMICI CURIAE BRIEF OF ASSOCIATION OF NATIONAL ADVERTISERS, INC. AND AMERICAN ADVERTISING FEDERATION IN SUPPORT OF APPELLEES, URGING AFFIRMANCE

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Case No. 11-1482 (Hon. Richard J. Leon)

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CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

All parties and *amici* appearing in this Court, rulings under review, and related cases are listed in the Brief for Plaintiffs-Appellees R.J. Reynolds Tobacco Co., *et al.*

STATUTES AND REGULATIONS

All applicable statutes, etc., are reproduced in the addendum to the Brief for Defendants-Appellants U.S. Food and Drug Administration, *et al.*

CORPORATE DISCLOSURE STATEMENT

Pursuant to Circuit Rule 29(b), Rules 26.1 and 29(c)(1) of the Federal Rules of Appellate Procedure, and Circuit Rule 26.1, undersigned counsel for *Amici Curiae* Association of National Advertisers, Inc. and American Advertising Federation (together, the "Advertising Associations") certify that, to the best of our knowledge and belief:

The Association of National Advertisers, Inc., is incorporated as a nonprofit trade association, has no parent corporation, and has no stock or other interest owned by a publicly held company.

The American Advertising Federation is a nonprofit trade association with no stock and no parent corporation.

Pursuant to Circuit Rule 26.1(b), the general nature and purpose of the Advertising Associations is that they are trade associations that serve their members by advocating clear and coherent legal standards governing advertising, and by opposing laws that violate established First Amendment protections for commercial speech, including by supporting and seeking to advance those rights in fora such as this Court.

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INTRODUCTION

Amici Association of National Advertisers, Inc. ("ANA") and American Advertising Federation ("AAF") (collectively, "Advertising Associations") hereby submit this brief in support of Appellees because of *amici*'s ongoing concern over the fundamental constitutional principles at stake. The challenged Food and Drug Administration ("FDA") rules require producers of tobacco products to carry "shocking and repelling" government-mandated images and textual warnings to proselytize the public. *R.J. Reynolds Tobacco Co. v. FDA*, ___ F. Supp. 2d ___, 2011 WL 5307391 at *1 n.1, *7 (D.D.C. Nov. 7, 2011). In granting a preliminary injunction, the District Court observed that "instead of focusing on its own alleged primary goal – providing information to consumers – … the Government's emphasis on the images' ability to provoke emotion, strongly suggests that [its] *actual* purpose is not to inform, but rather to advocate a change in consumer behavior." *Id.* at *7 (footnote omitted). Accordingly, it correctly held that plaintiffs had established a likelihood of success on the merits, finding the FDA's unprecedented rules confiscate plaintiffs' property for the purpose of skewing the marketplace of ideas.

As undersigned *amici* noted below, the required graphic warnings do not just fail to survive First Amendment scrutiny – attempting to control public discourse for fear people might otherwise make bad choices is not even a legitimate purpose. The government has numerous non-regulatory means at its disposal to persuade the public to change its ways, and the Supreme Court has held that the state may not regulate

private speech "in order to tilt public debate in a preferred direction." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671-72 (2011) (emphasis added). This principle applies regardless whether the subject of the regulation is a political idea or a product, because the First Amendment's general command is "the speaker and the audience, not the government, assess the value of the information." *Id.* (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

INTEREST OF *AMICI*[1]

The ANA leads the marketing community by providing insights, collaboration and advocacy on behalf of 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 representing the nation's leading brands and corporations. The Advertising Associations are dedicated to preserving our nation's commitment to the First Amendment and,

[1] This brief was not authored in whole or part by counsel for a party. No person or entity other than *amici curiae* or their counsel made a monetary contribution to preparation or submission of this brief. All parties consented to filing of this brief.

particularly, the commercial speech doctrine. *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

The Advertising Associations have participated as *amici* in litigation challenging certain of the marketing provisions of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (the "Tobacco Control Act") that violate core First Amendment principles,[2] and in this case argued that the FDA's Final Rule implementing Section 201 of that Act is unconstitutional. *See Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36628 (2011) (the "*Graphic Warnings Rule*").[3] *Amici* participated because the important issues at stake are not limited to tobacco. Rather, they affect a wide range of products and services about which some may believe the government knows "best," a concern the District Court also expressed in granting the preliminary injunction. *See R.J. Reynolds*, 2011 WL 5307391 at *7 & n.26, *10. *See also infra* § II. If the government can deputize tobacco companies through their product packaging and advertisements to deliver its message, there is no reason it could not do so elsewhere. Both history and "the logi-

[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), *appeal docketed sub nom.*, *Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir. Mar. 9, 2010); 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).

[3] *See* Brief of *Amici Curiae* ANA *et al.*, *R.J. Reynolds Tobacco Co. v. United States*, 2011 WL 530791 (No. 11-1482(RJL), filed Sept. 16, 2011); Brief of *Amici Curiae* ANA *et al.*, *R.J. Reynolds Tobacco Co. v. United States*, (D.D.C. Nov. 7, 2011) (No. 11-1482(RJL), filed Nov. 18, 2011).

cal extension" of the government's effort here show it will not hesitate to do so. *Id.* at *10.

BACKGROUND

The *Graphic Warnings Rule* implements one of the Tobacco Control Act's many restrictions and requirements that target advertising, marketing, and promotion. While the Act states it intends to "continue to permit the sale of tobacco [ ] to adults," one of its overarching goals is "to promote cessation" of use generally. *Compare* Pub. L. No. 111-31, § 3(7), *with id.* §§ 2(33)-(34), 3(9). Its principal tools to curtail tobacco use involve an assortment of broad restrictions on advertising and marketing. These include prohibitions on using color and images in most tobacco ads and displays; brand-name sponsorship by tobacco providers of athletic, musical, artistic, or other social or cultural events; distribution of cigarette samples, or even of branded non-tobacco promotional items; and joint marketing of tobacco and certain non-tobacco goods. *Id.* §§ 101(a)-(b), 102(a)(2).

The rules at issue here implement part of the Act that mandated changes to the content of warnings that must appear on cigarette packages and ads. The *Graphic Warnings Rule* requires tobacco companies to use disturbing, emotionally charged images and accompanying warnings on all cigarette ads and packaging as of October 22, 2012. 21 C.F.R. § 1141.10. These stark graphics include an image of a man smoking through what appears to be his tracheostomy opening to accompany the warning "cigarettes are addictive." 21 C.F.R. § 1141.12; http://www.fda.gov/

cigarettewarningfile. For "cigarettes cause fatal lung disease," the *Rule* requires a picture of traumatized lungs. *Id.* There is also "lesion on lip" for the "cigarettes cause cancer" warning, a crying "baby in incubator" for "smoking during pregnancy" and, for "smoking can kill you," a chest-stapled cadaver. *Id.* In addition to cigarette packs and cartons, the graphics must appear on all advertisements, including magazine and newspaper ads, pamphlets, leaflets, brochures, point-of-sale displays, posters, billboards, direct mailers, and online. *Required Warnings for Cigarette Packages and Advertisements*, 75 Fed. Reg. 69524, 69537 (2010) (the "*Graphic Warnings Notice*"). *See Graphic Warnings Rule*, 76 Fed. Reg. 36679, 36676-78; 21 C.F.R. § 1140.30.

ARGUMENT

This Court should affirm the grant of injunctive relief as plaintiffs are likely to succeed on their challenge that the regulations threaten freedom of expression.[4] The FDA's rules implementing the Tobacco Control Act's graphic warnings requirement 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 Broadcasting Ass'n v. United States*, 527 U.S. 173, 193 (1999), and that, when

[4] *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009); *People for the Ethical Treatment of Animals v. Gittens*, 215 F. Supp. 2d 120, 134 (D.D.C. 2002). By the time this appeal is argued, the District Court may well have permanently enjoined the rules. In that event, the same standard will apply, except the court will have found plaintiffs actually succeeded on the merits. *ACLU v. Mineta*, 319 F. Supp. 2d 69, 87 (D.D.C. 2004)

government seeks to further interests in the commercial arena, "regulating speech must be a last – not first – resort." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002). For present purposes, however, *amici* focus on one overriding flaw of the rules – the commandeering of space on commercial products and advertisements for the paternalistic purpose of controlling public debate and altering individual behavior. Such a purpose is foreign to the First Amendment. *See, e.g.*, *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 510, 516 (1986).

I. THE GRAPHIC WARNINGS RULE IS AN ILLEGITIMATE EFFORT TO DEPUTIZE PRODUCT PRODUCERS AND ADVERTISERS TO PROMOTE THE GOVERNMENT'S MESSAGE

A. The Rule is Unconstitutional Regardless of What Level of First Amendment Scrutiny Applies

The FDA's defense of its rule is predicated on the twin assumptions that the district court erroneously applied strict scrutiny and that the outcome would have been different if either intermediate or rational basis scrutiny applied because of the commercial speech context of this case. FDA Br. 24-25. Both suppositions are wrong. The government places far too much weight on the notion that the packaging and advertisements governed by the rule are "commercial" and far too little on the paternalistic nature of its mandate. The Supreme Court has made quite clear that a regulation's targeting of commercial speech does not necessarily determine the level of scrutiny. *44 Liquormart,* 517 U.S. at 501 ("The mere fact that messages propose commercial transactions does not in and of itself dictate the constitutional analysis

that should apply."). *See also City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416 n.11 (1993). Regardless of the level of scrutiny, a government regulation is invalid if its purpose conflicts with basic First Amendment commands.

This principle was reaffirmed most recently in *Sorrell*, a cased cited nowhere in the FDA's brief notwithstanding its direct application to this case.[5] The Supreme Court held it is "incompatible with the First Amendment" to censor or otherwise burden speech based on fear people will make bad decisions or to promote "'what the government perceives to be their own good.'" *Sorrell*, 131 S. Ct. at 2671 (quoting *44 Liquormart*, 517 U.S. at 503). Regardless whether expression is commercial or political, it is bedrock law that the government "may not burden the speech of others in order to tilt public debate." *Id.* at 2671. Any such attempt is subject to "heightened scrutiny," although the stricter standard is not necessarily outcome determinative. *Id.* at 2664. Thus, the Court in *Sorrell* was unmoved by state arguments that commercial speech regulation was necessary to promote public health, and found "the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied." *Id.* at 2667.

[5] As Judge Posner wrote recently, "pretending that potentially dispositive authority against a litigant's contention does not exist" is "pointless." *Gonzalez-Servin v. Ford Motor Co.*, 662 F.3d 931, 934 (7th Cir. 2011) (citations omitted) ("The ostrich is a noble animal, but not a proper model for an appellate advocate.").

B. A Speech Regulation Must Fail Where its Purpose is Illegitimate

Regulating speech and forcing companies to highlight the government's message in order to scare people into "improving" their behavior is antithetical to the First Amendment. The government has no legitimate role in seeking to "balance" the marketplace of ideas by regulating private speech, particularly where its purpose is "to diminish the effectiveness of marketing." *Sorrell*, 131 S. Ct. at 2663. This principle applies even where the government is convinced people may make health-related decisions based on "incomplete and biased information," as "fear that speech might persuade provides no lawful basis for quieting it." *Id.* at 2661, 2670.

Numerous Supreme Court rulings have rejected such a "highly paternalistic approach." *Linmark Assocs, Inc. v. Township of Willingboro*, 431 U.S. 85, 97 (1977). The Court has made clear the government lacks legitimate interests either in suppressing truthful commercial information or controlling debate about it "in order to prevent members of the public from making bad decisions." *Thompson*, 535 U.S. at 374 (citing *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976)). *See also Central Hudson Gas & Elec. Corp.*, 447 U.S. at 574-575 (Blackmun, J., concurring in judgment) (the Court has never recognized as legitimate "the State's interest in discouraging purchases of the underlying product that is advertised"). Indeed, the constitutional defect is "far more basic" where commercial speech regulation rests on belief people will act "irrationally" absent government intervention. *Linmark Assocs.*, 431 U.S. at 96-97.

The First Amendment "directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *44 Liquormart*, 517 U.S. at 503. As constitutional scholar Burt Neuborne put it:

> When society provides its members with lawful choices, respect for individual dignity compels that the choices be the autonomous expression of individual preference. It is impossible to respect individual autonomy with the left hand while selectively controlling the information available to the individual with the right hand. A purportedly free individual choice premised on a government controlled information flow is a basic affront to human dignity.[6]

Sorrell reaffirmed that the government lacks any interest in regulating speech "to reverse a disfavored trend in public opinion." 131 S. Ct. at 2671. It certainly may use its own resources to urge a different course of action, but it could not "ban campaigning with slogans, picketing with signs, or marching during the daytime" to achieve that result. *Id.* Likewise, it cannot "seek to remove a popular but disfavored product … by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers." *Id.*

Nor may the government require private parties to vilify their own products. The Supreme Court has expressly disallowed "forced association with potentially hostile views." *Pacific Gas & Elec. Co. v. Public Utils. Comm'n*, 475 U.S. 1, 18 (1986)

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[6] Burt Neuborne, *The First Amendment and Government Regulation of Capital Markets,* 55 BROOK. L. REV. 5, 37 (1989).

(plurality op.). Here, the Tobacco Control Act's restrictions are even worse, since they combine the *Graphics Warnings Rule*'s compelled message requirements with other severe speech restrictions. Congress simply has no authority "to license one side of a debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules." *RAV v. City of St. Paul*, 505 U.S. 377, 392 (1992).

The FDA's claim that existing health warnings have grown "stale" or that people pay insufficient attention to the textual statements does not legitimize the government's purpose. Its measure of success boils down to the notion that people would be better off if they could be persuaded to follow the government's health recommendations. Perhaps so. Such a purpose may call for a public education campaign or government-sponsored public service announcements, but it cannot justify broad restrictions on commercial speech or conscripting private speakers to deliver the government's message.

C. The Purpose of the *Graphic Warnings Rule* is to Change Behavior, Not to Inform

The District Court correctly held the *Graphics Warnings Rule*'s "*actual* purpose is not to inform, but rather to advocate [ ] change in consumer behavior." *R.J. Reynolds*, 20111 WL 5307391, at *7. The graphics for the new warnings are expressly designed to be propagandistic rather than informative – a purpose that is clear from the face of the Act, and from the *Graphic Warnings Rule* itself. It is to dissuade consumers from purchasing lawful products on which the warnings appear. The Act explicitly states

its "purposes" include promoting cessation.[7] It seeks to achieve that purpose largely by restricting tobacco companies' speech while simultaneously mandating carriage of the government's message.[8]

The FDA's protests notwithstanding,[9] there can be no serious doubt tobacco users already know smoking poses serious health risks. 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. *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 problem is not that people do not know smoking entails health risks; it is that too few – in the government's estimation – act on this knowledge.

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[7] *See supra* at 4 (quoting Pub. L. No. 111-31, § 3(9)). The Act rests on the assumption that "[c]omprehensive advertising restrictions will have a positive effect on the smoking rates of young people," *id.* § 2(22), (25), its marketing restrictions on the proposition that "advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use." *Id.* § 2(27).

[8] The FDA claims its goal is merely to educate or inform, *R.J. Reynolds*, 2011 WL 5307391, at *7, but the Supreme Court has found that review of statutory language, the regulations at issue, and statements by the regulators can reveal the true purpose is unconstitutional. *See Arizona Free Enterprise Club's Freedom Club PAC v. Bennett*, 131 S. Ct. 2806, 2825 & n.10 (2011); *Sorrell*, 131 S. Ct. at 2663, 2671-72.

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

The FDA openly embraced the purpose of persuading people to change their ways in adopting the *Graphic Warnings Rule*. It acknowledged the "primary goal" is to have graphic warnings appear on cigarette packages and advertisements "both to discourage nonsmokers … from initiating cigarette use and to encourage current smokers to consider cessation."[10] This, in turn, reflects a view that "health warnings that evoke strong emotional responses" ultimately are "reasonably likely" to foster "healthier behaviors, such as trying to quit smoking or deciding not to start." *Id.* at 36641. Similarly, in its rulemaking notice, the FDA observed that the *Rule* is intended to support smokers' intentions "to quit or decrease [] consumption, and to discourage nonsmokers, particularly youth, from initiating cigarette use." *Graphic Warnings Notice*, 75 Fed. Reg. at 69535.

In adopting the final rule, the FDA specifically measured whether the graphic warnings made respondents feel "depressed," "discouraged," or "afraid," and selected final images based on their ability to provoke strong emotional reactions. *Graphic Warnings Rule*, 76 Fed. Reg. at 36638. *See also R.J. Reynolds*, 2011 WL 5307391, at *7. Clearly, the focus of this effort was to choose shocking visual images, rather than finding warnings that could impart neutral factual information. The FDA had even

[10] *Graphic Warnings Rule*, 76 Fed. Reg. at 36634. *See also id.* at 36640 ("The purpose of graphic health warnings is to effectively communicate [] negative health consequences" with expectations that supposed "greater understanding" "will motivate some smokers to stop smoking and prevent some nonsmokers from starting[.]").

acknowledged that **such warnings differ from "disclosure requirements that apply to other products that FDA regulates," *which "have a different purpose*."** *Graphic Warnings Notice*, 75 Fed. Reg. at 69539 (emphasis added). Specifically, while medical products like drugs and devices, for example, "require that … labeling and advertising disclose all material risk information" to facilitate safe use, *id.* at 69539-40, the warnings here seek to "encourage cessation and discourage initiation." *Id.* at 69540. *See also R.J. Reynolds*, 2011 WL 5307391, at *7.

The FDA does not deny its purpose is to elicit "strong emotional and cognitive reactions to graphic warnings," but argues doing so more effectively and graphically communicates "scientifically established adverse health consequences of smoking." This, in turn, changes "attitudes and beliefs," and eventually can lead to "changes in intentions to quit or to start smoking and then later can lead to lower likelihood of smoking initiation and greater likelihood of successful cessation." *Graphic Warnings Rule*, 76 Fed. Reg. at 36641.

But this is beside the point. Reference to "scientifically established" evidence hardly means the rules' purpose is just to educate and inform. Virtually all arguments include some fact, but here, the clear purpose is to require tobacco companies to publish government *arguments* against smoking. FDA Commissioner Margaret Hamburg was quite clear about this when she stated the warnings will ensure "every single pack of cigarettes in our country will in effect become a mini-billboard" for the govern-

ment's anti-smoking message,[11] or, as the District Court called it, its "obvious anti-smoking agenda." *R.J. Reynolds*, 2011 WL 5307391, at *7. HHS Secretary Kathleen Sebelius likewise explained the rule will "rebrand[] cigarette packs." *Id.* *See also* White House Press Briefing (June 21, 2011) (www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser.).

Any claim these "mini-billboards" just present "facts" is absurd. First, this argument flatly contradicts the government's own rationale for banning color and graphics in cigarette marketing, which it said was necessary because young people "are particularly 'susceptible to peripheral cues such as color and imagery.'" Reply Br. for Defendants-Appellees/Cross Appellants, *Discount Tobacco City & Lottery, Inc. v. United States*, Nos. 10-5234 & 10-5235 (6th Cir.) at 8 (quoting 61 Fed. Reg. 44468). The government cannot argue in one breath the use of any color or imagery in marketing is an unfair persuasive technique, and in the next that a government mandate requiring lurid and frightening full-color images offer "just the facts, ma'am."

But one need not explore the illogic of these contradictory arguments to understand the *Graphic Warnings Rule*'s true purpose. The regulators freely admit their purpose is advocacy, not education. Secretary Sebelius bluntly acknowledged the FDA's intent when she announced the required labels:

[11] FDA, Tobacco *Strategy* Announcement (Nov. 10, 2010) (www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm).

> We want kids to understand smoking is gross, not cool, and there's really nothing pretty about having mouth cancer or making your baby sick if you smoke. So some of these are very driven to dispelling the notion that somehow this is cool and makes you cool. [12]

Commissioner Hamburg likewise stressed that those "who are under the impression that smoking is cool or glamorous will be confronted by a very different reality when they're tempted to pick up a cigarette pack" after the Rule's expected effective date. *Id.*

The intended message is clear: "If you smoke, you will become a gruesome pariah with Dickensian teeth who abuses children and dies early and alone." *The Smoky Horror Show*, THE ECONOMIST, June 21, 2011 (http://www.economist.com/blogs/schumpeter/2011/06/tobacco-regulation?page=2). "Such is the message conveyed by graphic new cigarette labels, unveiled by America's Food and Drug Administration," THE ECONOMIST noted, describing the warnings as "the latest attempt by a government to nauseate and petrify its citizenry." *Id.* The World Health Organization acknowledges that such images are designed to "elicit strong emotions, such as fear." *Id.* Clearly, the intent was to choose graphic warnings that are provocative, visually confrontational, and propagandistic, rather than to offer factual and neutral information.

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[12] Kathleen Sebelius, Sec'y of Health & Human Servs., Press Briefing by Press Secretary Jay Carney, Secretary of Health and Human Services Kathleen Sebelius, and FDA Commissioner Margaret Hamburg (June 21, 2011), http://thepage.time.com/2011/06/21/carney-briefs-36/ ("June 21 Press Briefing").

The FDA complains "[t]he court misunderstood both the concept of salience and FDA's analysis" in suggesting a governmental purpose to provoke negative emotional reactions indicates intent to stigmatize. FDA Br. 46-47. This critique drips with the paternalistic "government knows best" attitude that permeates the *Graphic Warnings Rule*. The purpose of the rules is not to *stigmatize* products, the FDA lectures; it is only to "*effectively convey*" health consequences of smoking, so long as "effectiveness" is measured by the extent to which consumers equate cigarettes with open sores, diseased lungs, and butchered cadavers. However, the District Court did not "misunderstand." It simply saw through the FDA's circular semantics. *R.J. Reynolds*, 20111 WL 5307391, at *7 & n.23.

D. The *Graphic Warnings Rule* Unconstitutionally Compels Speech

Not only is the purpose of the *Graphic Warnings Rule* constitutionally deficient, its mandate imposes excessive burdens on free expression, as the District Court correctly found. *R.J. Reynolds*, 2011 WL 5307391, at *5-*8. Compelling tobacco companies to display government-prescribed graphic images and accompanying warnings violates the First Amendment, which secures "both the right to speak [ ] and … to refrain from speaking at all." *Id.* at *5 (quoting *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)). Except for purely factual and non-controversial disclosures, the government may not compel private entities to publish messages selected or dictated by the government. *Id.* at 715. This is because, where regulations "[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). The Supreme Court has noted 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 & Institutional Rights, Inc.*, 547 U.S. 47, 61 (2006). This is as true for "corporations as for individuals," *Pacific Gas & Elec. Co.*, 475 U.S. at 16, and that includes tobacco companies as much as any other advertiser or company. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001).

The *Graphic Warnings Rule*'s lurid images 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, to protect consumers from "confusion or deception." *R.J. Reynolds*, 2011 WL 5307391, at *5 (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985)). *See also*, *e.g.*, *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 131-34 (2d Cir. 2009); *National 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. *E.g.*, *Pacific Gas & Elec. Co.*, 475 U.S. at 15; *Wooley*, 430 U.S. at 714.

Compelling tobacco companies to devote half their cigarette packages and 20 percent of advertising space to governmentally prescribed warnings "both penalizes the expression of particular points of view and forces speakers to alter their speech to conform with an agenda they do not set." *Pacific Gas & Elec. Co.*, 475 U.S. at 9. Such requirements are particularly offensive constitutionally where they require speakers to foster views contrary to their interests. Notwithstanding *Zauderer*, no Supreme Court decision suggests the government may require corporate messages that are "biased against or [ ] expressly contrary to the corporation's views." *Id.* at 16 n.12. Moreover, the Court has expressly rejected that compelling such expression furthers the constitutional goal of providing "more speech," because "the State cannot advance some points of view by burdening the expression of others."[13]

Indeed, as the District Court observed, sometimes "the line between the constitutionally permissible dissemination of factual information and the impermissible expropriation of … advertising space for Government advocacy can be frustratingly blurry." *R.J. Reynolds*, 2011 WL 5307391, at *5. But "the evidence here overwhelmingly suggests that the Rule's graphic-image requirements are *not* the type of purely factual and uncontroversial disclosures" contemplated in *Zauderer*. *Id.* The District Court went on to find "it is abundantly clear from viewing these images that

[13] *Id.* at 20. The Supreme Court has stressed that the fact that a product "poses some threat to public health or public morals" does not justify regulation "by the simple expedient of placing the 'vice' label on selected lawful activities." *44 Liquormart*, 517 U.S. at 514.

the emotional response they were crafted to induce is calculated to provoke the viewer to quit, or never to start, smoking: an objective wholly apart from disseminating purely factual and uncontroversial information." *Id.* (footnote omitted). And, as the court noted, it did not help that the government "repeatedly failed to answer this Court's question … about when the dissemination of purely factual, uncontroversial information crosses the line into advocacy." *Id.* at *5 n.19. The government continues to argue the warnings are purely informational, yet still fails to attempt to explain where this line lies, or how it is drawn.

Even if that line could be located, requiring warnings with purely factual and uncontroversial information may violate the First Amendment if they are "unjustified or unduly burdensome." *Id.* at *5. The decision in *Entertainment Software Association v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), well illustrates this point. In *Blagojevich*, 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 the 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" and an innocuous (hypothetical) shellfish warning could not stand if it was merely too big, it is

impossible to see how the writ-large, lurid imagery the FDA has adopted survives constitutional scrutiny.

The government argued to the District Court that tobacco companies have little reason to complain because "half of cigarette packs, ... and 80% of advertisements remain available for their speech," Def.'s Sum. J. Mot. at 20 (quoting *Commonwealth Brands*, 678 F. Supp. 2d at 531). This is reminiscent of the Beatle's song *Taxman*: "Should five percent appear too small, be thankful I don't take it all." And it is no defense in a First Amendment case for the government to argue that it refrained from taking over all of the tobacco companies' modes of communication. The "distinction between laws burdening and laws banning speech is but a matter of degree." *Sorrell*, 131 S. Ct. at 2664 (quoting *United States v. Playboy Entm't Group, Inc.*, 529 U.S. 803, 812 (2000)).

The graphics proposed here far exceed current, eminently noticeable textual warnings, which also are proposed to become more prominent and emphatic. Or, as the District Court put it in granting the preliminary injunction, "the sheer size and display requirements for the graphic images are anything but narrowly tailored." *R.J. Reynolds*, 2011 WL 5307391, at *7. Together, purposefully disturbing imagery combined with large text warnings will turn cigarette packs into "mobile billboards" for the government's "ideological messages" about smoking. *Wooley*, 430 U.S. at 715. *Cf.*, Hamburg Tobacco Strategy Announcement, *supra* note 11 (new warnings are "mini-billboards"). The graphics are *intended* to be "controversial," draw attention,

and repel consumers from buying a legal product. The 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 "ha[ve] not been controversial for many decades."[14]

Ultimately, the FDA relies on the claim that "there is no more efficient method of reaching smokers than through the use of graphic and highly visible warning labels." Def.'s Sum. J. Mot. at 23 (citation omitted). But this runs headlong into the constitutional command, recently reaffirmed by the Supreme Court, that "the First Amendment does not permit the State to sacrifice speech for efficiency." *Arizona Free Enterprise*, 131 S. Ct. at 2824 (quoting *Riley*, 487 U.S. at 795). Accordingly, the *Graphic Warnings Rule* is unconstitutional and the District Court ruling should be affirmed.

II. THE CONSTITUTIONAL ISSUES AT STAKE TRANSCEND FREE EXPRESSION REGARDING TOBACCO PRODUCTS

Amici Advertising Associations are very concerned because the First Amendment principles involved in this case extend far beyond the rights of tobacco companies. If the government prevails with the novel argument that companies may be compelled to devote space on their packaging and ads for government-mandated messages of this type, no product is safe from such regulation. As the District Court

[14] *Commonwealth Brands*, 678 F. Supp. 2d at 531-32. The court in *Commonwealth Brands* reached its conclusion without seeing the images, as the FDA had yet to unveil them. *R.J. Reynolds*, 2011 WL 5307391 at *5 n.17. Images like "hole in throat," "crying baby in incubator," "lesion on lip," and cadaver with chest staples can hardly be called purely "informational" or "uncontroversial." *Id.*

noted, "[o]ne can only wonder what the Congress and the FDA might conjure for fast food packages and alcohol containers if … they were not compelled to comply with … First Amendment jurisprudence." *R.J. Reynolds*, 2011 WL 5307391, at *7 n.26.

The risk is confirmed by the argument in this case by *amicus* Defending Animal Rights Today & Tomorrow ("DARTT"), which is participating, it explained, because it "has embarked on a campaign to require sellers of fur-bearing products to attach a graphic label depicting a skinned animal," and it "is concerned that the trial court's ruling … will render unconstitutional any legislation or regulation which would require such a label." Brief of *Amicus Curiae* Defending Animal Rights Today & Tomorrow in Support of Neither Party at viii. Once such paternalistic notions gain a legal foothold, demands to apply similar requirements will soon follow – as history well shows.

The government operates numerous product-related programs designed to educate consumers and that otherwise make the government a participant in the marketplace of ideas. For example, the Surgeon General promotes breastfeeding by encouraging hospitals to refuse advertisements for infant formulas.[15] The Environmental Protection Agency promotes "Energy Star" guidelines to advocate energy efficiency.[16] Congress has authorized a media campaign designed to reduce

[15] The Surgeon General's Call to Promote Breastfeeding (2011) at 43 (www.surgeongeneral.gov/topics/breastfeeding/calltoactiontosupportbreastfeeding.pdf).

[16] *See* U.S. Environmental Protection Agency (www.energystar.gov).

underage drinking.[17] The Department of Agriculture issues nutritional guidelines.[18] Such programs do not raise constitutional concerns insofar as they are solely informational and do not attempt to use express or implied governmental force to skew the marketplace of ideas. But it is important to recognize the inherent temptation in such programs to use government authority to get members of the public to make "correct" decisions. If this Court were to uphold the FDA's constitutional authority to convert products into platforms for government messages, there is no doubt the practice would spread to other products beyond tobacco.[19]

In this regard, the FCC's experience in applying its now-defunct Fairness Doctrine to tobacco products provides a cautionary tale. In the late 1960s, the Commission interpreted its rule to require broadcasters to air counter-advertising for

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[17] *See* Sober Truth on Preventing Underage Drinking Act, 42 U.S.C. § 290bb-25b, 120 Stat. 2890, Pub. L. No. 109-422 (2006).

[18] *See* U.S. Department of Agriculture (www.choosemyplate.gov).

[19] In implementing the Interagency Working Group on Food Marketed to Children, authorized by the Omnibus Appropriations Act of 2009, H.R. 1105, 111th Cong. (2009), the Federal Trade Commission, FDA, Centers for Disease Control, and U.S. Department of Agriculture proposed "voluntary guidelines" to control marketing food to children or adolescents. *See* Interagency Working Group on Food Marketed to Children: Preliminary Proposed Nutrition Principles to Guide Industry Self-Regulatory Efforts – Request for Comments (2011). However, even where such efforts are characterized as "voluntary," they often are backed by the threat of regulation. *See*, *e.g.*, White House Task Force on Childhood Obesity Report to the President, *Solving the Problem of Childhood Obesity Within a Generation* at 32 (May 2010) ("If voluntary efforts to limit the marketing of less healthy foods and beverages to children do not yield substantial results, the FCC could consider revisiting and modernizing rules on commercial time during children's programming.").

cigarette product advertising on the theory that such advertising was needed to provide the public with a "balanced" presentation of views on a controversial issue. *WCBS-TV*, 8 F.C.C.2d 381, *stay and recon. denied*, 9 F.C.C.2d 921 (1967). At the time, the Commission expressly rejected as a "parade of horribles" claims that "if governmental and private reports on the possible hazard of a product are a sufficient basis" for counter-advertising, "the ruling would apply to a host of other products, such as: automobiles, food with high cholesterol count, alcoholic beverages, fluoride in toothpaste, pesticide residue in food, aspirin, detergents, candy, gum, soft drinks, girdles, and even common table salt." *WCBS-TV*, 9 F.C.C.2d at 942-43.

Despite the FCC's confidence in its ability to cabin cigarettes as "a unique situation and product,"[20] it soon was overrun by calls for mandatory counter-advertising in a wide variety of situations. Demands for time arose from retail store advertising during a labor dispute, automobile advertisements, gasoline advertising, institutional advertising praising commercial television, advertisements advocating oil exploration, institutional advertisements for a power company, army recruiting, advertisements for snowmobiles, and even dog food advertisements.[21]

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[20] *Amendment of Part 73 of the Federal Communications Commission Rules With Regard to the Advertisement of Cigarettes*, 16 F.C.C.2d 284, 292 (1969).

[21] *Public Interest Research Group v. FCC*, 522 F.2d 1060 (1st Cir. 1975) (snowmobiles); *Neckritz v. FCC*, 502 F.2d 411 (D.C. Cir. 1974) (gasoline); *Friends of Earth v. FCC*, 449 F.2d 1164 (D.C. Cir. 1971) (high powered automobiles and high-test gasoline); *Green v. FCC*, 447 F.2d 323 (D.C. Cir. 1971) (military service); *Retail Store Employee's Union, Local 880 Retail Clerks Int'l Ass'n v. FCC*, 436 F.2d 248 (D.C. Cir.

While the FCC rejected some demands for counter-advertising (army recruiting, gasoline additives, snowmobiles, etc.), it accepted others (oil exploration, utility rates, retail advertising). In one case where the FCC did not mandate responsive ads, the Court of Appeals did, rejecting the Commission's claims that cigarettes were a "unique" product or that the agency could "plausibly differentiate the case presently before us." *Friends of Earth*, 449 F.2d at 1170 (advertisements for high-powered cars).

Ultimately, the FCC was forced to admit it had been a "great mistake" to require counter-advertising and the agency expressly declined to do so in the future. *Fairness Report*, 48 F.C.C.2d 1, 26 (1974). In particular, the Commission found the policy had become "particularly troublesome" because it could not be limited to cigarette advertising as originally promised. *Id.* at 25. The D.C. Circuit agreed the agency had "great difficulties" fashioning a coherent policy regarding counter-advertisements and found "if anything, [the FCC] understated the problem." *National Citizens Comm. for Broad. v. FCC*, 567 F.2d 1095, 1100 (D.C. Cir. 1977). Eventually, the Commission abandoned the Fairness Doctrine altogether after concluding it was inconsistent with First Amendment principles. *Complaint of Syracuse Peace Council*, 2 FCC Rcd. 5043 (1987), *aff'd*, *Syracuse Peace Council v. FCC*, 867 F.2d 654 (D.C. Cir.

1970) (ads for department store picketed by union); *Complaint by Media Access Project*, 44 F.C.C.2d 755 (1973) (ads by power company about need for rate increases, expansion, etc.); *Complaint by Mrs. Fran Lee*, 37 F.C.C.2d 647 (1972) (dog food and pet products); *Complaint by Anthony R. Martin-Trigona*, 19 F.C.C.2d 620 (1969) (ads about broadcast network and the free television industry).

1989). As often is the case, however, these legacy regulations lingered on the FCC's books long after their demise, and only very recently were deleted. *Amendment of Parts 1, 73 and 76 of the Commission's Rules*, 26 FCC Rcd. 11422 (MMB 2011).

It is rare that federal agencies voluntarily relinquish grants of authority, and it is highly doubtful any such thing would occur here. If this Court were to approve the FDA's extraordinary rule, it certainly would become the model for the next effort to regulate commercial speech to ensure consumers make the "right" choices. As the District Court noted, "when one considers the logical extension of the Government's defense of its compelled graphic images to possible graphic labels that the Congress and the FDA might wish to someday impose on various food packages (*i.e.,* fast food and snack food items) and alcoholic beverage containers (from beer cans to champagne bottles)," the constitutional implications are clear. *R.J. Reynolds*, 2011 WL 5307391, at *10. The propriety of the district court's entry of preliminary injunctive relief is likewise clear.

CONCLUSION

The FDA's *Graphic Warning Rule* represents an unjustified incursion into First Amendment protections for commercial speech. The FDA plays down free expression concerns by pointing out that the specific graphics are like those required by Canada and other nations like the United Kingdom and Australia, and basing arguments on those countries' experience with such warnings. *E.g.*, FDA Br. 11-12, 14-15, 18, 30-32, 44-45. Such assurance is cold comfort, since none of those

countries enjoys the same level of speech protection as our First Amendment provides. *E.g.*, *R.J. Reynolds*, 2011 WL 5307391, at *7 nn.21, 26. This Court should not allow the dilution of American freedoms by reference to the regulatory regimes of foreign governments. As the District Court noted in granting the preliminary injunction: "while the Congress and the FDA might be genuinely challenged to craft tailored images that pass constitutional muster, that does not excuse them from striving to do so in the first instance," especially as "First Amendment jurisprudence in this area of compelled commercial speech should have *compelled* them to at least try." *R.J. Reynolds*, 2011 WL 5307391, at *8 n.28.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)(5)-(7)

This brief complies with the type-volume limitation of Circuit Rule 32(a)(2)(A) because it contains 6,796 words, excluding the parts of the brief exempted by Circuit Rule 32(a)(1), as determined by the word-counting feature of Microsoft Word.

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to D.C. Circuit Rule 25(c), service of the foregoing will be made electronically via CM/ECF system upon the following this 4th day of April, 2012:

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