

**R.J. REYNOLDS TOBACCO COMPANY, LORILLARD
TOBACCO COMPANY, COMMONWEALTH BRANDS, INC.,
LIGGETT GROUP LLC, and SANTA FE NATURAL TOBACCO
COMPANY, INC. v. UNITED STATES FOOD AND DRUG
ADMINISTRATION**

2012 U.S. Dist. LEXIS 26257 (D.D.C. Feb. 29, 2012)

RICHARD J. LEON, United States District Judge.

MEMORANDUM OPINION

Plaintiffs in this case ("plaintiffs") are five tobacco companies, which include the second-, third-, and fourth-largest tobacco manufacturers and the fifth-largest cigarette manufacturer in the United States. In June 2011, defendant United States Food and Drug Administration ("FDA") published a Final Rule requiring (among other things) the display of nine new textual warnings--along with certain graphic images¹ such as diseased lungs and a cadaver bearing chest staples on an autopsy table--on the top 50% of the front and back panels of every cigarette package manufactured and distributed in the United States on or after September 22, 2012. Alleging that the Rule violates the First Amendment, plaintiffs moved for a preliminary injunction on August 19, 2011, enjoining the enforcement of the Rule until fifteen months after resolution of plaintiffs' claims on the merits. As such, plaintiffs raised for the first time in our Circuit the question of whether the FDA's new and mandatory graphic images, when combined with certain textual warnings on cigarette packaging, are unconstitutional under the First Amendment. The Court granted plaintiffs' motion on November 7, 2011. *See R.J. Reynolds Tobacco Co. v. FDA*, No. 11-1482, 2011 U.S. Dist. LEXIS 128372, 2011 WL 5307391, at *1, n.1 (D.D.C. Nov. 7, 2011). Since then both parties have moved for summary judgment. Upon review of the pleadings, oral argument, the entire record, and the applicable law, the Court concludes that these mandatory graphic images violate the First Amendment by unconstitutionally compelling speech. For that and the other reasons stated herein, the Court GRANTS plaintiffs' Motion for Summary Judgment and DENIES the Cross-Motion for Summary Judgment.

BACKGROUND

I. Statutory and Regulatory History

A. The Act

The Family Smoking Prevention and Tobacco Control Act ("Act" or "the Act"), which President Obama signed into law on June 22, 2009, gives the FDA the authority to regulate the

¹ As I previously stated in my Memorandum Opinion granting plaintiffs' Motion for Preliminary Injunction, although the FDA conveniently refers to these graphic images as "graphic warnings," characterizing these graphic images as "warnings" is inaccurate and unfair as they are more about shocking and repelling than warning. Indeed, as discussed fully in Section II.A, these images are not used to warn but rather to deter individuals from purchasing the package. Accordingly, I will refer to them simply as graphic images.

manufacture and sale of tobacco products, including cigarettes. Pursuant to that authority, Congress directed the Secretary of the U.S. Department of Health and Human Services ("the Secretary") to "issue regulations that require color graphics depicting the negative health consequences of smoking." In addition, Congress required all cigarette packages manufactured, packaged, sold, distributed, or imported for sale or distribution within the United States to bear one of the following nine textual warnings:

"WARNING: Cigarettes are addictive.

WARNING: Tobacco smoke can harm your children.

WARNING: Cigarettes cause fatal lung disease.

WARNING: Cigarettes cause cancer.

WARNING: Cigarettes cause strokes and heart disease.

WARNING: Smoking during pregnancy can harm your baby.

WARNING: Smoking can kill you.

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

WARNING: Quitting smoking now greatly reduces serious risks to your health."

Congress required that these new textual warnings and graphic images occupy the top 50% of the front and back panels of all cigarette packages, and the top 20% of all printed cigarette advertising. It gave the FDA "24 months after the date of enactment" of the Act to issue regulations implementing the requirements of Section 201. Finally, the new textual warnings and graphic-image labels were scheduled to take effect 15 months after issuance of the Rule.

B. The Rule

1. Proposed Rule

On November 12, 2010, the FDA submitted for public comment a Proposed Rule unveiling 36 graphic color images that could be displayed with the 9 new textual warnings created by Congress. In addition, the Proposed Rule required cigarette packaging and advertising to include "a reference to a smoking cessation assistance resource" and set forth related requirements for what that resource must provide. Finally, as part of its preliminary benefits analysis, the FDA estimated that "the U.S. smoking rate will decrease by **0.212** percentage points" as a result of the Proposed Rule, a statistic the FDA admits is "in general not statistically distinguishable from zero."

2. Final Rule

After a period of notice and comment in which the FDA reviewed more than 1,700 comments, it published a Final Rule on June 22, 2011. Of the 36 graphic images originally proposed, the FDA chose 9 for publication. The new graphic images, which will rotate according to an agency-approved plan, include color images of a man exhaling cigarette smoke through a tracheotomy hole in his throat; a plume of cigarette smoke enveloping an infant receiving a kiss from his or her mother; a pair of diseased lungs next to a pair of healthy lungs; a diseased mouth

afflicted with what appears to be cancerous lesions; a man breathing into an oxygen mask; a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso; a woman weeping uncontrollably; and a man wearing a t-shirt that features a "no smoking" symbol and the words "I QUIT." An additional graphic image appears to be a stylized cartoon of a premature baby in an incubator. Plaintiffs allege that many of these images are technologically manipulated,² enhanced, or animated, or that they depict actors to achieve the desired image. And indeed, the FDA cited these nine images' "salience"--defined as a warning's ability to evoke emotion--as a primary selection criterion.³

In addition to being paired with one of the nine new textual warnings introduced by Congress, each of the graphic images prominently displays "1-800-QUIT-NOW": a telephone number the FDA selected to fulfill its own regulatory obligation to offer smoking cessation assistance on each package. Based on the 15-month implementation period set out by Congress, the new textual warnings and graphic images are scheduled to take effect for all cigarette packages manufactured on or after September 22, 2012, and for all cigarette packages introduced into commerce on or after October 22, 2012. In response to the Final Rule, plaintiffs filed a Motion for Preliminary Injunction, which this Court granted on November 7, 2011. Plaintiffs also filed a Motion for Summary Judgment and Permanent Injunction on August 19, 2011; defendants filed a Cross-Motion for Summary Judgment on October 21, 2011; and oral argument was held on February 1, 2012.

ANALYSIS

I. Standard of Review

Summary judgment is appropriate when the movant demonstrates that there is no genuine issue of material fact in dispute and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party bears the burden, and the court will draw "all justifiable inferences" in the favor of the non-moving party. Nevertheless, the non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Factual assertions in

² The FDA does not dispute that "some of the photographs were technologically modified to depict the negative health consequences of smoking," although it insists that "the effects shown in the photographs are, in fact, accurate depictions of the effects of sickness and disease caused by smoking."

³ The Rule reads, in pertinent part: "First, many of the proposed required warnings *elicited significant impacts on the salience measures (emotional and cognitive measures)*, which the research literature suggests are likely to be related to behavior change. For example, the literature suggests that risk information is most readily communicated by messages that *arouse emotional reactions*, and that smokers who report greater negative emotional reactions in response to cigarette warnings are significantly more likely to have read and thought about the warnings and more likely to reduce the amount they smoke and to quit or make an attempt to quit. The research literature also suggests that warnings that generate an *immediate emotional response* from viewers can result in viewers attaching a negative affect [sic] to smoking (i.e., feel bad about smoking), thus undermining the appeal and attractiveness of smoking."

the moving party's affidavits may be accepted as true unless the opposing party submits its own affidavits, declarations, or documentary evidence to the contrary.

II. First Amendment Claim

Plaintiffs oppose the placement of the Government-mandated warnings on the top 50% of the front and back portions of their cigarette packaging.⁴ In particular, plaintiffs argue that the new Rule unconstitutionally compels speech, *see Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573-74 (1995); *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), and that such speech does not fit within the "commercial speech" exception under which certain types of Government-mandated, informational disclosures are evaluated under a less restrictive standard, *see Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985). As a result, they argue, the Government's conduct must be analyzed under the strict scrutiny standard.⁵ I agree.

A. Applicable Level of Scrutiny

A fundamental tenant of constitutional jurisprudence is that 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. A speaker typically "has the autonomy to choose the content of his own message." *Hurley*, 515 U.S. at 573. And, in fact, "[f]or corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U.S. 1, 16 (1986) (plurality opinion). As plaintiffs so aptly stated, although "the Government may engage in [] advocacy using its own voice[,] . . . it may not force others, such as Plaintiffs, to serve as its unwilling mouthpiece." *See Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2671 (2011) ("The State can express [its] views through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction."). Thus, where a statute "'mandates speech that a speaker would not otherwise make,' that statute 'necessarily alters the content of the speech.'" *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 651 (7th Cir. 2006) (quoting *Riley v. National Federation of Blind, Inc.*, 487 U.S. 781, 795 (1988)). As the Supreme Court itself has noted, this type of compelled speech is "presumptively unconstitutional." *Rosenberger v. Rector & Visitors of the Univ. of Va.*, 515 U.S. 819, 830 (1995).

In the arena of compelled commercial speech, however, narrow exceptions do exist and allow the Government to require certain disclosures to protect consumers from "confusion or deception." *Zauderer*, 471 U.S. at 651. Indeed, courts apply a lesser standard of scrutiny to this

⁴ Plaintiffs do not challenge the substance of the nine new textual messages Congress created by statute.

⁵ The parties continue to disagree fundamentally on the applicable level of scrutiny. While plaintiffs advocate for an application of strict scrutiny, they also argue that the Rule *fails* under any constitutional standard. And as defendants contend that the Rule is subject to no more than intermediate scrutiny, *see Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 573 (1980), they also continue to insist that the Rule *withstands* any level of scrutiny.

narrow category of compelled speech through which the Government may require disclosure only of "purely factual and uncontroversial information." Even under this paradigm, however, compelled disclosures containing "purely factual and uncontroversial information" may still violate the First Amendment if they are "unjustified or unduly burdensome." Unfortunately for the defendants, the images here neither meet the *Zauderer* standard, nor are narrowly tailored to avoid an undue burden to the plaintiffs' speech. How so?

First, after reviewing the evidence here it is clear that the Rule's graphic-image requirements are *not* the type of purely factual and uncontroversial disclosures that are reviewable under this less stringent standard.⁶ To the contrary, the graphic images here were neither designed to protect the consumer from confusion or deception, nor to increase consumer awareness of smoking risks; rather, they were crafted to evoke a strong emotional response calculated to provoke the viewer to quit or never start smoking. Indeed, a report by the Institute of Medicine--an authority chiefly relied upon by the Government--very frankly acknowledges this very purpose. According to the IOM Report, "[i]t is time to state unequivocally that the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products, especially by children and youths, as a means of reducing tobacco-related death and disease." Further, "[e]ven though tobacco products are legally available to adults, the paramount health aim is to reduce the number of people who use and become addicted to these products, through a focus on children and youths," and, therefore, the "warnings must be designed to promote this objective."

Not surprisingly the use of the graphic images accomplishes just that: an objective wholly apart from disseminating purely factual and uncontroversial information. That Dr. David Hammond--a researcher upon whom the Government relies--recommended that the graphic warnings should "elicit negative emotional reactions" to convince smokers to quit undercuts any argument that the images are purely factual. Indeed, the FDA measured the efficacy of the graphic images by their "salience," which the FDA defines in large part as a viewer's emotional reaction.

Further, the graphic images are neither factual nor accurate. For example, the image of the body on an autopsy table suggests that smoking leads to autopsies; but the Government provides no support to show that autopsies are a common consequence of smoking. Indeed, it makes no attempt to do so. Instead, it contends that the image *symbolizes* that "smoking kills 443,000 Americans each year." The image, however, does not provide that factual information. Similarly, the image of a man exhaling cigarette smoke through a tracheotomy hole in his throat is not being used to show a usual consequence of smoking. Instead, it is used to *symbolize* "the addictive nature of smoking"--a fact that is not accurately conveyed by the image. Put simply, the Government fails to convey any factual information supported by evidence about the actual health consequences of smoking through its use of these graphic images.

The images, coupled with the placement of the toll free number, do not "promote informed

⁶ As this Court previously stated, "the fact *alone* that some of the graphic images here appear to be cartoons, and others appear to be digitally enhanced or manipulated, would seem to contravene the very definition of 'purely factual.'"

choice" but instead advocate to consumers that they should "QUIT NOW." A telling example is the image depicting a man wearing a t-shirt that features a "no smoking" symbol and the words "I QUIT" next to the "1-800-QUIT-NOW" phone number. This image contains no factual information, and even the Government concedes this image "encourag[es] cessation." Likewise, the Secretary and the Commissioner of the FDA ("the Commissioner") have acknowledged that the graphic images convey an anti-smoking message--specifically, the images were designed to: convey that "smoking is gross"; help "encourage smokers to quit"; "rebrand[] our cigarette packs"; and "dispel[] the notion that somehow [tobacco use] is cool." Thus, while the line between the constitutionally permissible dissemination of factual information and the impermissible expropriation of a company's advertising space for Government advocacy can be frustratingly blurry, here the line seems quite clear.

Rather than fit the *Zauderer* paradigm, "the disclosures mandated in this case are much more similar in form and function to those at issue in *Blagojevich*, 469 F.3d at 643, 652." There, the Seventh Circuit refused to apply the *Zauderer* standard of scrutiny to a state law that required video game retailers to affix a four-square-inch sticker with the number "18" (representing age 18) on any game deemed "sexually explicit" under the statute. "Just as the Seventh Circuit recognized that a compelled video-game label based on what the state deemed to be 'sexually explicit' was 'far more opinion-based than the question of whether a particular chemical is within any given product,' so too are the graphic images promulgated as part of the FDA's rule a more subjective vision of the horrors of tobacco addiction." Indeed, like the stickers in *Blagojevich*, the graphic images "ultimately communicat[] a subjective and highly controversial message." The Rule, therefore, does not fit into the *Zauderer* exception for purely factual and uncontroversial information. *See Pac. Gas & Elec.*, 475 U.S. at 15 n.12 ("Nothing in *Zauderer* suggests . . . that the State is equally free to require corporations to carry the message of third parties, where the messages themselves are biased against or are expressly contrary to the corporation's views."). Thus, these images must withstand the strict scrutiny analysis the Supreme Court imposes on Government regulations which compel commercial speech.

B. Analysis Under Strict Scrutiny

To withstand strict scrutiny, the Government carries the burden of demonstrating that the FDA's Rule is narrowly tailored to achieve a compelling government interest. Unfortunately for the Government, it fails to satisfy this burden.

First, although the Government contends that it has a compelling interest--"conveying to consumers generally, and adolescents in particular, the devastating consequences of smoking and nicotine addiction"--its "stated purpose does not seem to comport with the thrust of its arguments, or with the evidence it offers to support the Rule." To the contrary, it is clear that the Government's *actual* purpose is not to inform or educate, but rather to advocate a change in behavior--specifically to encourage smoking cessation and to discourage potential new smokers from starting. The Government's reliance on the graphic images--which were chosen based on their ability to provoke emotion, a criterion that does not address whether the graphic images affect consumers' knowledge of smoking risks--coupled with the toll free number, further supports the conclusion that the Government's actual purpose is to convince consumers that they

should "QUIT NOW."⁷ Indeed, at oral argument, the Government effectively conceded this purpose when it acknowledged: "Now, it's no secret that the Government wants people to stop smoking." Although an interest in informing or educating the public about the dangers of smoking *might* be compelling, an interest in simply advocating that the public not purchase a legal product is not.⁸ However, even if the Government's interest is in fact "compelling," the Rule is clearly not narrowly tailored to achieve the Government's purpose. How so?

As I noted previously, "the sheer size and display requirements for the graphic images are anything but narrowly tailored." Under the Rule, plaintiffs are forced to act as the Government's mouthpiece by dedicating the top 50% of the front and back of all cigarette packages manufactured and distributed in the United States to display the Government's anti-smoking message: *not* to purchase this product. These dimensions *alone* clearly demonstrate "that the Rule was designed to achieve the very objective articulated by the Secretary of Health and Human Services: to 'rebrand[] our cigarette packs,' treating (as the FDA Commissioner announced last year) 'every single pack of cigarettes in our country' as a 'mini-billboard.' A 'mini-billboard,' indeed, for its obvious anti-smoking agenda!" The FDA's contention that neither it nor this Court has the authority to second-guess Congress, even if the congressional mandate violates the First Amendment, is an oh-too-convenient dodge. As the parties have conceded, there is no evidence that Congress even considered the First Amendment implications when drafting the Act. To say the least, implementing a Final Rule consistent with a congressional mandate does not require a Court to hold that the Rule automatically passes constitutional muster. Congress must pass laws, and the FDA must implement final rules, that are consistent with the requirements of the Constitution. Thus, just as the four-square-inch sticker "*literally* fail[ed] to be narrowly tailored" because it "cover[ed] a substantial portion of the box," in *Blagojevich*, so too must these graphic images fail to meet the narrowly tailored requirement the Government must demonstrate.

⁷ The Government's interest in advocating a message cannot and does not outweigh plaintiffs' First Amendment right to not be the Government's messenger. *See Wooley v. Maynard*, 430 U.S. 705, 717 (1977) ("[W]here the State's interest is to disseminate an ideology, no matter how acceptable to some, such interest cannot outweigh an individual's First Amendment right to avoid becoming the courier for such message."). This Court is acutely aware of the health risks of smoking. And although the Government may want to convince consumers to stop smoking to protect their health, plaintiffs are correct in stating that their industry should not "serve as the government's unwilling spokesman in that paternalistic endeavor."

⁸ Even assuming that the interest is compelling, the Rule does not achieve or further this interest. "Consumers are overwhelmingly aware of the risks of smoking and indeed overestimate those risks, which is why the introduction of graphic warnings does not move the needle either in terms of behavior or in terms of knowledge of the risks that the warnings address." Indeed, the Rule itself makes clear that the warnings may cause smoking rates in the United States to decrease by 0.088%--a rate which is "not statistically distinguishable from zero." The Government "therefore cannot reject, in a statistical sense, the possibility that the rule will not change the U.S. smoking rate."

Finally, with respect to the content of the graphic images, it is curious to note that plaintiffs have offered several alternatives that are easily less restrictive and burdensome for plaintiffs, yet would still allow the Government to educate the public on the health risks of smoking without unconstitutionally compelling speech. First, the Government could disseminate its anti-smoking message itself, for example, by increasing its anti-smoking advertisements or issuing additional statements in the press urging consumers to quit smoking or both. Although doing so might impose costs on the Government, "[c]itizens may not be compelled to forgo their [First Amendment] rights because officials . . . desire to save money." *Palmer v. Thompson*, 403 U.S. 217, 226 (1971). Of course, by now it is clear that the Government's actual concern is not the potential for added cost as the FDA recently announced that it will be spending \$600 million on a new--presumably believed to be effective--anti-smoking multimedia campaign. Second, the Government could change the display requirements. Specifically, the Government could reduce the space appropriated for the proposed "warnings" to 20% of the packaging or require "warnings" only on the front or back of the packaging. Third, the Government could change the content by selecting graphics that conveyed only purely factual and uncontroversial information rather than gruesome images designed to disgust the consumer. Fourth, the Government could increase cigarette taxes. And lastly, the Government could improve efforts to prevent the unlawful sale of cigarettes to minors. Any one of these suggestions would be less restrictive than the Rule's current requirements. Unfortunately, because Congress did not consider the First Amendment implications of this legislation, it did not concern itself with how the regulations could be narrowly tailored to avoid unintentionally compelling commercial speech.

Therefore, because the Government has failed to carry both its burden of demonstrating a compelling interest and its burden of demonstrating that the Rule is narrowly tailored to achieve a constitutionally permissible form of compelled commercial speech, the Rule violates the First Amendment and plaintiffs' Motion for Summary Judgment must be, and is, GRANTED.

CONCLUSION

For all the foregoing reasons, plaintiffs' Motion for Summary Judgment is GRANTED, and defendants' Cross-Motion for Summary Judgment is DENIED. An order consistent with this decision is attached herewith.

ORDER

ORDERED that the FDA is permanently enjoined, until 15 months following the issuance of new regulations implementing Section 201(a) of the Tobacco Control Act that are substantively and procedurally valid and permissible under the United States Constitution and federal law, from enforcing against Plaintiffs in this action the new textual and graphic warnings required by Section 201(a) of the Tobacco Control Act.