

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

R.J. REYNOLDS TOBACCO)
COMPANY, et al.,)
)
Plaintiffs,)
)
v.)
)
UNITED STATES FOOD AND)
DRUG ADMINISTRATION, et al.,)
)
Defendants.)

No. 1:11-cv-1482 (RJL)

**DEFENDANTS’ SUPPLEMENTAL BRIEF IN SUPPORT OF THEIR
OPPOSITION TO PLAINTIFFS’ MOTION FOR A PRELIMINARY INJUNCTION**

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The Court's questions at the preliminary injunction hearing focused on plaintiffs' contentions regarding the use of images in conjunction with text in the warnings required by Congress, and this brief responds to the issues discussed in the colloquies with counsel.

Plaintiffs do not contest the accuracy of the text of the warnings required by the Tobacco Control Act or question Congress's authority to require their inclusion in cigarette packaging and advertising. Nor do they dispute that Congress mandated that the text be complemented by images of the type already required in Canada and other countries.

Plaintiffs argue that inclusion of images transforms the warnings into "compelled speech" subject to strict scrutiny. Their contentions are without anchor in First Amendment doctrine, and fundamentally misapprehend the way in which images reinforce the accompanying text. As shown below, a host of studies and extensive scientific literature establish that viewers read, recall, and process text information more often and more effectively when the text is combined with an associated image. Plaintiffs complain that visual images evoke an emotional response. But they do not contend that the images are inaccurate or convey a different message than the text. If the images inspire concern or even anxiety about the consequences of smoking, they do so only because the images, in combination with the text, convey accurate information about the consequences of consuming plaintiffs' highly addictive product, which "kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134–35 (2000) (quoting 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996)).

A. 1. At several points in the preamble to the final rule, FDA addressed contentions that images provoke emotions rather than convey information. The agency noted, for example, that commenters had criticized various images as "disturbing" or "eliciting emotions," including the image "depicting a man smoking through a tracheostomy opening," the image "depicting healthy

lungs juxtaposed with lungs damaged by smoking,” the image “depicting a lesion consistent with that caused by oral cancer,” and the image “depicting a man with an autopsy scar.” 76 Fed. Reg. 36,628, 36,696 (June 22, 2011).

As FDA noted, “[t]he comment did not assert, however, that the effects shown in the images are false, *i.e.*, that they are not manifestations of negative health consequences of smoking, such as throat, lung, and oral cancer, and death.” *Ibid.* The agency emphasized: “The fact that the images are disturbing or evoke emotion does not mean that they are not factual representations of the effects of smoking. . . . As such, it is not surprising that the warnings regarding the negative health consequences of smoking would evoke emotions such as fear of being stricken with life-threatening cancer or disgust at what it might be like to have that happen.” *Ibid.*

FDA repeatedly explained that consideration of the emotional response of viewers is germane because it predicts the likelihood that viewers will notice and process the information contained in the text. The agency noted that “[t]he overall body of scientific evidence indicates that health warnings that evoke strong emotional responses enhance an individual’s ability to process the warning information, leading to increased knowledge and thoughts about the harms of cigarettes and the extent to which the individual could personally experience a smoking-related disease.” *Id.* at 36,641. The images selected “were designed to correlate with [the] warning statements,” and the “available evidence base highlights the value of the text and images in graphic health warnings relating to one another in a meaningful way.” *Id.* at 36,637 (citations omitted).

2. The evidence before Congress and the FDA amply demonstrated that the message of the text is conveyed more effectively when combined with an accompanying image. One study showed that while “‘83 percent of Canadian students mentioned health warnings in a recall test of cigarette packages,’ only ‘7 percent of U.S. students’ did the same.” *Commonwealth Brands, Inc. v. U.S.*, 678

F. Supp. 2d 512, 531 (W.D. Ky. 2010) (citation omitted). In another study, when “U.S. college students were shown images of the Canadian cigarette warnings and the current warnings appearing on cigarette packs sold in the United States . . . the Canadian graphic warnings significantly increased aided recall of the warnings, increased depth of message processing, and increased the perceived strength of the message.” 75 Fed. Reg. 69,524, 69,531 (Nov. 12, 2010) (citation omitted). These findings are consistent with focus group research in which young adults in the United States “reported that the Canadian warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States.” 75 Fed. Reg. at 69,531 (citation omitted).

Recent research confirms that warnings combining images and text are more effective in conveying the risks identified in the text. For instance, from 1995 to 2005, Australia required cigarette manufacturers to display large, text-only warnings covering the top 25% of the front of the pack. David Hammond *et al.*, *Effectiveness of Cigarette Warning Labels in Informing Smokers about the Risks of Smoking*, 15 *Tobacco Control* iii19, iii20 (2005). After Australia introduced pictorial warnings in 2006, a longitudinal study of youth “found that students were more likely to read, attend to, think about, and talk about health warnings after the pictorial warnings were implemented.” David Hammond, *Health Warnings Messages On Tobacco Products: A Review*, 20 *Tobacco Control* 327, 330 (2011) (discussing 2008 study); *see also* Karine Gallopel-Morvan *et al.*, *The Use of Visual Warnings in Social Marketing: The Case of Tobacco*, 64 *J. Business Research* 7, 7 (2011) (study comparing the EU’s large text-only warnings to its new pictorial warnings concluded that the results “clearly demonstrate[] that visual messages, as opposed to text warnings, are more

effective”). Research also “suggests that larger pictorial warnings sustain their effects longer,” as compared to their text-only counterparts. *See* Hammond, 20 Tobacco Control at 333.¹

3. These results should not be surprising. It is axiomatic in cognitive psychology that “pictures are easier to remember than words.” S. David Leonard *et al.*, *Comprehension and Memory*, in WARNINGS AND RISK COMMUNICATION 148 (Michael S. Wogalter *et al.*, eds. 1999). The brain has distinct coding systems for words and for images, and information in the “image” memory system is more likely to be retained and is more easily retrieved. This is particularly the case for words “representing abstract concepts.” *Ibid.* Information that is coded in both systems is particularly easy to remember “because theoretically more ‘paths’ are created in memory, making the information more accessible (more likely to be cued) at later times.” *Ibid.* Thus, even apart from tobacco-specific research, studies have “found that pictorials in combination with conspicuous print facilitated recollection of warning contents,” and that “the enhanced memory was directly related to the fact that the warning was noticed in the first place.” Wendy A. Rogers *et al.*, *Warning Research: An Integrative Perspective*, 42 Human Factors 102, 114 (Spring 2000); *see also, e.g.*, Steven Young & Michael Wogalter, *Comprehension and Memory of Instruction Manual Warnings: Conspicuous*

¹ After reviewing a broad range of scientific evidence regarding the effect of health-warning messages on tobacco products, including the benefits of adding graphics to already large text-only warnings, Dr. Hammond concluded that, as compared to text-only warnings, “pictorial warnings are more likely to be noticed and read by smokers, are associated with stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking.” Hammond, 20 Tobacco Control at 330. Plaintiffs nevertheless cite the same publication to insist that Dr. Hammond believes that pictorial warnings are ineffective. *See* Pl. Reply Br. 11 n.12; Hearing Tr. at 73, 76–77. In the passage quoted by plaintiffs, Dr. Hammond notes the difficulties inherent in determining the extent to which pictorial warnings accounted for the documented decline in Canadian smoking rates following their introduction, noting that the decline may also have been influenced by other public health measures. *See id.* at 331. As we explain in our Opposition (at 23–24), the critical question in assessing the warnings is their effectiveness in conveying health risk information, not the extent to which the warnings are shown to decrease smoking rates.

Print and Pictorial Icons, 32 Human Factors 637, 646 (1990) (comparing the relative effectiveness of instruction-manual warnings with and without pictorials, and finding that “warnings that have both conspicuous print and illustrative pictorial icons enhance comprehension and memory of the warnings’ message content”).

4. Conveying information in cigarette warnings poses special difficulties that make the use of images particularly appropriate. First, although the health consequences of smoking are severe, they generally do not become manifest for many years. Because of that time lag, smokers—and adolescents in particular—tend to disregard or discount discomforting factual information about the consequences of using plaintiffs’ product. See Paul Slovic, *Cigarette Smokers: Rational Actors or Rational Fools?*, in *SMOKING: RISK, PERCEPTION, & POLICY* 97, 109–10 (Paul Slovic ed., 2001); *U.S. v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 936 (D.D.C. 2006) (“[T]he general public, and youth in particular, significantly underestimate the risks of beginning and continuing to smoke.”), *aff’d in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S. Ct. 3501 (2010).

Second, plaintiffs’ current customers comprise a market of addicts who are particularly prone to discount or ignore text-only content. Plaintiffs’ own expert in *Commonwealth Brands* emphasized the tenacity of the addiction to nicotine, the “substance in tobacco that inveterate smokers crave.” Rodu Decl. ¶ 40 (R. 72-1, No. 1:09-cv-117 (W.D. Ky)). The consequences of that addiction, Dr. Rodu stressed, are deadly: he acknowledged that if people stopped smoking, “there would be over 400,000 fewer tobacco-related deaths in America each year.” *Id.* ¶ 5.

Third, new consumers, who are not already addicted, are primarily children and adolescents. Congress found that the “overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18.” Legislative Finding 31. Congress also found that “[a]dvertising,

marketing, and promotion of tobacco products have been especially directed to attract young persons,” Legislative Finding 15, who “are particularly vulnerable to cigarette marketing because they are not capable of making a fully informed decision whether to start or continue smoking for a variety of reasons, including the fact that they underestimate personal risks and lack the judgment which can only be developed through experience.” *Philip Morris*, 449 F. Supp. 2d at 578. Studies have long since established that children and adolescents acquire information far more readily when text is accompanied by illustrations. Summarizing the results of over 50 studies, one study explained that “[i]llustrations can help learners understand what they read, can help learners remember what they read, and can perform a variety of other instructional functions.” See W. Howard Levie & Richard Lentz, *Effects of Text Illustrations: A Review of Research*, 30 *Educ. Comm. & Tech. J.* 195, 226 (1982).

Smoking rates are also closely correlated with education levels. FDA noted that “49.1 percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree,” and “that graphic health warnings may be particularly important communication tools for these smokers, as there is evidence suggesting that countries with graphic health warnings demonstrate fewer disparities in health knowledge across educational levels.” 76 *Fed. Reg.* at 36,630 (citations omitted); see also *Commonwealth Brands*, 678 F. Supp. 2d at 531 (“[G]raphical warnings ‘may be particularly important for communicating’ with consumers with low levels of education, given evidence that such smokers ‘are less likely to recall health information in text-based messages than people with more education.’”) (citation omitted).

B. 1. The health warnings mandated by Congress pass muster under any level of scrutiny. The relevant legal standard, as discussed in our opposition, is the “less exacting scrutiny” accorded

to warnings and disclosures of accurate information in the commercial context. *Milavetz, Gallop & Milavetz, P.A. v. U.S.*, 130 S. Ct. 1324, 1339–40 (2010); *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). The health warnings also satisfy the intermediate scrutiny standards applicable to commercial speech, *see Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980), and, if it were thought to apply, strict scrutiny. The government has a compelling interest in effectively conveying the health risks of smoking, and the evidence before Congress showed that plaintiffs’ proposed alternatives are ineffective. Plaintiffs assert that Congress should have omitted images altogether and confined the text to the format “in which the Surgeon General’s warnings have been displayed for years.” Comment Letter at 3-4. But nations throughout the world have recognized that text-only warnings do not effectively communicate health risks, even when they are far more prominent than plaintiffs assert is permissible. And text warnings in the current format are not merely ineffective but, the evidence before Congress showed, virtually invisible. *See* Opp. to P.I. Mot. 16–18.

2. Plaintiffs’ invocation of the compelled speech doctrine is, in any event, altogether implausible. They maintain that “the proposed warnings convey to smokers the Government’s view that they should change in a significant way how they lead their lives,” and argue that “[t]he viewpoint the Government proposes to be conveyed on the manufacturers’ packaging and advertising is thus every bit as ideological as the message at issue in *Wooley v. Maynard*, 430 U.S. 705 (1977): ‘Live Free or Die.’” Comment Letter at 2. They declare that, “[i]n effect, the message and viewpoint of FDA’s proposed graphic warnings is: ‘Live Smoke-Free or Die.’” *Ibid.*

Accurate information about the very real, very significant health risks of plaintiffs’ products does not constitute an “ideological message.” As Dr. Rodu emphasized in his *Commonwealth Brands* declaration, it is uncontested that persons seeking to avoid the deadly consequences of

smoking should not consume cigarettes. Rodu Decl., *supra*, ¶ 40; *see also Nat'l Citizens Comm. for Broad. v. FCC*, 567 F.2d 1095, 1100 n.13 (D.C. Cir. 1977) (citing with approval *Larus & Brother Co. v. FCC*, 447 F.2d 876, 880 (4th Cir. 1971), which upheld the FCC's determination that the broadcast of "anti-smoking messages" did not trigger an obligation under the fairness doctrine to broadcast views advocating smoking "because the issue is no longer a matter of public controversy").

Plaintiffs not only publicly recognize the risks associated with their product but further declare that, in light of those undisputed risks, consumers should not begin to smoke or should cease smoking. Santa Fe Natural Tobacco Company offers this message to nonsmokers: "[W]e cannot stress this enough: If you don't smoke, don't start." <http://www.sfntc.com>. Elsewhere on the site the company asserts: "We never encourage non-smokers to start, or existing smokers to smoke more." <http://www.sfntc.com/Quit-Smoking/Overview.aspx>. The website provides links to twenty cessation resources and wishes smokers "the best of luck" in trying to quit. *Ibid.* Lorillard's website states that "[t]he only way to avoid the health effects of cigarette smoking is to not smoke. The best way to reduce the health effects of cigarette smoking is to quit, and quitting smoking greatly reduces serious risks to health." <http://www.lorillard.com/?s=quit+smoking>. And in a recent submission to FDA, Reynolds acknowledged that "it is indisputable that quitting is the only safe alternative to using any tobacco product." R.J. Reynolds, Citizen Petition 4, Docket No. FDA-2011-P-0573 (Jul. 8, 2011); *see also* R.J. Reynolds, *Guiding Principles and Beliefs*, available at www.rjrt.com/prinbeliefs.aspx ("The best course of action for tobacco users concerned about their health is to quit.").

No parallel exists between this case and *Wooley v. Maynard*, in which the Supreme Court held that motorists could not be required to display the motto "Live Free or Die" on their license plates. 430 U.S. at 715–17. As the Court explained in *Zauderer*, the *Wooley* decision reflects the

fundamental principle that the government may not “prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.” *Zauderer*, 471 U.S. at 651 (citation and internal quotation marks omitted). In contrast, “[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [the seller’s] constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.” *Ibid.*

Decisions of the courts of appeals likewise cast no doubt on the validity of the warnings at issue here. Cases cited by plaintiffs distinguish between uncontroversial factual disclosures (which are reviewed under the relaxed standard of *Zauderer*) and “subjective” or “opinion-based” disclosures. In *Entertainment Software Ass’n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), for example, the Seventh Circuit invalidated a law that required video game manufacturers to place a warning label on games deemed to be “sexually explicit.” *Id.* at 651–52. The label was to be applied only to games “that the average person, applying contemporary community standards would find, with respect to minors, is designed to appeal or pander to the prurient interest.” *Id.* at 643. That definition incorporated “widely divergent local standards” of offensiveness, *id.* at 650, making it “subjective and highly controversial” and therefore subject to strict scrutiny, *id.* at 652.

The Seventh Circuit, *id.* at 651–52, distinguished these subjective warnings from the Vermont statute sustained by the Second Circuit in *National Electrical Manufacturers Ass’n v. Sorrell*, 272 F.3d 104, 107 (2d Cir. 2001), which required manufacturers to label products containing mercury and to inform consumers that these products should be recycled or disposed of as hazardous waste. The Second Circuit noted that “the compelled disclosure at issue . . . was not intended to prevent ‘consumer confusion or deception’ per se, but rather to better inform consumers about the

products they purchase.” *Id.* at 115. The Second Circuit stressed that requiring “commercial actors [to] disclose commercial information ordinarily does not offend the important utilitarian and individual liberty interests that lie at the heart of the First Amendment,” and that it is sufficient to establish “a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose.” *Id.* at 114–15 (citing *Zauderer*, 471 U.S. at 651).

Pacific Gas & Electric Co. v. Public Utilities Commission, 475 U.S. 1 (1986), which plaintiffs invoked at the hearing, *see* Tr. 33–34, underscores plaintiffs’ misunderstanding of the compelled speech precedent. PG&E included in its monthly billing envelope a newsletter featuring items including political editorials. 475 U.S. at 5. In order to “offer the public a greater variety of views” on these subjects, California required PG&E to include the speech of a third party that frequently opposed PG&E in ratemaking proceedings. *Id.* at 12. The Supreme Court held that the speech at issue was *not* commercial speech, noting that the PG&E newsletter “extends well beyond speech that proposes a business transaction.” *Id.* at 8–9. The Court concluded that the case was on all fours with *Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241, 244–45 (1974), which invalidated a Florida law requiring newspapers to give political candidates an opportunity to reply to any article impugning the candidate’s character or record. *See* 475 U.S. at 9–12.

The warnings at issue here bear no resemblance to the regulations in the cases plaintiffs cite. Rather than an ideological message, the warnings convey accurate factual information about a product that is deadly and addictive when used as intended by the manufacturers.

