

the images would have been acceptable without the cessation hotline number.

Second, must the warnings correct misleading impressions

Whatever the answers to these questions, companies today are better able to promote their products, and government is less able to promote health than was the

be able to afford their medicines. Today, by contrast, courts are using the First Amendment to the detriment of consumers' welfare, by invalidating laws that would protect the public health.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

***Whereas the Court once gave the government more leeway when invoking its interests in public health than when asserting other state interests, it now tends to hold health-related rules to the same constitutional standards as other types of rules.***

from the company's cigarette packaging or current advertisements, or may they also correct misimpressions from past promotional materials?

Third, if courts will not defer to the judgment of public health authorities about the need for disclosure mandates, what kind of empirical evidence must the FDA present in order to justify the use of graphic warnings?

case in the past. Ironically, early protection of commercial speech rested in large part on the need to serve consumers' welfare. In 1976, for example, the Supreme Court struck down a Virginia law that prevented pharmacists from advertising their prices for prescription drugs.<sup>5</sup> The law especially hurt persons of limited means, who were not able to shop around and therefore might not

From the Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law, and the Indiana University School of Medicine — both in Indianapolis.

This article was published on June 26, 2013, at NEJM.org.

1. Orentlicher D. The commercial speech doctrine in health regulation: the clash between the public interest in a robust First Amendment and the public interest in effective protection from harm. *Am J Law Med* 2011;37:299-314.
2. Sorrell v. IMS Health, Inc., 131 S. Ct. 2653 (2011).
3. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012).
4. Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012).
5. Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

DOI: 10.1056/NEJMp1304513

Copyright © 2013 Massachusetts Medical Society.

## The FDA and Graphic Cigarette-Pack Warnings — Thwarted by the Courts

Ronald Bayer, Ph.D., David Johns, B.A., and James Colgrove, Ph.D.

On August 24, 2012, in *R.J. Reynolds Tobacco Company v. Food and Drug Administration*, the U.S. Court of Appeals for the District of Columbia ruled that the regulations proposed by the Food and Drug Administration (FDA) mandating the inclusion of graphic warnings on cigarette packs (see photo) violated the First Amendment: they would compel companies to express antitobacco messages on their own dime. Seven months later,

on March 14, 2013, the Department of Justice announced that the government would not appeal that decision to the Supreme Court.

In explaining the decision not to defend the regulations, which had been developed pursuant to congressional mandate under the 2009 Family Smoking Prevention and Tobacco Control Act, Attorney General Eric Holder stated that the FDA would “undertake research to support a new rulemak-

ing consistent with the Tobacco Control Act.” If new graphic warnings that emerged from the process were also deemed unconstitutional, “there will be an opportunity to seek full Supreme Court review at that time.”<sup>1</sup> Howard Koh, Assistant Secretary for Health, described the setback in cautious language: “Although we pushed forcefully for graphic health warning labels to appear on cigarette packages, the D.C. Circuit’s ruling against the warn-



Graphic Warning Label.

ing labels won't deter the FDA from seeking an effective and sound way to implement the law." News headlines stressed the administration's retreat, noting that the FDA had "scrapped" or "abandoned" or was "forced to ditch" the vivid images.

The decision not to appeal makes clear that efforts to limit commercial speech in the United States today face strong constitutional and political constraints. The courts are increasingly willing to accord constitutional rights to corporations and have been particularly unwilling to limit forms of commercial speech.

Tobacco-control advocates had a remarkably restrained response to the administration's decision. Matthew Myers, president of the Campaign for Tobacco Free Kids, expressed "disappointment" but welcomed the FDA's commitment to developing "new warnings that comply both with legal rulings and the 2009 law." The president of the American Cancer Society Cancer Action Network urged the FDA "to work expedi-

tiously" to develop new graphic warnings. Neither the American Lung Association nor the American Public Health Association, both strong proponents of the FDA proposal, issued any formal comment.

By contrast, when the appeals court struck down the warnings last August, the Cancer Action Network had said, "We are deeply disappointed with today's [ruling, which is] a victory for Big Tobacco in its effort to obstruct and delay the implementation of the new graphic warning labels." The Campaign for Tobacco Free Kids declared the ruling "wrong on the science and law." The American Heart Association said the judges had "thrown out one of the best tools we have" for reducing smoking. All these groups implored the government to move swiftly to appeal to the Supreme Court. And 22 state attorneys general filed an amicus brief supporting the warning labels and defending the emotional response they were designed to evoke: "The impact about which the tobacco companies complain is nothing other than an appropriate response to the appalling — but uncontroversially accurate — facts about the health effects and addictiveness of cigarettes."

What happened between August and March that accounts for the differing responses? Attorneys and antitobacco advocates describe the Justice Department move as strategic — necessitated by a careful analysis of the appeals court decision and the Supreme Court's posture on commercial speech. Some feared that the Court would use the opportunity of an appeal to reach beyond the graphic warnings the

FDA had proposed — or to articulate even more exacting standards for reviewing commercial speech cases, hobbling future public health initiatives. Rather than risk such defeat, advocates concluded that the FDA should rethink the nature of the warnings and marshal more convincing evidence of their effectiveness.

Interestingly, the Justice Department decision opened an opportunity for advocates to express concern about how the FDA had grounded its case. That effort had occurred by congressional mandate under a tight time frame. Some advocates now express publicly, if guardedly, criticisms that might have subverted the goal of confronting the tobacco industry when the case was ongoing. After all, the appeals court had asserted that the FDA had used "questionable social science" to make the case for "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." The FDA had cited its own statistical modeling showing that adopting the warnings could reduce smoking rates by only 0.088% — which the court had characterized as not "a shred of evidence" that the rule would directly advance the government's interest in reducing smoking. Stanton Glantz, a tobacco-control researcher at the University of California, San Francisco, and fierce opponent of the tobacco industry, agreed that the FDA had failed to present a compelling case because it relied on a "poorly done" cost-benefit analysis that "grossly understated the benefits and overstated the costs of the warning labels." Glantz said the agency needed to "move beyond" its models and "pay attention to behavioral sci-

Peer Countries Requiring Graphic Warnings on Cigarette Packs and Year of Implementation.*	
Country	Year
Canada	2001
Australia	2006
Belgium	2006
New Zealand	2008
United Kingdom	2008
Switzerland	2010
Norway	2011
France	2011
Spain	2011
Denmark	2012
Iceland	2013
Ireland	2013

\* Data are from the Canadian Cancer Society, October 2012 ([http://global.tobaccofreekids.org/files/pdfs/en/WL\\_status\\_report\\_en.pdf](http://global.tobaccofreekids.org/files/pdfs/en/WL_status_report_en.pdf)).

entists who actually understand the determinants of smoking behavior.<sup>22</sup>

Published studies show that graphic warnings evoke the desired emotional and cognitive responses. But the evidence is less definitive on the question of whether they reduce smoking prevalence. A 2011 systematic review of studies in Canada, the United States, Australia, and the

promote cessation behavior and that larger pictorial warnings are most effective in doing so.”<sup>3</sup> A 2013 Canadian report asserted that graphic warnings had a significant effect on smoking prevalence but called for further research.<sup>4</sup>

As the FDA crafts new graphic warning labels that might pass constitutional muster, whatever behavioral evidence it can produce will play a crucial role. A recent *New York Times* editorial called on the FDA to “move quickly to find court-acceptable graphic images” and to “develop stronger evidence that graphic images will reduce the number of new or current smokers.”<sup>5</sup> But “court-acceptable” images that are also effective may be impossible to create. The appeals court rejected the use of cartoons that evoke emotion, while demanding proof of behavioral effects that may depend on the evocation of powerful feelings.

It is unclear whether the FDA can produce sufficient evidence to convince a skeptical Supreme Court. Concerns that the Supreme Court might use this occasion to deem the Tobacco Control Act unconstitutional, however, have

ducting new research will take time in the face of the chill surrounding public health interventions that intrude on commercial speech. At best, it will be 2 to 3 years before new graphic warning labels will appear on U.S. cigarette packages. This costly setback for public health may well be measured in morbidity and mortality.

The World Health Organization’s 2008 Framework Convention on Tobacco Control endorsed graphic warning messages as part of a broad public health campaign. By 2011, 40 countries, including 12 peer nations (see table), had required such labeling. Increasingly, the United States stands alone, because of a constitutional doctrine privileging commercial speech above public health.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Center for the History and Ethics of Public Health, Mailman School of Public Health, Columbia University, New York.

This article was published on June 26, 2013, at NEJM.org.

1. Holder E Jr. Letter to the Honorable John Boehner, Re: R.J. Reynolds v. Food & Drug Administration, No. 11-5332 (D.C. Cir.). March 15, 2013 (<http://www.mainjustice.com/files/2013/03/Ltr-to-Speaker-re-Reynolds-v-FDA.pdf>).
2. Glantz S. The FDA made the right decision not to appeal the current warning labels. 2013 (<http://tobacco.ucsf.edu/fda-made-right-decision-not-appeal-current-warning-labels>).
3. Hammond D. Health warning messages on tobacco products: a review. *Tob Control* 2011;20:327-37.
4. Azagba S, Sharaf MF. The effect of graphic cigarette warning labels on smoking behavior: evidence from the Canadian experience. *Nicotine Tob Res* 2013;15:708-17.
5. Wins and losses in the fight against tobacco. *New York Times*. April 28, 2013.

DOI: 10.1056/NEJMp1306205

Copyright © 2013 Massachusetts Medical Society.

***As the FDA crafts new graphic warning labels that might pass constitutional muster, whatever behavioral evidence it can produce will play a crucial role.***

United Kingdom concluded that “while it is not possible to precisely quantify the impact of health warnings on smoking prevalence or behavior,” the evidence “suggests that health warnings can

been dispelled: on April 22, 2013, the Court declined to review a decision by the 6th Circuit Court of Appeals holding the law constitutional.

Creating new graphics and con-