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David Orentlicher

University of Nevada, Las Vegas -- William S. Boyd School of Law

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The FDA's Graphic Tobacco Warnings and the First Amendment

David Orentlicher, M.D., J.D.

In the past, constitutional principle gave the government broad authority to regulate tobacco or pharmaceutical advertising. The state's power to safeguard the public health was strong, and companies' freedom to plug their products was weak.

But the Supreme Court has changed course. Whereas it once did not view "commercial" speech as the kind of speech the First Amendment protects, it now gives businesses nearly the same rights to market their goods as it does individuals to speak their minds. And as the Court has broadened corporate freedom to advertise, it has narrowed governmental power to preserve the public's health. 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.¹

As a result, government today is much more susceptible to challenge when it tries to regulate the promotional activities of the tobacco or pharmaceutical industry. In 2011, the Supreme Court rejected Vermont's effort to restrict the use of prescription data by drug companies' sales representatives.² And last year, the U.S.

Court of Appeals for the D.C. Circuit vetoed the new graphic warnings for cigarette packages that had been issued by the Food and Drug Administration (FDA).³ The Supreme Court's increasing sympathy for corporate speech and decreasing deference to public health authorities makes it more difficult for government to protect the public's health. The fate of the graphic cigarette warnings is illustrative.

Congress authorized the graphic warnings when it passed the Family Smoking Prevention and Tobacco Control Act in 2009. The Act requires the use of nine new textual warnings for cigarette packages and directs the Department of Health and Human Services to select color graphics to accompany the warnings. The images have to depict the "negative health consequences" of smoking, with text and graphic taking up the top halves of each pack's front and back panels.

In June 2011, the FDA unveiled the nine images, including some that were quite explicit. One image showed a man smoking through a tracheostomy (see image). Another showed the corpse of a man with staples in his chest on an autopsy table. Several tobacco companies promptly sued, alleging that the graphic-

warning requirements violated their First Amendment rights. The companies prevailed in both the district court and the D.C. Circuit.

In one sense, the result was not surprising, given the Supreme Court's increased sympathy toward corporations and their First Amendment rights. Regulations of commercial speech often succumb to judicial scrutiny.

However, there was good reason to think that the D.C. Circuit would uphold the graphic warnings. Even as the Supreme Court has narrowed the power of government to regulate corporate speech, it has preserved an important authority to regulate. The graphic warnings seemed to fall within that authority.

The preserved authority reflects the distinction the Supreme Court makes between the regulation of corporate speech that informs and the regulation of corporate speech that misinforms. On the one hand, the Court usually objects when the government tries to block truthful speech by businesses. In the prescription-data case, the Vermont law would have restricted the free flow of information about physicians' prescribing practices. On the other hand, the Court typically approves when the government tries



to prevent false or deceptive speech by businesses. For example, the government may forbid companies from saying things that are not true. It also may require companies to make disclosures that will allow consumers to make informed choices and not be misled by advertising hype. Common disclosure requirements include the corporate prospectus for stock offerings, the total interest payments for a home mortgage, nutritional information for foods, and the textual warnings for cigarettes.

The graphic cigarette warnings appeared to serve purposes similar to those of other required disclosures. The warnings would promote understanding of the risks of smoking and prevent people from being misled by cigarette marketing.

Indeed, the U.S. Court of Appeals for the Sixth Circuit had upheld Congress's authority to mandate graphic warnings.⁴ As that court observed, people often do not read textual warnings

on cigarette packages. And even when read, the warnings may not be effective in informing consumers about the risks to their health. Adding color images can ensure that textual warnings are noticed, read, and understood. Sometimes a picture really is worth a thousand words.

Even though the Supreme Court let the Sixth Circuit's decision stand, its effect is limited. The Sixth Circuit considered only whether Congress may require *some* graphic warnings. The D.C. Circuit considered the constitutionality of the FDA's *actual* warnings.

In rejecting the warnings by a two-to-one vote, the D.C. Circuit identified two problems. First, the majority did not think the images were needed to prevent cigarette companies from misleading consumers. Other statutory provisions already prohibited many kinds of deceptive labeling or advertising. The court was not willing to defer to the FDA's judgment that the new images

were necessary. Second, the warnings were not designed simply to ensure that consumers fully understand the risks to their health from cigarettes. Instead, wrote the majority, the warnings would primarily serve to convey the government's antismoking message. Indeed, each of the new images would include the phone number for the National Cancer Institute's tobacco cessation hotline, 1-800-QUIT-NOW. Whereas government may use its own resources to publicize its perspectives, it generally may not force individuals or corporations to spend their dollars to disseminate its viewpoint.

Rather than seek Supreme Court review of the D.C. Circuit's decision, the FDA opted to return to the drawing board and develop new graphic warnings. In the meantime, we are left with some important questions.

First, when do graphic warnings cross the line between trying to inform and trying to persuade? Does it depend on how "shocking" or how prominent they are? Two of the three D.C. Circuit judges thought that the images were designed to evoke an emotional response rather than to convey factual information. The dissenting judge cited the FDA's point that warnings more effectively communicate information when they elicit a strong emotional reaction. In addition, the images would provide information about risk when viewed in conjunction with their accompanying text. For example, the image of the man smoking through a tracheostomy accompanied the warning "Cigarettes are addictive" and would have illustrated the tenacity of nicotine addiction. In the dissenter's view,

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.

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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.⁵ 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.

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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.”¹ 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-