



## Repackaging Cigarettes — Will the Courts Thwart the FDA?

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On August 12, 2012, the High Court of Australia upheld the constitutionality of tobacco laws requiring cigarette packages to be plain, with no colorful designs or brand logos, but dominated by

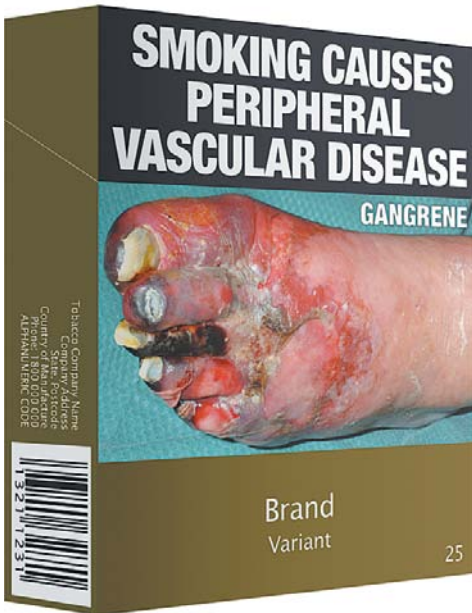
graphic images depicting the health consequences of smoking — including mouth ulcers, lung tumors, and gangrenous limbs (see first image). On August 24, in *R.J. Reynolds v. U.S. Food and Drug Administration* (FDA), the U.S. Circuit Court of Appeals for the District of Columbia deemed unconstitutional FDA regulations requiring similar graphic warnings, finding that the mandated packaging violates cigarette companies' right to free speech by compelling them to express antitobacco messages "on their own dime."

The American Medical Association, the American Heart Association, the American Lung Asso-

ciation, and the American Cancer Society had urged the court to uphold the mandate as a vital public health strategy. The decision underscores the differences between U.S. free-speech norms and those in other liberal democracies where aggressive antitobacco packaging has been adopted. Belgium, Canada, France, New Zealand, Norway, and Britain, in addition to Australia, have moved to require graphic cigarette labeling. Ultimately, the Supreme Court will hear the FDA case, which will have major ramifications for the government's ability to regulate commercial speech for the public's health and safety.

In mid-2009, President Barack Obama signed the Family Smoking Prevention and Control Act, which regulated the manufacture, distribution, and marketing of tobacco products. Passed with overwhelming congressional support, the Act stipulated that warnings must cover 50% of the front and back panels of cigarette packages. It specified the text of the warnings, which were to be accompanied by FDA-selected color graphics showing the negative health consequences of smoking. In November 2010, the FDA submitted 36 potential images for public comment, and a final rule adopting 9 of them was issued in June 2011 (see second image).

The FDA recognized that the legal and scientific justification for its new rules would be subjected to intense public and constitutional scrutiny. The Supreme



**A Graphic Warning Label Approved for Use on Cigarette Packages in Australia.**

A slide show of additional warning labels is available with the full text of this article at NEJM.org.

Court's commercial speech doctrine, and the increasingly exacting manner in which it's been deployed, would ultimately determine the fate of this crucial public health measure.

The First Amendment safeguards discourse in social and public affairs, art, science, and politics. For most of U.S. history, the Supreme Court held that the Constitution did not protect commercial speech — broadly defined as speech by a commercial enterprise for business purposes. In 1975, when the Court first recognized a constitutional right to market products, commercial speech was viewed as “lower-value” expression.

In 1980, in *Central Hudson*, the Court established a “mid-level” test for the constitutional review of commercial speech cases: Is the

message lawful and nondeceptive? Does the state have a “sub-

stantial interest” in curtailing the speech? Does the regulation “directly advance” that interest? Is the regulation “no more extensive than necessary”?

The Supreme Court, however, has progressively increased protection for commercial speech, often invalidating public health regulations because the state could not clearly demonstrate their necessity for achieving public health objectives.<sup>1</sup> In 1995, for example, the Court struck down restrictions on displaying information about alcohol content on beer labels and on advertising by private casinos. In 2001, in *Lorillard*, it struck down Massachusetts restrictions on tobacco advertising and sales, finding them more extensive than necessary. By 2011, the Court established a “heightened” standard of review for regulations that curtailed speech on the basis of the speaker's identity and the content of the message.

If the Supreme Court applied the *Central Hudson* standard to graphic tobacco images, the FDA would at least have to present evidence that the rule advanced the public health and was not unnecessarily extensive. The graphic-images rule, however, applies to a particular speaker (tobacco companies) and stipulates specific content (required images). If the Court used a heightened standard of scrutiny, the agency would be highly unlikely to prevail.

For the FDA, the case for the new warnings was straightforward. Graphic images were necessary to enhance consumers' capacity to make choices, fully informed of smoking's consequences. Current warnings on cigarette packages and in adver-

tisements, the agency concluded, were “invisible” and “ineffective” — all but useless in protecting the public health. Drawing on a well-accepted distinction between simple cognitive awareness and true comprehension,<sup>2</sup> the FDA asserted that “really understanding” required “warnings that include images communicating health information far more effectively.” The government's interest in this regard was both substantial and compelling.

According to the health organizations supporting the FDA position and some of the 22 state attorneys general who helped to broker the landmark Master Settlement Agreement, the long history of tobacco-industry deception necessitated an innovative strategy. Only emotionally charged messages could effectively counteract the misunderstandings that decades of advertising had created.

The tobacco industry and its allies — the U.S. Chamber of Commerce, the American Advertising Federation, and the Washington Legal Foundation — argued that the FDA's claims were false and dangerous. Americans did, in fact, know the risks of smoking. Public health campaigns and current warning requirements enabled consumers to make informed choices. Indeed, the only evidence that informative efforts had “failed” was that consumers nevertheless chose to exercise the freedom to smoke, to use a legal product. What motivated the FDA and its allies was not a devotion to autonomy but a commitment to using every possible technique to cajole smokers into giving up the choice they'd made. “The true purpose of the graphic warnings,” claimed the tobacco industry, “is not to inform but to use



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**One of the Graphic Warning Labels Proposed for Use in the United States.**

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emotionally charged graphics to browbeat ‘irrational’ consumers into adopting the government’s preferred course of action . . . . Some researchers may think this approach is good policy, but it is at war with the First Amendment.”<sup>3</sup>

These arguments have come before two federal appellate courts. In March 2012, the Sixth Circuit Court upheld the FDA’s proposed regulation, endorsing the agency’s assertion that graphic warnings would foster genuine freedom of choice. The purpose of the FDA rule, that court asserted, was to prevent consumers from being misled about the health risks of tobacco — an

acceptable role of government, according to commercial speech doctrine. “What matters in our view is not how many consumers ultimately choose to buy tobacco products but that the warnings effectively communicate . . . health risks so that consumers possess accurate factual information.”<sup>4</sup>

Five months later, the D.C. Circuit Court of Appeals rejected the claim that consumer choice was at stake. Rather, the government had sought on the basis of “questionable social science” to press its campaign against smoking by converting each cigarette package into an antismoking billboard. “These inflammatory images and the provocatively named hotline (1-800-QUIT-NOW) cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting.”

What’s so striking about the controversy leading up to these divergent judicial determinations is that public health advocates felt constrained by the specter of the commercial speech doctrine to frame their case on the narrowest possible grounds — the need to enhance consumer choice. By contrast, the tobacco industry could characterize graphic warnings as an (unacceptable) attempt to influence the behavior of smokers and potential smokers in the name of public health.

In 2007, the Institute of Medicine wrote, “It 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.”<sup>5</sup>

That this unambiguous public health assertion could not provide the justification for the FDA’s initiative is another reminder of the way in which the U.S. conception of commercial speech limits not only what can be done in the name of public health, but also the candor with which such efforts can be defended.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://NEJM.org).

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An audio interview with Dr. Bayer is available with the full text of this article at [NEJM.org](http://NEJM.org).

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