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Smoking and the First Amendment

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provide solutions to all the complex problems of health worker migration, it offers needed guidance on possible policy and legislative approaches. There is growing evidence that its legal framework can work as a platform for cooperation to strengthen health workforce systems. Sixty-nine countries have thus far designated a national authority responsible for the exchange of information on health worker migration and Code implementation. However, greater efforts are needed to ensure effective implementation. It is time for states to muster the political will and resources to act to strengthen health workforce systems everywhere.

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1. Frenk J, Chen L, Bhutta ZA, et al. Health professionals for a new century: transforming education to strengthen health systems in an interdependent world. Lancet 2010;376:1923-58.
2. Medical Education Partnership Initiative (MEPI). Bethesda, MD: Fogarty International Center, National Institutes of Health, June 2010 (http://www.fic.nih.gov/Programs/Pages/medical-education-africa.aspx).
3. HHS partners with PEPFAR to transform African medical education with $130M investment. Bethesda, MD: National Institutes of Health, October 2010 (http://www.fic.nih.gov/Programs/Pages/medical-education-africa.aspx).

Smoking and the First Amendment

Kevin Outterson, J.D.

On June 22, 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act into law.[1] For the first time, Congress had given the Food and Drug Administration (FDA) authority to directly regulate tobacco products, with the aim of improving public health. And indeed, effective tobacco control would be a remarkable public health achievement — and might be possible if the law is allowed to stand. But on November 7, 2011, a federal judge in Washington, D.C., issued a preliminary injunction blocking some of its key provisions as unconstitutional restrictions on commercial speech, and the battle seems likely to end up in the Supreme Court.

A slide show is available at NEJM.org

The Tobacco Control Act made three changes to cigarette warnings. First, existing warnings on cigarette packages (which have been required since 1966) must be replaced with nine new specified verbal warnings (see box), one of which must appear on every package. Second, nine new graphic images must be paired with the textual warnings on a rotating basis; the FDA selected images that it expects to have the greatest anti-smoking effect (see images and slide show). Finally, companies must move the warnings from the side of the package and devote at least the top 50% of both the front and back panels to the government-mandated messages.

The case decided in November, *R.J. Reynolds Tobacco Company v. FDA*,[2] challenged the second two of these three changes, as implemented through an FDA rule published on June 22, 2011.[3] The judge, Richard Leon, refused to apply the well-known *Central Hudson* test for commercial speech, under which the government must establish that the rule "directly advances" its "substantial" interest and is "not more extensive than is necessary." Instead, Leon applied the more demanding "strict scrutiny" test, whereby the government's interest must be "compelling" and the regulation "narrowly tailored" to that compelling purpose. Finding that the regulation failed this test, the court enjoined the FDA from enforcing the regulations regarding graphic images and mandatory space allocations. The Department of Justice immediately appealed this ruling.

Last year, the FDA fared better in a case decided in Kentucky, *Commonwealth Brands v. United States*,[4] in which the court upheld these new warnings under *Central Hudson*. Why did these decisions diverge?

First, the selection of the standard of review is key. Under *Central Hudson*, a court considering the constitutionality of regulations examines whether they achieve the intended purpose, and it explores the roads not taken — options available to the government that could achieve success without violating the First Amendment. Under the strict-scrutiny standard, the inquiry is much more exacting, and few regulations survive it. In *Reynolds Tobacco*, the court imposed strict scrutiny because the graphic images were not "purely

FDA-Mandated Warnings for Cigarette Packages.

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.

factual and noncontroversial" but were instead very striking images designed to maximize "salience" and emotional impact. By contrast, the court in *Commonwealth Brands* found the graphic images to be well suited to the purposes of the Tobacco Control Act.

Which brings us to the second key question: What is the purpose of the Tobacco Control Act? Public health experts might believe that the substantial state interest behind the law was reducing the health effects of tobacco use. But when a law restricts commercial speech, courts seek precise justifications for the regulations at issue. The question therefore narrows to the purpose of the graphic-image and space-allocation rules. In *Commonwealth Brands*, the government successfully argued that its substantial interest was warning people about the dangers of smoking. The tobacco companies insisted the goal was correcting consumer ignorance about the health risks of smoking. Although these goals seem similar, they lead to remarkably different legal results. The tobacco companies argued that "numerous national surveys demonstrate that over the last half century, the awareness of smoking-related risks is widespread." In fact, in their view, "'surveys demonstrate that Americans perceive a significantly higher lost life expectancy due to smoking' than is warranted based on the Surgeon General's reports, and 'young people overestimate the dangers of smoking to an even greater degree' than adults."[4] In short, the companies say, Americans already know too much about the dangers of tobacco use and don't need new graphic warnings.

The court in *Commonwealth Brands* did not disagree with this empirical research but found it irrelevant. In that case, Judge Joseph McKinley concluded that the government's substantial interest "is to ensure that the health risk message is actually *seen* by consumers in the first instance." If that is the goal, then large graphic warnings on all cigarette packages are appropriate. The court found support in a 2007 report from the Institute of Medicine, which found existing warnings to be "unnoticed and stale." The new rules directly advanced the government's carefully articulated interest in warnings that would actually be noticed.

Finally, the judges' contrasting attitudes toward international experience and the World Health Organization (WHO) Framework Convention on Tobacco Control played a pivotal role. The tobacco companies challenged the scope of the advertising-space rules, arguing that they were "more extensive than is necessary." Both courts discussed a recent Seventh Circuit case, *Entertainment Software v. Blagojevich*, that reviewed a state law requiring a 4-square-inch "18" sticker on any video game that was deemed to be "sexually explicit." The Seventh Circuit overturned the law because the need for such a large sticker was unsupported by evidence. It then mused about public health labeling run amok, saying it "certainly . . . would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning." The *Reynolds Tobacco* court found this analogy persuasive and therefore blocked the space-allocation rules. By contrast, the court deciding *Commonwealth Brands* looked to the WHO Framework Convention, noting that "Unlike *Entertainment Software*, where the state failed to give any reason for why a smaller warning would be inappropriate, Congress has provided reasons for the particular features of the warning requirement here. Most obviously, it relied on the international consensus reflected in the Framework Convention on Tobacco Control, which calls for warnings that 'shall be rotating,' 'shall be large, clear, visible and legible,' 'should be 50% or more of the principal display areas but shall be no less than 30% of the principal display

areas,' and 'may be in the form of or include pictures or pictograms.'"

The Framework Convention is legally binding in 174 countries. The United States signed the convention, but President George W. Bush did not send it to the Senate for ratification. Nevertheless, Congress passed and Obama signed the Tobacco Control Act, which largely follows the convention's proposed space-allocation rules. In *Commonwealth Brands*, McKinley highlighted this connection to reach his conclusion that these rules were "necessary." By contrast, Leon was openly skeptical of Canadian, English, and Australian experiences with tobacco control and failed to mention the Framework Convention at all, despite having read the *Commonwealth Brands* opinion. Applying the strict-scrutiny test, he found the space-allocation rules unconstitutional.

These cases will be litigated over the next few years, as they make their way toward the Supreme Court. Already, however, they provide more data points in a disturbing trend: powerful corporations are increasingly using an expanding definition of the First Amendment to challenge public health regulations.[5] For public health advocates, one lesson is that the purpose and mechanism for new regulations must be carefully articulated and documented, especially if any conceivable First Amendment issue can be raised.

Emphasis should also be placed on regulations such as bans on smoking in public places, increased taxes to discourage consumption, raising the legal age for tobacco use, smoking-cessation programs including health insurance incentives, and outright bans on tobacco use — all of which are free from First Amendment concerns.

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1. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776.
2. R.J. Reynolds Tobacco Company, et al. v. U.S. Food and Drug Administration, Civil Case No. 11-1482 (RJL) (D.C.D.C., Nov. 7, 2011).
3. FDA, Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22, 2011).
4. Commonwealth Brands, Inc. v. U.S., 678 F.Supp.2d 512 (2010).
5. Outterson K. Higher First Amendment hurdles for public health regulation. N Engl J Med 2011;365(7):e13. (Available at NEJM.org.)

The Emperor of All Maladies — The Beginning of the Beginning

Robert Schwartz, M.D.

Richard Feynman, the eminent physicist, once said that "great ideas . . . do not last unless they are passed purposely and clearly from generation to generation." In 1979, Horace Freeland Judson, in his magnificent *The Eighth Day of Creation,* passed to his generation the great ideas of molecular biology. Now, Siddhartha Mukherjee gives his generation an account of the great ideas of oncology in his Pulitzer Prize–winning book *The Emperor of All Maladies: A Biography of Cancer* (New York: Scribner, 2010). Mukherjee's book unfolds the twists and turns, successes and failures, and hopes and despairs that led to our understanding of cancer's biology and its treatment, up to the point of the development of imatinib. It emphasizes oncology's development during the century between William Halsted's radical mastectomy and Brian Druker's imatinib. Mukherjee elucidates the extraordinarily complex story of the great surge in oncology that began in 1965.

A high point of this surge occurred in the late 1990s, when Druker and Nicholas Lydon developed a new kind of drug for treating chronic myelogenous leukemia (CML). The novelty of this compound, imatinib (Gleevec), a derivative of 2-phenylaminopyridine, is its ability to interfere specifically with the out-of-control tyrosine kinase that causes CML. Most anticancer drugs of