



## FDA Regulation of Tobacco — Pitfalls and Possibilities

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After more than half a century of debate and discussion, it is likely that during the coming year, Congress will pass legislation bringing tobacco products under the regulatory authority of the

Food and Drug Administration (FDA). The regulatory status of cigarettes arguably represents one of the most paradoxical stories in American medicine and public health: the single most dangerous legal product in U.S. consumer society has eluded virtually all federal regulation until now. Using a combination of scientific misinformation, intensive political lobbying, and a culturally resonant argument that smokers must take personal responsibility for harms they incur from its product, the tobacco industry has fought off all attempts to bring the manufacture, marketing, and sale of cigarettes under the authority of the FDA or any other federal agen-

cy.<sup>1</sup> While competing aggressively against one another for market share (see historical cigarette ads), the tobacco companies drew together for the purposes of denying the harms of smoking and exerting their political influence to deflect any serious form of regulation. Indeed, in response to the proposal put forward by former FDA Commissioner David Kessler in the mid-1990s that tobacco be regulated as a drug, the industry fought tooth and nail to deny the FDA this authority. After a protracted legal battle, in 2000 the Supreme Court found in a 5-to-4 decision that the FDA did not have statutory authority to regulate cigarettes. If the agen-

cy were to begin regulating tobacco, it would require explicit legislative approval from Congress.<sup>2</sup>

Although scientists have well understood for more than 50 years that cigarettes cause lung cancer and other fatal diseases, we still do not have regulations concerning product content. Even now, tobacco companies are not required to inform the public about the additives in their cigarettes. Nor have we ever had consistent scientific monitoring or control of the carcinogenic “tars” or the content of highly addictive nicotine in cigarettes. Furthermore, the companies have continued to make claims that are widely regarded as deceptive, calling some brands “low-tar,” “light,” or “ultra-light,” falsely implying that they confer less risk.

All this could change soon with the passage of the Family Smok-



Lucky Strike, circa 1930.

Lucky Strike addressed early health concerns by claiming that “toasting” offered a less irritating smoke. Many early theories of carcinogenesis emphasized the significance of irritants.



Camel, late 1940s.

As new evidence of the serious harms of smoking accrued, this prominent advertising campaign claimed that Camels were the preferred cigarette of American physicians.

ing Prevention and Tobacco Control Act, which the House Energy and Commerce Committee approved in April by a vote of 38 to 12. Introduced in February 2007 by longtime tobacco-control advocate Representative Henry Waxman (D-CA), the bill would strengthen advertising restrictions and prohibitions on marketing to youth; require new and more prominent warning labels; compel companies to disclose all ingredients in tobacco products; and authorize the FDA to restrict harmful additives, as well as monitor and reduce nicotine yields. A new division of the agency, funded by user fees paid by the industry, would implement and enforce these regulations. The legislation explicitly prohibits com-

panies from making claims that their products are approved by the FDA. The bill bans candy and fruit flavorings that have recently been used to make cigarettes more appealing to young people, but its failure to prohibit the use of menthol has drawn considerable criticism from tobacco-control groups and former health officials. The bill treats menthol as it does other potentially harmful substances in cigarettes: if the FDA were to find that it was dangerous, it could limit or ban its use in the future. The legislation prohibits the FDA from banning tobacco sales or the use of nicotine in tobacco products, but the agency could eventually mandate the reduction of nicotine to nonaddictive levels.<sup>3</sup>

Although the bill has attracted bipartisan support, it has a considerable number of detractors within Congress and the Bush administration, as well as among major tobacco companies. Last year, even though a White House advisory panel recommended that tobacco be regulated as a drug, FDA Commissioner Andrew von Eschenbach rejected the idea of saddling his agency with this additional burden, and it now appears that the Bush administration will oppose the bill. Strikingly, the threat of FDA regulation of tobacco is dividing the once virtually unbreakable alliance of major tobacco companies, which have a long history of cooperation and collusion in fighting regulation wherever and whenever it was

proposed. Philip Morris, the dominant player among the U.S. tobacco companies, has endorsed the bill, whereas the other major companies vigorously oppose it. Some, arguing that FDA regulation would cement Philip Morris's sizable market advantage, have dubbed the proposed legislation the "Marlboro Monopoly Act."

Moreover, even as Altria (the domestic parent company of Philip Morris USA) has at last acceded to FDA regulation, it has recently spun off the far more profitable Philip Morris International (PMI). Although Altria is working to maintain its dominant position in the substantial but considerably reduced U.S. market, PMI and the other tobacco companies well understand that future profits in the cigarette trade will come largely from sales abroad. As a result, the stabilization and "normalization" of what has come to be widely regarded as a rogue industry may offer considerable advantages as the market for tobacco products moves predominantly into the developing world. While Altria is promoting FDA regulation, PMI is test-marketing a new high-tar, high-nicotine cigarette in Southeast Asia. Even if FDA regulation fulfills its promise of further reducing smoking-related morbidity and mortality domestically, in the future it will be critical that public health efforts take a global approach to tobacco control.

The World Health Organization (WHO) estimates that in the past century, 100 million smokers died worldwide from smoking-related diseases, but 10 times as many (1 billion) are expected to die this century if current rates of smoking are merely maintained —



#### True, 1970s.

By implying that their product carried less risk, the makers of True cigarettes attempted to appeal to smokers who were considering quitting.

this, despite all we know about the harms of smoking. In 2003, WHO promulgated its first-ever treaty, the Framework Convention on Tobacco Control, which was designed to combat this coming pandemic by creating an alliance of countries committed to tobacco control through a series of common public health measures and tax policies. The treaty has now been signed and ratified by more than 150 countries. Notably, the Bush administration has not sent the treaty to the Senate for ratification.

Given the opportunity to put tobacco control back on the federal agenda, virtually all major public health and medical specialty groups, including the American Cancer Society, the American Heart Association, the American Lung Association, and the American Medical Association, strongly support the FDA bill. Nonetheless, a few prominent tobacco-control advocates such as Stanton Glantz

of the University of California, San Francisco, have expressed skepticism, arguing that Philip Morris's support indicates that the legislation would probably benefit its corporate interests. And certainly, from a historical point of view, Congressional legislation passed under the rubric of "regulation" has often come back to haunt public health advocates. The weak and largely ineffective warning labels on cigarette packages are perhaps the best manifestation of the tobacco industry's knack for turning regulatory efforts to its own interest. Once tobacco products began to sport such labels, the industry repeatedly argued in litigation, with considerable success, that its product was preempted from liability by Congressional mandate. Although there is no evidence that such legal protections were intended by earlier tobacco legislation, we now know from previously secret internal documents that the industry actually favored such legislation as a weapon in its defense against lawsuits.<sup>4</sup>

Thus, it behooves public health advocates and Congress to more fully understand all the implications of FDA regulation. Some critics have referred to the inherent compromises required to enact such a bill as "dancing with the devil." In this case, the devil will be in the details. Will FDA regulation lead to interventions that further reduce the prevalence of smoking in the United States and its effect on the burden of disease? Currently, more than one of five adults is a regular smoker, and more than 430,000 deaths occur each year as a result of cigarette use. The proposed legislation, if passed, would be



Marlboro, circa 1990.

Philip Morris introduced the Marlboro Man in the 1950s as the symbol of a new “rugged and masculine” filtered brand, in an effort to address increasing public concerns about the risks of smoking.

only the beginning; for regulation to succeed from a public health perspective, ongoing vigilance would be required on the part of Congress and tobacco-control advocates to ensure that the statute protected the public from the harms of smoking through prevention and cessation efforts, as well as through the critical and independent scientific assessment of conventional and new products. Nonetheless, despite its initial limitations, the bill offers important new federal leverage for reducing smoking-related disease, disability, and deaths.

As Congress debates the regulation of tobacco by the FDA, it would be wise to consider ways of tying serious efforts to reduce tobacco use in this country to efforts to reduce the burden of tobacco-related diseases throughout the world. Saving lives from the manifold harms of tobacco should not be viewed as a zero-sum game. Nor should FDA regulation of U.S. tobacco products be seen as offering new respectability to an industry that, as a federal judge has ruled, has been committing racketeering and fraud for more than half a century.<sup>5</sup>

Dr. Brandt reports serving as an expert witness for the Department of Justice in *United States v. Philip Morris et al.* in 2004 and receiving funding from the Flight Attendant Medical Research Institute for research on secondhand smoke. No other potential conflict of interest relevant to this article was reported.



An interview with Allan Brandt and a slideshow of historical tobacco ads are available at [www.nejm.org](http://www.nejm.org).

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#### FOCUS ON RESEARCH

## Gastric Cancer in Japan — Honing Treatment, Seeking Causes

David Forman, Ph.D., and Paola Pisani, Spec.Stat.Med.

Related article, p. 453

In this issue of the *Journal*, Sasako and colleagues (pages 453–462) present results from a randomized trial of surgery for gastric cancer conducted in 24 specialized hospitals in Japan. The 523 enrolled patients all had a diagnosis of curable gastric cancer and were randomly assigned

to receive either Japan’s standard surgical treatment — gastrectomy plus extensive removal of regional lymph nodes — or the same procedure plus para-aortic nodal dissection. There were no significant differences between the two groups in either overall 5-year survival (around 70% in both groups)

or recurrence-free survival (around 63% in both groups). Given these results, combined with the additional complexity of para-aortic nodal dissection, it is clear that the addition of this procedure to the basic operation offers no benefit to the patient.

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