

EDITORIALS



Tobacco, Public Health, and the FDA

Gregory D. Curfman, M.D., Stephen Morrissey, Ph.D., and Jeffrey M. Drazen, M.D.

More than a decade ago, David Kessler, then Commissioner of the Food and Drug Administration (FDA), launched a bold initiative to regulate tobacco. He believed that since nicotine is an addictive substance, it fell under the statutory authority of the FDA to regulate it as a drug and cigarettes as the delivery vehicle.

His effort failed, however, when the U.S. Supreme Court decided in a 5-to-4 ruling (*FDA v. Brown & Williamson Tobacco Corp.*) that the Food, Drug, and Cosmetic Act of 1938, which defined the FDA's authority, did not grant the agency jurisdiction to regulate tobacco. Writing for the Court, Justice Sandra Day O'Connor concluded that "it is plain that Congress has not given the FDA the authority to regulate tobacco products."¹ The Court's decision was based on its reading of the statutory language in the act, not on what was best for the health of the public.

On June 22, President Barack Obama changed all that. With the signing of the Family Smoking Prevention and Tobacco Control Act of 2009, which was passed by sizable majorities in both the House and the Senate (and which we endorsed), the FDA has been given broad authority to regulate tobacco products. We believe that this historic legislation can have an unparalleled positive impact on the health of the American public.

The act establishes the Center for Tobacco Products, a unit within the FDA that will be funded by user fees from tobacco manufacturers and importers — \$235 million in fiscal year 2010, rising to \$712 million over the next 10 years. The center is charged with regulating tobacco products for the explicit purpose of protecting the health of the public. The FDA will now have the authority to require that all ingredients, com-

pounds, and additives in tobacco products be reported to the agency, and those found to have harmful health effects may be banned. Nicotine levels in cigarettes may be regulated, but neither nicotine nor cigarettes may be banned outright. In keeping with the act's focus on protecting those under 18 years of age, flavorings in cigarettes, which are meant to appeal to young smokers, are banned, with the exception of menthol, which could be banned later if found to be a health hazard. No new tobacco product can be marketed unless first approved by the FDA.

Importantly, the act will also allow regulation of so-called modified risk tobacco products, which are typically identified by terms on the package such as "light," "low," or "mild." The use of such terms will no longer be permitted unless the product has been shown to significantly reduce harm. Warning labels on cigarette packages will be made more graphic and will require the use of color. Tobacco companies may no longer sponsor sporting events.

For the first time in almost 40 years, state and local governments will be allowed to regulate the marketing of tobacco, establishing restrictions that may be more rigorous than those of the FDA. In addition, the act requires that the 1996 Tobacco Rule, which was put in place by Commissioner Kessler and deemed unconstitutional by the Supreme Court, must be reinstated. This rule places restrictions on tobacco advertising, including a ban on outdoor advertising within 1000 ft of a school. It is anticipated that this regulation may be the focus of a constitutional challenge on the basis that such advertising represents commercial speech subject to First Amendment protection. Still, there is good reason to believe that this carefully crafted provision, which

is narrowly tailored to focus on smoking prevention in the nation's young, will survive any such legal challenge.

The long-term impact of the Family Smoking Prevention and Tobacco Control Act on the health of the public will depend critically on its implementation through strict regulations, rigorously enforced. FDA Commissioner Margaret Hamburg and Principal Deputy Commissioner Joshua Sharfstein promise to be strong advocates for rigorous enforcement.

In a recent article in the *Journal*, Hamburg and Sharfstein laid out their new mission.² They regard the FDA as a public health agency whose purpose is not just to regulate the nation's food and drug supplies, but to protect the health of American citizens. Hamburg has also indicated that she is eager to undertake the regulation of tobacco and said in an interview, "We now have an opportunity to really make a difference with what is probably the No. 1 public health concern in the nation and the world."³

Few threats to the health of the public are as onerous as tobacco. Each year more than 435,000 Americans die of tobacco-related illnesses, principally heart, vascular, and lung diseases. Tobacco use is also associated with substantial morbidity and diminished quality of life. More than one in five Americans still smoke, an astonishing fig-

ure given the overwhelming evidence of harm. In addition to excess morbidity and mortality, tobacco adds considerably to health care costs at a time when reducing costs is a national priority. The total annual health care expenditures caused by smoking run to \$96 billion.⁴ Along with other critical prevention goals, such as controlling obesity and increasing levels of physical activity, the elimination of cigarette smoking is central to improving the health of our citizens and mitigating the growth of health care costs.

The Family Smoking Prevention and Tobacco Control Act of 2009 comes at a propitious moment in U.S. history. We strongly support the FDA's new leaders and urge them to implement the act aggressively. As a medical journal, we are committed to eliminating the public health threat tobacco represents to American society and the world.

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 2. Hamburg MA, Sharfstein JM. The FDA as a public health agency. *N Engl J Med* 2009;360:2493-5.
 3. Harris G. New F.D.A. chief says she'll toughen enforcement efforts. *New York Times*. June 17, 2009:A19.
 4. Campaign for Tobacco-free Kids. Toll of tobacco in the United States of America. April 2009. (Accessed June 22, 2009, at <http://www.tobaccofreekids.org/research/factsheets/pdf/0072.pdf>.)
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Typhoid Vaccines Ready for Implementation

Myron M. Levine, M.D., D.T.P.H.

Enteric fevers encompass typhoid fever caused by *Salmonella enterica* serotype Typhi (*S. Typhi*) and paratyphoid fever caused by serotype Paratyphi A or B (*S. Paratyphi*). These human-restricted pathogens are acquired by ingesting contaminated water or food, and in the individual patient, one cannot differentiate clinically which agent is causing illness. *S. Typhi* expresses a capsular "Vi" (for virulence) polysaccharide, whereas *S. Paratyphi* A and B cannot synthesize Vi.

Before the use of antibiotics, typhoid fever had a case fatality rate of 10 to 20%. Transmission of enteric fever is minimized or eliminated if populations have access to treated water supplies and sanitation to remove human fecal matter. Where such amenities are unavailable, the risk

of typhoid fever can be substantially diminished by immunization with typhoid vaccines.

Early typhoid vaccines (heat-inactivated whole *S. Typhi* organisms preserved in phenol) were developed in the 1890s. Six decades later, the World Health Organization (WHO) sponsored large-scale, randomized, controlled field trials, in which investigators found that similar killed whole-cell vaccines conferred substantial protection against typhoid.¹ However, because these vaccines commonly elicited debilitating adverse reactions (fever and malaise), they were rarely used to control endemic typhoid fever.¹

After a report in 1948 that chloramphenicol drastically ameliorated enteric fevers and reduced the case fatality rate to less than 1%, the treatment