

## EDITORIALS



## The FDA and Tobacco Regulation

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Soon the U.S. Senate will vote on a bill<sup>1</sup> with unprecedented implications for the health of the American people. The bill would, for the first time, grant authority to the Food and Drug Administration (FDA) to regulate tobacco products.

In late July, the House passed its version of the bill by a veto-proof margin, but the vote in the Senate is expected to be much closer. President George W. Bush, whose administration has not usually shown a keen interest in the health of the American public, has indicated that he will veto the bill if it comes to his desk. Thus, the margin of victory in the Senate will be crucial to the future of this landmark legislation.

The past several years have witnessed egregious examples of corporate greed and misconduct. The debacles involving Enron, WorldCom, and more recently, Countrywide have done much to tarnish the image of corporate America. But no part of the corporate world has raised more concern than the tobacco industry. Its infractions have not been limited to greed; they also extend to the blatant disregard for the health of the public.

According to statistics tracked by the Centers for Disease Control and Prevention, about 400,000 Americans die each year from diseases caused by cigarette smoking.<sup>2</sup> The biggest killers are lung cancer and other smoking-related cancers, chronic obstructive pulmonary disease, and coronary heart disease. Thus, over a 5-year period, 2 million Americans die from conditions caused by tobacco. As staggering as these mortality figures are, they are dwarfed by the extensive morbidity and loss of productivity related to tobacco use.

The good news is that over the past 40 years, the prevalence of smokers in the United States

has declined sharply, from 42% in 1965 to 20% today.<sup>3,4</sup> But even with this progress, almost one in four American men and one in five American women still smoke and are vulnerable to smoking-related death and disease. Millions of others suffer the effects of secondhand smoke. Between 2000 and 2004, smoking cost the U.S. health care system nearly \$100 billion a year, and the loss in productivity cost the country almost another \$100 billion a year.<sup>2</sup>

The burden of smoking-related illness falls disproportionately on those of lower socioeconomic status. The tobacco companies prey especially on the poor, the uneducated, and those with mental illness and substance abuse, along with the most vulnerable population of all, the nation's youth. Tobacco is the only commercial product that has no benefit and is unequivocally hazardous to human health. But even though the FDA can regulate spinach and jalapeño peppers, the agency has never had the authority to regulate tobacco.

An effort by former FDA commissioner David Kessler to regulate nicotine as a drug ultimately met with failure. In *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*,<sup>5</sup> the U.S. Supreme Court ruled in 2000 in a 5-to-4 decision that since Congress had developed a separate regulatory structure for tobacco outside the FDA, it never intended to give the agency regulatory authority over tobacco. Justice Stephen Breyer, who is an expert in regulation and has written two books on the subject, wrote a dissent. He asserted that tobacco products, because they affect the "structure or function . . . of the body," fall within the scope of the federal Food, Drug, and Cosmetic Act. He further asserted that "the statute's basic purpose — the protection of public

health — supports the inclusion of cigarettes within its scope.”<sup>6</sup>

The agency’s authority would change if the new bill, the Family Smoking Prevention and Tobacco Control Act, were to become law. The bill gives the FDA broad authority to regulate the manufacture of tobacco products, as well as the sale, distribution, and promotion of tobacco products if it would protect the public health. A particularly important part of the act would require that ingredients and additives in tobacco products, including potentially harmful constituents of tobacco smoke, be provided to the government. Thus, for the first time, the manufacturers would have to identify what substances are in their tobacco products. If those substances were found to be harmful, they would be subject to regulation. The bill stops short, however, of allowing the FDA to ban tobacco products outright or reduce nicotine levels to zero (although it could require that they be lowered); that authority would be retained by Congress itself. Neither could the FDA set an underage limit of more than 18 years for purchasers of tobacco products, control where they are sold, or make them available by prescription only.

Advertising and promotion could be restricted within the boundaries imposed by the First Amendment, and no longer could so-called “modified risk” tobacco products, which imply that they are less harmful by using words such as “light,” “mild,” and “low” on the package and in advertising, be marketed without FDA approval. Cigarettes with fruit, spice, or other flavorings, which typically appeal to children and adolescents, would be banned. The controversial exception, however, is menthol, an ingredient in more than one quarter of all cigarettes in the United States and in three quarters of those sold to black Americans. Menthol would not be banned at the outset but could later be banned if evidence was produced that it was harmful.

The act would also require that nine different warning labels — larger and more prominently placed than current labels — be displayed on cigarette packages and advertising materials; the warnings would be dispersed across geographic distribution areas and rotated so that all the warnings would be displayed in any given distribution area at the same time. The costs associated with the regulation of tobacco by the

FDA would be covered by user fees paid by the tobacco companies.

Despite its flaws, the bill has been endorsed by a number of prominent medical societies and public health organizations. Still, it is opposed by some tobacco opponents in part because Philip Morris, the largest tobacco company in the United States, supports it. There is concern that Philip Morris has taken this unusual action to solidify its dominant position, since the act would make it more difficult to introduce new tobacco products into the U.S. market. Concern has also been raised that regulation, much of which the bill does not mandate but leaves to the discretion of the FDA, might be weakened by industry lobbying. At the same time, FDA oversight might mitigate the legal liability of tobacco companies.

We support passage of the bill because, although it is imperfect, it is an important first step toward alleviating the enormous health consequences of tobacco-related illness. We urge the Senate to pass it and to do so with a veto-proof margin. Its ultimate impact on the health of the public will then depend on the will of the FDA to issue sufficiently strict regulations and to enforce them. We agree with Justice Breyer, who in his 2000 dissent made it clear that the authority to regulate tobacco — the single product most dangerous to the health of the American public — belongs with the FDA.

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5. Food and Drug Administration v. Brown & Williamson Tobacco Corp. Opinion of the Court. 529 U.S. Sup. Ct. 98-1152 (2000).
6. Food and Drug Administration v. Brown & Williamson Tobacco Corp. Breyer S, dissenting. 529 U.S. Sup. Ct. 98-1152 (2000).

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