FDA Tobacco Product Regulations: A Powerful Tool for Tobacco Control

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The 2009 passage of the Family Smoking Prevention and Tobacco Control Act launched the most far-reaching public health intervention in a generation.[1] For the first time ever, the U.S. Food and Drug Administration (FDA) is fully authorized to use its regulatory authority to combat the nation's leading cause of preventable death: tobacco. However, FDA regulation is not only a powerful new tool to reduce tobacco-related disease and death, it also poses new opportunities and challenges to public health practitioners at every level of government, academia, research, and advocacy.

It is difficult to overstate the human and economic cost of tobacco use in the United States. Approximately 443,000 Americans die each year from diseases caused by cigarette use, and another 8.6 million suffer from at least one serious illness due to their smoking.[2,3] No less sobering is the fact that 20% to 25% of U.S. high school students currently use tobacco products and that each day, approximately 4,000 people younger than 18 years of age start smoking and 1,000 children younger than 18 years of age become regular smokers.[4] Because nine out of 10 adult smokers start smoking during their teenage years, these boys and girls are to become—to coin a term used in the past by some tobacco industry officials—the "replacements" for adult smokers as they quit or die.[5] Few would question that the preventable loss of nearly 500,000 lives each year merits an aggressive federal response.

Before FDA regulation of tobacco products, the principal components of the U.S. tobacco-control strategy included public education, prevention programs, treatment access, epidemiology and surveillance, tax/price incentives, and clean air measures. The collective impact of these efforts has been impressive: between 1965 and 2001, the U.S. adult cigarette smoking rate dropped from approximately 42% to nearly 23%.[6] However, declines in smoking prevalence have stalled during the last five years. In 2009, 20.6% of U.S. adults were smokers.[7] The trend has been similar among young people, with smoking rates among students in grades nine through 12 remaining at 20%.[8] Moreover, as state and local actions (e.g., taxes on cigarettes) have raised prices and public smoking restrictions have become more widespread, the development and use of smokeless and dissolvable tobacco products has increased. Now, with the

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addition of FDA tobacco product regulation as a new component to the nation's tobacco-control strategy, the public health community has an opportunity to wage a renewed—and expanded—war on tobacco use.

Unlike its partners in the tobacco-control community, the FDA is empowered to regulate tobacco products, including regulating tobacco product advertising, marketing, distribution, and manufacturing. Regulating tobacco product manufacturing includes developing product standards for nicotine levels or levels of other harmful ingredients, identifying requirements for products to be marketed as having a modified risk, and setting good manufacturing practices for tobacco products.

The American public has already seen the beginning of what tobacco product regulation means in practice. Since President Barack Obama signed the Tobacco Control Act on June 22, 2009, the FDA's actions to protect the public health have included launching and enforcing a ban on fruit- or candy-flavored cigarettes;[9] prohibiting the labeling of products with the misleading terms "light," "low," and "mild;"[10] and issuing a broad set of laws restricting access to and marketing of cigarettes and smokeless tobacco products to young people. These new laws, which are targeted to reduce tobacco use in young people, include setting and enforcing a national minimum age of 18 years for tobacco product purchases, banning the distribution of free cigarette samples, ending brand-name sponsorship of sporting events and concerts by tobacco companies, and ending all vending machine sales of cigarettes where children could access them.[11] In November 2010, the FDA introduced its proposal for new, specific graphic health warnings on cigarette packages and advertising and will determine how to set tobacco product standards on the design and characteristics of tobacco products to protect the public's health.

Undergirding these and other elements of the FDA's tobacco product regulatory strategy is the Tobacco Control Act's embrace of a population health standard. Using this standard requires the FDA to assess the impact of tobacco products on the population as a whole, product users and non-users alike. The application of a population health standard has always been the goal of tobacco-control programs and policies. However, it is relatively new to the FDA, which traditionally judges the safety and effectiveness of a regulated product based primarily on how it impacts those who use it.

Additionally, the FDA's strategy is grounded in a firm commitment to regulatory science, which is the use of scientific knowledge gained through carefully executed research to craft effective regulations and to identify emerging issues where future regulatory action may be appropriate. It is a process that brings public health practitioners, academia, and the broader research community together with regulators to develop new tools, standards, and approaches for assessing the performance of regulated products. In this respect, regulatory science is not only crucial to the work of the FDA and similar agencies, but it is also becoming elemental to the science of public health itself.

Two areas in which the FDA is employing regulatory science are in its consideration of tobacco product standards as well as tobacco product advertising and marketing programs. In these cases, assessing and expanding the scientific base to guide decision makers will result in the adoption of regulatory policies and practices that meet the public health goals intended in the Tobacco Control Act. In the arena of tobacco product standards, the FDA will employ regulatory science to:

- Establish sound manufacturing practices as related to tobacco product manufacturing, storage, and distribution.
- Examine the impact of regulatory actions on the exposure of users and non-users of tobacco.
- Create innovative tools for measuring the ingredients of various tobacco products that may be harmful or potentially harmful.
- Develop surrogate markers for tobacco exposure-related disease development in humans or relevant predictive systems.

To implement effective regulatory actions related to tobacco product advertising and marketing programs, regulatory science is also being used to:

- Further understand the advertising and marketing factors related to how young people acquire tobacco.
- Increase the effectiveness of health warnings and the graphic depiction of health effects of tobacco use on health warnings, with an emphasis on populations/subpopulations at risk of acquiring tobacco.
- Increase the effectiveness of advertising restrictions to minimize the acquisition of tobacco products by young people.
- Expand understanding of the roles various tobacco products play in the acquisition of tobacco products by young people.

Clearly, the importance of building and expanding the science base necessary to conduct these and other activities offers many opportunities for others

in the public health community to collaborate with the FDA. In fact, collaboration with public health partners is fast becoming a defining characteristic of FDA tobacco product regulation and related activities. For example:

- The State and Territorial authorities responsible for carrying out traditional tobacco-control programs have been and will become part of the FDA's national enforcement system (through contracts from the FDA).
- The FDA's public education responsibilities not only include building awareness of tobacco product regulations, but also promoting prevention in young people.
- The FDA's scientific programs—as well as many of its other activities—are grounded in the outstanding work of the Centers for Disease Control and Prevention, the Office of the Surgeon General, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, among others. Collaboration and expansion of those relationships is one key to supporting the FDA's responsibilities in tobacco product regulation.

However, it is important to point out that the FDA's ability to collaborate isn't without its limits. In passing the Tobacco Control Act, Congress set precise boundaries on the FDA's activities. Unlike the federal government's other tobacco-control initiatives, product regulation is funded by user fees that, under law, can only be used for efforts in direct support of the provisions of the Tobacco Control Act. This is why an array of tobacco-control programs that may be more than worthy of public support cannot be financed by the FDA.

In the months and years ahead, there will be numerous opportunities for the FDA to work in concert with its tobacco-control partners. And it is eager to do so. Tobacco product regulation may be a vital, new component of tobacco control, but at the end of the day, it is still one element of what must be a multipronged strategy.

As many in the public health community know, FDA regulation is only one element of a new federal assault against tobacco-related disease, disability, and death. HHS Secretary Kathleen Sebelius and Assistant Secretary for Health Howard Koh are implementing a comprehensive strategy to integrate tobacco-control activities throughout the department. Actions that are now part of the HHS initiative include expansion of comprehensive tobacco cessation benefits to all Medicare beneficiaries who smoke, enhancement of service capacities of the national network of state tobacco quitlines, changing social norms related to tobacco use by engaging in national counter-marketing media campaigns, and a new commitment to the use of regulatory science throughout the department. The HHS strategy will have the effect of catalyzing the positive impact of FDA authorities regulating the manufacture, distribution, and marketing of tobacco products.

When signing the Tobacco Control Act, President Obama may have summed up our challenge best by saying, "We know that even with the passage of this legislation, our work to protect our children and improve the public's health is not complete." Working together as one integrated tobacco-control movement, we have the opportunity to complete that mission and make the suffering caused by tobacco use part of America's past, not America's future.

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11. Public Law No. 111-31, §102.