Congress Should Establish a Tobacco Regulation Program at the Food and Drug Administration

William B. Schultz

This year, more than 400,000 people in the United States will die from a tobacco-related disease because they smoke cigarettes, just as 400,000 or more people have died early from tobacco each year for the past 20 years. It is more than the number of people who will die from automobile accidents, alcohol, AIDS, heroin, homicides, suicides, and fires, combined. Almost all of these Americans began smoking during childhood, and most have tried to quit. Unable to do so, many switched to low tar/low nicotine cigarettes, having been misled by the tobacco companies into believing that these products are safer than traditional cigarettes.

The federal government regulates foods, drugs, automobiles, and most other consumer products. It regulates workplace safety, the use of pesticides on the farm, and air quality. Although Congress mandated the familiar warning labels on cigarettes more than 40 years ago, there is no government agency charged with regulating this popular and deadly product.

The regulation of tobacco will be unlike regulation of any product on the market today. In contrast to drugs, foods, and medical devices, the goal of tobacco regulation will not be to require that the product be safe. Unfortunately, there is no such thing as a safe cigarette, and cigarettes kill about half of their regular users. Because 45 million Americans are addicted to tobacco products, a ban on cigarettes is not possible. Instead, the goal of a federal tobacco program must be to reduce tobacco use among children, to increase the number of adults who quit, and to adopt measures that make tobacco products less harmful.

Such a program will require wide-ranging expertise and significant resources. To reduce use among children, advertising directed at children would, consistent with the First Amendment, be restricted. To increase the number of adults who quit using tobacco products, effective nicotine replacement therapies and other cessation devices would be approved, but products that have not been shown to work would be prohibited.

Tobacco company promotion of products with unproven claims that they are safer (such as products marketed as "light" and "low") would also be illegal. In the future, no tobacco product could be promoted as "less harmful" or "safer" without first obtaining approval, based on sound scientific evidence, that those claims are accurate, much like prescription drugs must be approved as effective before they may be marketed. Finally, for those who continue to use tobacco products, a regulatory agency would have the authority to invest in research and to impose standards on the design and ingredients of these products to make them less harmful.

Successfully implementing such a program will require a broad range of regulatory skills. The agency’s expertise must include the evaluation of human data as well as First Amendment limitations on regulating claims. The agency would need the expertise to identify potential areas of research for the development of less hazardous products, and would have regulatory authority to inspect manufacturing facilities and to prosecute violations of the law.

The Food and Drug Administration (FDA) is the only regulatory agency that can do this job. FDA’s experience makes it the world’s leading authority on the design of studies to show whether drugs and medical devices work and on evaluating data to determine whether they are safe. It is responsible for regulating the claims that may be made about the benefits of drugs, medical devices, and foods, and for ensuring that their manufacturing facilities meet government standards. Today, FDA is the agency responsible for regulating tobacco cessation products such as the nicotine patch.

The other agencies that could be considered to do this job are far less qualified than FDA. The Federal Trade Commission enforces antitrust and advertising laws. It has expertise in law and economics, but not in the science of impact on health. The U.S. Department of Agriculture regulates agriculture, meat, and poultry and manages the government’s farm subsidy programs. It has expertise in agricultural products, but does not have the scientific background to do the job. The Centers for Disease Control and Prevention runs a tobacco research program and is expert in understanding disease. It has expertise in science, but it has no skills in devising a regulatory program or in enforcing the law. Finally, the Environmental Protection Agency regulates air, water, toxic waste dumps, and pesticides. It has expertise in law and science, but not in the law of advertising claims or the science necessary to regulate tobacco products. FDA is the only one of these federal agencies that has expertise and experience regulating products used by consumers, based on scientific evidence, for the purpose of protecting public health. FDA is by far the best agency to regulate tobacco products.

The principal argument against establishing a tobacco program at FDA is that the agency is already overburdened and short of the funds necessary to carry out its important responsibilities. In recent years, budgetary cutbacks have crippled the FDA food program, and just last fall Congress gave important new responsibilities to FDA with respect to monitoring drugs after they are approved. Due to resource constraints, the approval times for generic drugs have increased to a median time of almost 19 months, which many experts regard as unacceptable. Whereas the agency’s programs that are
funded by industry user fees, including the program to review new drug applications, have continued to operate effectively, the programs funded through Congressional appropriations have been starved for resources. There is no money in the FDA budget for a tobacco program.

Fortunately, a tobacco program at FDA would not compete with other FDA programs for resources. Instead, the legislation being considered by Congress includes a user fee assessed on tobacco manufacturers and importers. Once the program is up and running, this user fee will raise hundreds of millions of dollars a year, higher than funds currently appropriated for any FDA program, except the regulation of drugs. Thus, the tobacco program, which would be managed by a separate FDA tobacco center, would have more funds than Congress appropriated this year for the regulation of the food supply or the regulation of medical devices.

It has also been argued that the duties of regulating tobacco products will divert an FDA Commissioner’s attention from his or her other important duties. Whereas the Commissioner will have the responsibility for the overall direction of the program, the day-to-day work will be overseen by a new Director of the Center for Tobacco Products and the new staff. In any event, the importance of the opportunity to advance public health offered by an effective FDA tobacco program, in my opinion, cannot be overstated.

In evaluating prescription drugs, FDA officials worry about risks as rare as 1 in 10,000. Similarly, food safety officials monitor for extremely small risks, sometimes as small as 1 in 1 million. If a prescription drug causes even 50 deaths, it is front-page news. Meanwhile, every day, 1,000 children become regular, daily smokers, and every year more than 400,000 Americans die from smoking. Although measuring the effect of a new program is a speculative exercise, even a reduction of 10% of the yearly deaths caused by tobacco products would have an enormous public health effect, saving 40,000 lives every year, equivalent to the annual number of highway deaths.

Giving FDA the authority to regulate tobacco products is one of the most significant steps we can take to improve public health and to save lives. Congress should promptly enact legislation to establish this program.

Disclosure of Potential Conflicts of Interest

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