

Testimony of Kathleen Hoke Dacheille
FDA Center for Drug Evaluation and Research
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My name is Kathleen Hoke Dacheille and I am speaking today on behalf of the Tobacco Control Legal Consortium. I am the Director of The Legal Resource Center for Maryland Public Health Law and Policy at the University of Maryland School of Law, a legal center affiliated with the Consortium.

The Tobacco Control Legal Consortium is a nationally-recognized legal network for tobacco control policy. Drawing on experts in its seven affiliated legal centers, the Consortium works to assist states and communities with tobacco law-related issues, ranging from smoke-free policies to tobacco control funding to regulation of flavored tobacco products. The Consortium's team of legal and policy specialists provides legislative drafting and policy assistance throughout the public health community.

As you know, in June 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, giving the Food and Drug Administration unprecedented authority to protect the public health by regulating tobacco products. Because the ultimate success of the law depends on an active and engaged public health community that works to support the FDA with the best evidence and input available, the Consortium launched a special initiative to mobilize the public health community to improve and support the FDA's regulation of tobacco. In our work, we have studied the opportunities of federal regulation of nicotine and tobacco products and have identified gaps in regulation, which is what I would like to talk about today.

As the FDA contemplates regulating innovative products and treatments for tobacco dependence, the Tobacco Control Legal Consortium urges the FDA to do so as part of a comprehensive approach to the regulation of nicotine across FDA centers. It is imperative that the regulation of cessation and nicotine products by the Center for Drug Evaluation and Research be done in concert with the regulation of tobacco products by the Center for Tobacco Products. The failure to have a comprehensive plan for regulating tobacco and nicotine products will result in regulatory gaps, which will promptly be exploited by the tobacco industry, undermining the FDA's public health objectives.

For more than five decades, the tobacco industry has manipulated tobacco products to achieve the optimal manner in which to deliver the most effective dose of nicotine, with the goal of creating and sustaining addiction and thereby ensuring commercial success. As Judge Gladys Kessler found, the tobacco companies' "goal of their extensive efforts . . . to control the levels of nicotine delivery was to ensure that smokers obtained sufficient nicotine to create and sustain addiction" and the "financial viability of the tobacco industry as a whole" depends on this strategy. *U.S. v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006) (paragraphs 1493 and 1762).

Yet in 1994, not even 20 years ago, Representative Henry Waxman held a congressional hearing at which the CEOs of each of the seven largest tobacco companies testified that they believed that nicotine was not an addictive substance, even though internal tobacco industry documents indicate that they knew that nicotine was addictive as early as the 1960s. This maleficent behavior flourished in part due to the industry's success in preventing federal regulation of tobacco products. The Waxman hearing and subsequent public scrutiny triggered an even more concerted effort by the tobacco industry to prevent federal regulation of tobacco products.

In 1996, when the FDA asserted jurisdiction over tobacco products by promulgating regulations designed to reduce youth access, the tobacco industry mobilized to defeat the FDA's efforts. Tobacco product manufacturers provided form letters to tobacco retailers, placed petitions within retail stores for customers to sign, positioned letter-writing booths outside tobacco company cafeterias for employees to draft comments to the FDA, and encouraged the advertising industry to oppose the proposed rule on the basis of the anticipated reduction in advertising agency revenues. In total, the massive mobilization campaign yielded the largest response to a proposed rule in FDA history. According to the Federal Register (Volume 61, No. 168, 44418), the agency "received more than 700,000 individual pieces of mail, representing the views of nearly 1 million individuals." Tobacco product manufacturers also took to the courts, alleging the FDA lacked authority to regulate tobacco products. The industry prevailed in court and the lack of federal regulation of the products creating the leading cause of preventable death in the U.S. persisted for almost another decade.

In anticipation of, and in response to, the passage of the Family Smoking Prevention and Tobacco Control Act of 2009, tobacco product manufacturers have aggressively developed, tested, and marketed an array of new tobacco products, hoping to exploit loopholes in existing regulations. For example, as cigarette regulations have been implemented and cigarette use has declined, the industry has developed and invested in other tobacco products, such as snus and dissolvable tobacco products, the use of which has increased during this same period. And, although the large tobacco manufacturers were not principally involved in the development and marketing of the majority of electronic cigarettes on the market, recently they purchased e-cigarette companies—a strategy designed to protect the long-held practice of controlling nicotine delivery in a variety of forms. This development and investment in alternative means of nicotine delivery was a strategy that one tobacco company identified as a "high priority" in 1984, even noting that this priority outweighed any ethical issues posed by this strategy.

With such a wide range of novel tobacco and nicotine products available, it is important that the FDA's approach to nicotine be comprehensive and that any NRT regulations be developed in coordination with broad tobacco control laws. The agency must avoid creating gaps in which certain tobacco and nicotine products are unregulated. Failure to enact comprehensive laws poses serious risks to public health, from tobacco to the continuation of tobacco use by smokers and other tobacco users who may otherwise try to quit.

One example of a gap created in the absence of a comprehensive regulatory approach is related to e-cigarettes. As you know, the FDA initially attempted to regulate e-cigarettes as drug delivery devices, but the regulation was struck down in *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010). The *Sottera* Court distinguished between tobacco products and drugs, and held that e-cigarettes and other products made or derived from

tobacco can be regulated as “tobacco products” under the Act. Further, the court found that e-cigarettes are not drugs or drug delivery devices unless they are marketed for therapeutic purposes.

In response to *Sottera*, the FDA announced its intention to regulate e-cigarettes as tobacco products and plans to issue further guidance on the regulation of e-cigarettes. The FDA has stated its intention to propose regulations that would extend the agency’s “tobacco product” authorities in Chapter IX of the Food Drug and Cosmetics Act, which currently only apply to the types of products specifically listed in the Act, to other categories of tobacco products that meet the statutory definition of “tobacco product” in Section 201(rr) of the Act. The additional tobacco product categories would be subject to general controls, such as registration, product listing, ingredient listing, good manufacturing practice requirements, user fees for certain products, and the adulteration and misbranding provisions, as well as to the premarket review requirements for “new tobacco products” and “modified risk tobacco products.” In sum, as of now, none of the Act’s tobacco related provisions – including the provisions regarding claims that certain products are safer than others – apply to e-cigarettes.

As mentioned, the *Sottera* decision states that products made or derived from tobacco can be regulated under the Tobacco Control Act unless they are “marketed for therapeutic purposes,” in which case they are regulated as drugs and/or devices. To date, the Center for Drug Evaluation and Research has not yet issued guidance or a regulation on what constitutes “therapeutic” claims for e-cigarettes. In the meantime, the FDA issued a number of warning letters in 2010 to electronic cigarette distributors for various violations of the Federal Food, Drug, and Cosmetic Act including “violations of good manufacturing practices, making unsubstantiated drug claims, and using the devices as delivery mechanisms for active pharmaceutical ingredients.”

The lack of regulations or guidance from the Center for Drug Evaluation and Research or the Center for Tobacco Products is troubling due to the fact that these products – the effects of which are largely unknown – are heavily marketed and available throughout the country. Much of the marketing implies that these products are safer than tobacco products and can be used as cessation aids, without any evidence to substantiate those claims. Large tobacco companies, which have excelled in marketing nicotine products throughout the world, have bought e-cigarette companies to expand their businesses and, presumably, to increase addiction and dependence among consumers, steps necessary to maintain their profitability.

Just as troubling, the *Sottera* decision leaves a gap in regulatory authority where a product makes no therapeutic claim and contains no tobacco. For this reason, it is essential, from a public health perspective, that the FDA take a coordinated approach to regulating nicotine.

The tobacco industry has been exploring expansion into the NRT market for more than a decade, and it is beginning to implement those plans. In August of this year, Reynolds American, the parent company of R.J. Reynolds and American Snuff Company, entered the nicotine-replacement therapy market with the test launch of several new products. The test launch marked the beginning of a transformation of Reynolds American into what President and CEO Daniel Delen described as “a total tobacco company.” The new products being launched include Zonnic NRT gum, which the company is marketing through its Nicovum pharmaceutical

subsidiary. Other products in the works from Reynolds American include an electronic cigarette, nicotine extract products such as lozenges and smokeless pouches and pellets.

This activity is particularly concerning in light of Judge Kessler's 2006 opinion in *U.S. v. Philip Morris*, in which she found that the tobacco industry: for decades knew about nicotine's pharmacological properties and addictive nature; incorporated design techniques into their products to assure delivery of precise levels of nicotine that were necessary to maintain addiction; and took public positions, suppressed and concealed research, and destroyed documents so that the information would not be available to federal regulatory agencies. In light of Judge Kessler's ruling that the tobacco industry conspired to defraud the American public about the dangers of tobacco products, including that it can and does control nicotine levels to sustain addiction, it seems unlikely that Reynolds American is investing in NRT products to help reduce addiction to nicotine and encourage cessation. Instead, it seems quite likely that Reynolds and other tobacco companies are expanding into the NRT business to further their business of keeping consumers addicted to tobacco products. For this reason, it is essential that FDA's centers work together to regulate nicotine products in a comprehensive manner.

In sum, we strongly urge the FDA to develop a comprehensive plan for regulating tobacco and nicotine products to avoid creating regulatory gaps that undermine the FDA's public health objectives.

Thank you.