On the WLF Legal Pulse

Timely commentary from WLF's blog

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

August 30, 2021

With ENDS Deadline Looming, FDA Must Ignore Activists' "Regulate to Eliminate" Demands

by Glenn G. Lammi

The Food and Drug Administration (FDA) is facing a court-ordered deadline of September 9 to act on 550 companies' applications for marketing approval of electronic nicotine delivery systems (ENDS) and other "deemed" new tobacco products. FDA's impending decisions arise from over three decades of legal, legislative, and regulatory battles and negotiations. Most of the participants in those battles—manufacturers, activists, elected officials, and health regulators—agreed that a ban on all nicotine-containing products would be a public-health disaster. Instead, they negotiated passage of the 2009 Tobacco Control Act (TCA), a law that vastly expands FDA's authority over tobacco and sets out an approval pathway for non-combustible products that could reduce harms to consumers.

In the months before the approaching deadline, some activists who supported the TCA seem to be suffering from buyers' remorse. Six prominent anti-tobacco organizations have urged FDA to abandon the Premarket Tobacco Product Application (PMTA) process and instead subject ENDS products to the drug-approval process.

FDA attempted to regulate tobacco as a medical product twice, once in 1996 and again in 2009, just after Congress passed the TCA. Federal courts intervened each time. The agency should reject the activists' invitation to turn back the clock on tobacco regulation and continue reviewing ENDS applications in the scientific and apolitical manner Congress intended.

TCA Passage and the PMTA Process

Without the support of strident tobacco foes like Dr. David Kessler, Matthew Myers, and over 1,000 public-heath groups, the Tobacco Control Act would not have become law. In exchange for the law's strict controls over tobacco manufacturing, sales, and marketing, organizations like the Myers-led Campaign for Tobacco-Free Kids accepted the legality of existing tobacco products and an approval pathway for new products..

In designing that approval pathway, FDA embraced its increased regulatory authority and set a rigorous standard that new product applicants must meet. The applicants must prove that their innovations are "appropriate for the protection of public health," a standard that considers how the product will impact both current smokers and non-smokers. FDA is reviewing PMTA applications with the concept of harm reduction in mind. In announcing FDA's comprehensive plan for tobacco regulation, FDA's Commissioner and its Center for Tobacco Products director wrote, "the FDA is

---

Glenn G. Lammi is Washington Legal Foundation's Executive Director and Vice President of Legal Studies.

committed to striking an appropriate balance between protecting the public and fostering innovation in less harmful nicotine delivery."

Activists Revert to Their Prohibitionist Ways

Rather than applaud the high standards for PMTA approval and FDA's desire to improve public health through innovation, many of the same activists who sought the TCA's passage now demand that FDA take a drastic detour. In an April 27, 2021 letter to acting FDA Commissioner Woodcock, six advocacy groups broadly declared: "If any e-cigarette, . . . can be shown to be effective for smoking or tobacco cessation, its manufacturer should submit evidence of this therapeutic benefit to CDER [FDA's Center for Drug Evaluation and Research]."

The letter's demand contravenes congressional intent and federal-court precedents. If Congress had meant for a nicotine-containing product whose delivery mechanism moves consumers away from smoking to be reviewed as a drug, why would lawmakers have bothered to legislate an entirely new review process? Section 387a(a) of the TCA explicitly states that "tobacco products . . . shall be regulated by the [FDA] under this subchapter and shall not be subject to the provisions of subchapter V." Subchapter V of the Food, Drug & Cosmetic Act (FDCA, which the TCA amends) governs FDA's regulatory authority over prescription drugs and devices.

Perhaps the anti-tobacco activists believed FDA would ignore this clear legislative statement in 2021 because FDA itself ignored the statement in 2009. That year, FDA categorized an e-cigarette as an unapproved drug-device product in an enforcement action. The manufacturer successfully sued to enjoin FDA's regulation and in December 2010 a three-judge panel of the U.S. Court of Appeals for the D.C. Circuit (featuring Judges Brett Kavanaugh and Merrick Garland) affirmed the injunction in *Sottera, Inc. v. FDA*.

The appeals court noted that Congress passed the Tobacco Control Act in part to fill the regulatory gap left by the U.S. Supreme Court's *FDA v. Brown & Williamson* decision. In *Brown & Williamson*, the Supreme Court held that a 1996 FDA regulation defining tobacco products as drug-device combinations was inconsistent with the FDCA and thus invalid. The *Sottera* court reasoned that Congress's passage of the TCA, as well as the law's clear statement that the FDCA's drug and device provisions do not apply, reflect Congress's intent that FDA regulate tobacco *only* under the TCA.

The *Sottera* court also echoed the *Brown & Williamson* Court's common-sense concerns about subjecting a tobacco product to the drug or device approval process. That process requires manufacturers to prove their products will be safe and effective for their intended uses. How can a tobacco-product maker establish their product as "effective," let alone "safe," given the products' known risks? If a manufacturer cannot prove safety and efficacy, FDA must order the product removed from the market. That Catch-22 means that any ENDS product that effectively switches consumers from smoking to vaping must be banned. While that may well be the anti-tobacco activists' intended outcome, prohibition is decidedly *not* what Congress intended with the TCA.

The activists' April 21 letter accurately states that FDA *can* regulate a tobacco product as a drug if the manufacturer makes therapeutic claims about the product. The letter goes on to assert that certain ENDS manufacturers have emphasized e-cigarettes' value as an alterative to smoking, and that such claims amount to therapeutic smoking-cessation claims. But PMTA applicants must explain their products' potential as a switching mechanism to FDA so the agency can conduct health risk assessments. And the agency has dictated via rulemaking that "FDA does not consider claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine,

or that a tobacco product will provide the same effects as another tobacco product . . . to bring a tobacco product within its drug and device authority." Simply put, communications on a product's switching virtues are not therapeutic claims.

Stay the Course

FDA thus far has shown no interest in the activists' demand that it reinvent the PMTA process. The agency must know that the activists' preferred path is not in the best interest of public health. The promise of harm reduction that ENDS products offer is real. Such products are far from risk-free, but as an August 19 American Journal of Public Health essay stated, "We believe the potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks." Without alternatives to combustible tobacco, cigarette sales would likely rebound, an end result that even ENDS opponents can't possibly prefer.

The activists' frontal assault on the PMTA process should concern not only the 550 tobacco-product applicants but also any FDA-regulated business whose market access depends on a transparent, science-based approval regime.