

Congress, FDA struck out on e-cigarettes

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Five years ago, during a break in the debate over the Affordable Care Act (or Obamacare), Congress passed the Family Smoking Prevention and Tobacco Control Act, which gave the Food and Drug Administration (FDA), the federal watchdog over medications and medical devices, the authority to regulate tobacco products. Unlike health care reform, the FDA tobacco bill passed both houses of Congress with large bipartisan majorities and was trumpeted by the new Obama administration as a triumph over Big Tobacco.

Mere weeks before passage of the tobacco bill, disagreements arose regarding a new product — electronic or e-cigarettes. At the time, e-cigarettes were quite new to the U.S. They were expensive and were manufactured by just a handful of companies. Today, there are hundreds of manufacturers, and most convenience stores sell e-cigarettes at prices comparable to a pack of Marlboros.

The FDA recently proposed a rule deeming e-cigarettes to be tobacco products, which would bring them under the new requirements in the bill, and it is considering more than 70,000 public comments received on the proposal. This five-year delay in regulatory action came about because e-cigarettes were deliberately left out of the 2009 FDA tobacco bill.

The FDA tobacco bill was nearly a decade in the making, emanating from a Supreme Court decision in 2000 that rejected a 1996 attempt by the FDA to assert jurisdiction over cigarettes, when FDA Commissioner David Kessler had reasoned that cigarettes are nicotine drug-delivery systems and therefore are medical devices.

After contentious Congressional hearings on the bill in 2007, the 2009 debate in the Senate focused on whether the FDA is the right agency to regulate tobacco, on whether to provide incentives for smokers to quit and on whether there should be the same kind of evaluation mechanisms for the new tobacco program as exist for the drug and med-

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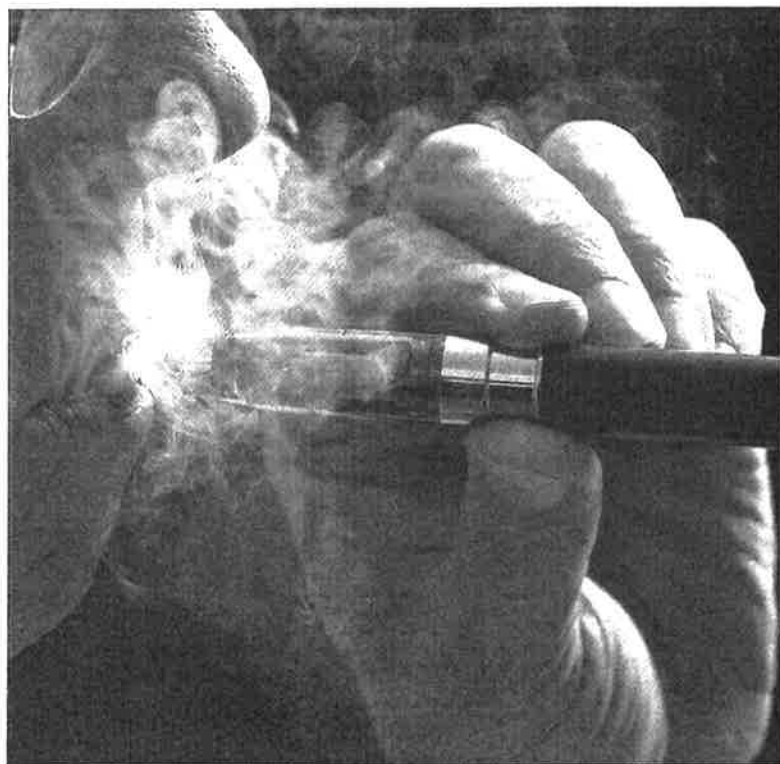
ical-device programs. A provision in the 2009 FDA tobacco bill clearly states that drugs and medical devices are not tobacco products, presumably to prevent duplicative regulation by different centers within the FDA.

By 2009, it wasn't clear if e-cigarettes met the bill's definition of tobacco products. There were differing opinions among e-cigarette manufacturers about how to proceed, but there was consensus that if e-cigarettes had to be regulated by the FDA, it would be better to be considered a tobacco product than a medical product.

During the Senate committee debate on the bill, Republican members offered for consideration language that would grant the FDA authority to regulate e-cigarettes as tobacco products and restrict the agency from regulating them as medical products. But the sponsors of the bill and the FDA leadership under the new administration wanted the option to use the FDA's medical product regulatory authority, so they were not open to including "regulate once but not twice" language. The amendment was withdrawn.

Advocates pointed to a provision in the bill, in which the FDA could "deem" products to be tobacco products, as a path forward on e-cigarettes. The deeming provision was ostensibly to address future products the authors and regulators couldn't yet envision that might not meet the definition of tobacco product, but which the agency would want to regulate anyway.

"Deeming" happens through notice-and-comment rulemaking under the Administrative Procedures Act (APA). While the APA confers important advantages such as public input and transparency, it can result in a lengthy process, requiring the agency to respond to every comment it receives — and the result is still subject to challenge.



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Over the past couple of years, as the FDA has explored whether to deem e-cigarettes to be tobacco products, e-cigarettes have gone essentially unregulated. Manufacturers have proliferated, costs have dramatically dropped, and e-cigarettes are everywhere.

If the FDA had been willing to agree in 2009 that they were tobacco products and not medical products, the agency would have had vast authority over e-cigarettes. For the past five years, the FDA could have acted against adulterated or misbranded products, required manufacturer registration and ingredient-reporting, and inspected manufacturers, among other actions. It's impossible to know how much ground was lost because of the FDA's overreaching position that e-cigarettes were possibly medical products.

Much of the public discussion on e-cigarettes has been caught up in a

long-running debate on harm reduction. Although it appears unlikely that e-cigarettes will cause lung cancer or any of the diseases attributable to cigarettes or exposure to second-hand smoke, the harm-reduction hypothesis seems worthy of study. What is beyond question is that in attempting to swing the fences five years ago, the proponents of the FDA tobacco bill struck out. We thus lost an opportunity to learn more about e-cigarettes, to slow their introduction, to temper health claims and to ensure their safe and consistent manufacture.

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