Hazy Outlook

BY BARRY S. SCHAEVITZ

What FDA mandates could mean for the future of e-cigarettes

E-cigarettes have become increasingly popular since they entered the market almost 10 years ago. Product innovation is the norm. Most importantly, there's growing discussion about the role e-cigarettes may play in a tobacco harm reduction strategy. An uncertain regulatory future, however, could limit consumer choice, stifle product innovation and end a promising discussion on a means of protecting the public health—one of the primary pillars of the U.S. Food and Drug Administration's (FDA) mandate in regulating tobacco.

On June 22, 2009, President Barack Obama signed into law legislation that for the first time gave the FDA authority to regulate tobacco products. Until that time, it was settled law—established by the U.S. Supreme Court—that the FDA did not have such authority. Specifically, the 2009 Family Smoking Prevention and Tobacco Control Act gave the FDA immediate regulatory authority over cigarettes, smokeless tobacco and roll-your-own tobacco, and the authority to regulate "any other tobacco products that the Secretary by regulation deems to be subject" to the law.

The law defines "tobacco product" in relevant part as "any product made or derived from tobacco that is intended for human consumption." The FDA can therefore regulate e-cigarettes, as the nicotine in e-cigarettes is derived from tobacco plants. Any doubt was removed by a 2011 court decision, holding that the FDA must regulate e-cigarettes as "tobacco products" unless they are offered for therapeutic or smoking-cessation purposes. On April 25, 2014, the FDA proposed a "deeming regulation" to deem all products meeting the statutory definition of "tobacco product"—including e-cigarettes—subject to the law. At the time of writing, the FDA was reviewing the roughly 135,000 comments it received on the proposed deeming regulation and a final rule was expected at any time.

The proposed deeming regulation attempts to address a number of complex issues and raises a number of others. Perhaps most significant for the e-cigarette space and its growing base of adult customers is the date—the "predicate date"—used to determine whether products already on the market will need to go through a lengthy and (by the FDA's admission) expensive premarket product review process. When Congress was considering the Tobacco Control Act in 2009, it decided that products "commercially marketed" in the U.S. as of Feb. 15, 2007, would not need to go through this review process. While such products would still be subject to the other provisions of the Tobacco Control Act—such as registration, ingredient reporting, harmful constituent levels and good manufacturing practices—they could stay on the market without a costly premarket review process.

While the products Congress determined in 2009 were most in need of immediate regulation—including cigarettes—would need to "look back" only two years to get to the Feb. 15, 2007, predicate date, products regulated under the proposed deeming regulation—including e-cigarettes—will need to "look back" eight years or more (depending on when the final rule is issued). This will put e-cigarettes at a tremendous disadvantage compared to cigarettes and could result in many or most of these products being required to go through the premarket review process. A likely result will be that many e-cigarette products are removed from the market, thereby ignoring if not violating one of the primary pillars of the FDA's mandate.

A few points about the February 2007 predicate date: First, it's completely arbitrary. Congress wanted to ensure—rather logically—that products brought to market after manufacturers knew how Congress intended to regulate them would not avoid the premarket review process. The Feb. 15, 2007, date is simply the date on which the Tobacco Control Act was introduced in Congress. There's nothing more significant about it. Second, a number of e-cigarette and public health stakeholders have urged the FDA to adopt a different predicate date for products like e-cigarettes. This would put immediately regulated products (like cigarettes) on equal

footing on this issue with subsequently regulated products (like e-cigarettes). The FDA's only response has been to say it lacks legal authority to do so. Many of the industry and public health stakeholders have argued that in fact the FDA does possess this authority. More importantly, leading members of Congress—the body that wrote and passed the Tobacco Control Act—have advised the FDA that it does possess such authority. Third, it's critical to remember that the predicate date does not exempt, as some have claimed, a product from the FDA authority. Any product commercially marketed in the U.S. before the predicate date still has to comply with all provisions regarding the product class.

What does the predicate issue mean in practical terms for e-cigarettes? Because e-cigarettes were not even available—let alone "commercially marketed"—in the U.S. before 2007, it means virtually every single e-cigarette brand will have to go through the premarket review process. The FDA itself estimates that such a review could take up to 5,000 hours and could cost up to $300,000—for each brand. On top of the cost, it's not clear that any manufacturer willing and able to go through the premarket review process will be successful and therefore be able to keep a product on the market. (To date, no new product application has been approved by the FDA.) The result of defying logic and common sense (not to mention statutory language and congressional guidance) could be the removal of a majority of e-cigarettes currently on the market.

Moreover, a 2007 predicate date will place a huge roadblock in front of the innovation that is so important for the e-cigarette space to reach its potential. Another provision of the Tobacco Control Act allows products on the market before the predicate date to act as "predicates" for products that come to market later. If the two products are found by the FDA to be "substantially equivalent," the latter product would not have to go through that costly premarket product review process. This substantial equivalence pathway is the means by which new products have been approved by the FDA since 2009. Because most e-cigarettes were not commercially marketed in 2007, a 2007 predicate will effectively close this pathway to the category.

Finally, public health agencies and officials are loudly debating the individual- and population-level health effects of e-cigarettes. Public Health England recently reported that e-cigarettes may be 95 percent less harmful than combustible cigarettes. The FDA has said "e-cigarettes may have the potential to reduce the death and disease toll from overall tobacco product use." The FDA should not only allow this discussion to continue but also encourage it. Effectively closing the e-cigarette category is bad for public health and contrary to the FDA's mission. V

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