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*Op-Ed*

# Electronic Cigarettes: Gateway to Understanding the FDA?

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A FUNNY THING HAPPENED IN THE DEBATE OVER ELECTRONIC cigarettes. For years, proponents of this new nicotine delivery system expressed deep skepticism about the idea of US Food and Drug Administration (FDA) regulation. "The e-cigarette industry enjoys a sort of free market utopia, where small companies remain profitable, and able to conduct business successfully," wrote one industry proponent in April 2014.[1] Electronic cigarette companies first fought the regulation of their technology as a drug delivery device. Then, after winning in court, the emerging industry objected to being regulated as a tobacco product.[2]

Recently, however, electronic cigarette supporters have been calling for the FDA to establish standards quickly. Poor-quality products and false labeling are undermining the market, one supporter wrote in the *New York Times* in January 2015. She added that the agency, by not yet establishing "sensible regulations . . . is making the situation worse."[3]

So which is it? Is the FDA poised to kill or to embrace a new technology, by acting or by not acting?

The confusion over the FDA's role in addressing electronic cigarettes exemplifies common misunderstandings of the regulatory process.

To start, much of the commentary on regulation mistakenly assumes that the FDA's first step in regulation is taking a position on a particular product's inherent value. So on the one hand, advocates assume that if the FDA endorsed electronic cigarettes, it would then pursue a "green light" regulatory approach with the goal of making them widely available. On the other hand, opponents are convinced that if the FDA opposed the new technology, it would pursue a "red light" regulatory strategy and snuff them out.

Working within this same paradigm, advocates and opponents on many different issues relentlessly lobby the agency. It is not rare for the FDA to hear from one patient or consumer whose life was saved by

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a technology asking that it be made more widely available, and then immediately afterward to hear from a family member of someone whose life was lost asking that it be removed from the market.

In fact, there is no "thumbs up" or "thumbs down" moment before the FDA commences with regulatory action. Rather than focusing on the inherent worth of a drug, device, biologic, or even tobacco product, the agency is primarily concerned with the technology's impact on the public. Where the benefits of a product exceed its risks, the FDA recognizes potential public health value and, where the risks exceed the benefits, it sees harm.

With respect to pharmaceuticals, for example, it is widely understood that a medication with serious side effects may be "safe and effective" as a first-line chemotherapy for cancer but is not "safe and effective" for minor ailments. By approving labeling for one use but not the other, the FDA is not making a judgment on the medication itself but, rather, on how it is to be used.

This is also the situation for electronic cigarettes. It is reasonable to assume that the FDA recognizes both their potential value, such as helping smokers of cigarettes and cigars to quit, and their potential harm, including serving as a gateway for youth to nicotine and raising the risk for a lifetime of tobacco use, addiction, and disease.

When there is evidence of both potential benefits and potential risks of a product in actual use, the FDA generally pursues neither a "green light" nor a "red light" approach to regulation. Instead, the agency aims for a "yellow light" strategy that puts into place conditions to maximize the benefits while minimizing the risks.

For high-risk pharmaceuticals, the FDA has restricted sales to specific pharmacies, has limited prescribing to specific subspecialties, and has imposed requirements for patients to participate in registries. In the case of electronic cigarettes, the agency could consider a wide range of provisions for the products to appeal to longtime cigarette and cigar smokers but not to young people. For example, the agency might well cast a skeptical eye on products with flavors, including strawberry shortcake or brownie sundae, with special appeal to children.

Through its own expert review as well as public engagement and comment, the FDA tries to get regulations correct the first time. But perfection, of course, is not possible. The agency therefore collects data to understand what changes should be made over time. Unlike true

believers (or opponents), whose minds are made up from the beginning, an effective regulator must be prepared to study evidence and also to change course.

For medications and medical devices, the FDA can independently develop or require manufacturers to conduct long-term studies to assess the balance of benefits and risks for patients. For electronic cigarettes, it is essential that the agency establish a surveillance system that can provide empirical data to guide changes in oversight over time.

That flexibility exists may come as a shock to many engaged with the FDA. In fact, it is widely assumed that by choosing a regulatory path, the regulators must act to the fullest extent of the law, thereby handcuffing themselves to the steering wheel of a policy and, if necessary, following it right over the cliff.

Such misunderstanding feeds into the sense of panic as the agency begins to regulate in a new area. But as a public health agency, the FDA has a long track record of using its authority innovatively to set the regulatory thermostat to the right level.

For example, for many years, a number of unapproved medications, such as pancreatic enzymes, played an important role in clinical care. Despite having the authority to take these products off the market, the FDA instead set up a process and a timeline for manufacturers to meet key regulatory milestones. Similarly, when fragments of an extraneous virus were found in a widely used childhood vaccine, the FDA could have banned the product from the market. Instead, the agency advised clinicians to delay using the product until a safety evaluation was conducted and then permitted its use based on reassuring findings.

Had the FDA been able to regulate electronic cigarettes as drug delivery devices, the agency (as it argued in court) could have taken a reasonable, stepwise approach to regulating the product.[4] As the FDA moves forward with regulating electronic cigarettes under its authority for tobacco products, it can do the same.

People who engage with the FDA through the lens of a specific technology have difficulty accepting that the FDA is keeping score with its own scorecard. Rather than access and sales, what counts is that over time, regulation is based on science, and advances the health of the American people.

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