FDA Cigarette Regulations Protect Big Tobacco, Not Public Health

Jacob Grier | Feb. 27, 2014 1:30 pm

Last week the Food and Drug Administration (FDA) exercised its authority to remove tobacco products from the market for the first time ever. “It's a big deal,” Matthew Myers, president of the Campaign for Tobacco-Free Kids, told *The New York Times*. Mitch Zeller, director of the FDA's Center for Tobacco Products, called the order “historic” and says it demonstrates “the role and power of regulation.” Countless news articles reported the ruling and noted its significance.

What nearly all of them missed, however, is that the manufacturer of the products in question–hand-rolled Indian cigarettes called bidis–says they have been off the American market for years. An attorney for Jash International, the company that makes the Sutra brand banned by the FDA, says they stopped selling them when a legal prohibition on flavored cigarettes took effect in 2010.

That the FDA's first significant action against a tobacco product turns out to be a mostly symbolic gesture is emblematic of the agency's record on tobacco thus far. The Tobacco Control Act gave the FDA authority over tobacco in 2009. In the time since, it has received approximately 4,000 applications for new tobacco products. With over four years in operation and currently more than 150 employees working on reviews, the FDA has managed to rule on only thirty-four of them, a slow pace it blames on deficiencies in the applications. The hold up has halted the release of new products and protected big tobacco companies from competition, an outcome that has implications for the cigar and e-cigarette industries that the FDA may target next.

The biggest change ushered in by the Tobacco Control Act is that all new cigarettes must receive explicit approval from the FDA before being allowed on the market. Products introduced prior to March 2011 have been provisionally allowed, but almost all of the 500 applications submitted since then are stuck in regulatory limbo. The Tobacco Control Act implies that these reviews should take only 90 days. The vast majority of the applications have been under review for more than a year, and only two cigarettes have ever successfully made it through the process. (A handful of smokeless tobacco products and accessories such as rolling papers have also been approved.)

To win approval, new products must prove that they are “substantially equivalent” to products already on the market, raising no new questions of health in regard to initiation, cessation, or harm to the user. Companies seeking to release a new product must submit a detailed comparison between it and a predicate product that is already on the market.

According to Bryan Haynes, a partner in the Tobacco Team at the law firm Troutman Sanders, the two approved cigarettes were relatively easy cases. Both from Lorillard, owner of the Newport brand and one of the three "Big Tobacco" companies in the United States, the approved products simply modified existing Newports by removing menthol and using fire safe paper. That they raised no new questions of health was obvious. The rejected applications from Sutra appear to have been deficient in equally obvious ways, including a failure to specify a predicate product.

Though these cases were clear on the merits, they are distinguished by their convenience too. Notably, Lorillard had filed a petition protesting the FDA's failure to act on applications within a reasonable period of time. The agency eventually denied the petition, but only after granting approval to the two Newport cigarettes. In doing so it avoided a potential legal challenge that could have ended up in court.

The contrast between the only cigarettes the agency has ever approved and the only ones it has ever ordered off the market–the former from a big tobacco company able to throw its weight around, the latter from a foreign company with very little presence in the United States–suggests that political expedience may have played a role in the FDA's decisions.

Further questions about the scientific basis of the FDA's decision making are raised by Hestia Tobacco, a start-up company whose regulatory struggles I profiled for *The Atlantic* in March of last year. Merely getting the Hestia brand name approved by the FDA required an entire year of inquiries. Then its substantial equivalence application was submitted in June of 2012. Nearly two years later, hardly any progress has been made on it. Indeed, as of last week the agency still hasn't determined whether Hestia has sufficiently proved that the cigarette to which it compares itself, Natural American Spirits, was commercially marketed in time to qualify as a valid predicate product. Rather than evaluating criteria relevant to health, Hestia is stuck arguing over old magazine advertisements and attempting to track down American Spirits invoices from seven years ago.

Hestia's difficulties highlight the anti-competitive effects of FDA regulation. The barriers to entry are immense and stacked in favor of existing tobacco companies that have extensive records detailing their earlier products.

These barriers are baked into the Tobacco Control Act, which resulted from an uneasy alliance between the Campaign for Tobacco-Free Kids and tobacco giant Philip Morris. It was speculated at the time of its passage that Philip Morris supported the bill to lock in its 50 percent share of the market, with competitor RJ Reynolds dubbing the law the "Marlboro Monopoly Act." If that was the intent, the gamble has certainly paid off: Since 2011, Marlboro has had to face competition from only two new cigarettes.

None of this would perhaps be of much concern if FDA regulation only affected cigarettes. It's a hassle for cigarette companies, but ultimately not of great consequence for public health. However, the agency has indicated that it intends to expand its authority to potentially include cigars and e-cigarettes, with potentially disastrous results for both.

The market for cigars is much more dynamic than that for cigarettes, with hundreds of new products coming out each year. Aficionados seek new cigars from their favorite brands or blenders, rolled into new forms, or featuring leaf from different origins. The market is much more like that for wine than for a generic commodity. If the FDA applies the same standards to cigars as it does to cigarettes, it would bring new releases to a standstill and end the premium market as we know it. Director Zeller stated recently he recognizes that the cigar market is different, which is an encouraging sign, but it's anyone's guess what this awareness will mean in practice.

Regulation of the emerging market for e-cigarettes is even more fraught with peril. Though the anti-smoking community is divided on the products, hardly anyone doubts that they are far safer than the real thing. Arguably, e-cigarettes have done more to reduce cigarette consumption than any action taken by the FDA. Yet new restrictions could halt their evolution as an effective replacement for tobacco. And since the law requires the FDA to evaluate products based on how they affect society as a whole, the agency could restrict their sale even though they are unambiguously safer than real cigarettes for the individual user.

Additional concern about FDA regulation of e-cigarettes is raised by the interests of the pharmaceutical industry. As e-cigarettes become popular as means of quitting or reducing smoking, they compete with traditional nicotine replacement therapies like gums and patches. Documents released last week reveal that GlaxoSmithKline, producer of Nicorette, urged European Union officials to impose stricter regulations on e-cigarettes. Here in the United States, Zeller arrived at his FDA post directly from working as a consultant to the same corporation.

Although the agency hails its ruling against Sutra bidi cigarettes as a landmark, the insignificance of the action underscores just how unprepared the FDA's Center for Tobacco Products is to take on additional responsibilities. In four years it has accomplished little more than a bureaucratic freezing of the cigarette market. Until it proves capable of making decisions efficiently, objectively, and fairly, it should refrain from extending its authority even further.