

# Three years later: an assessment of the implementation of the Family Smoking Prevention and Tobacco Control Act

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I had the privilege of serving at the US Food and Drug Administration (FDA) for 7 years and helping oversee the agency's 1994–1996 investigation of the tobacco industry. That effort enabled FDA to assert jurisdiction over cigarettes and smokeless tobacco products. From 1997 to 2000, FDA began to regulate these products and enforce certain youth access restrictions. In March 2000, after a lawsuit brought by the tobacco industry, the US Supreme Court overturned the FDA assertion of jurisdiction.

It was nearly a decade before FDA returned to the business of regulating tobacco products. On 22 June 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA)<sup>1</sup> into law.

The FSPTCA passed with overwhelming bipartisan support in both houses of the US Congress. It gives FDA broad regulatory powers to control the manufacture, sale and distribution of tobacco products. The law itself, and FDA's approach to implementation, have important implications for global tobacco product regulatory initiatives under the relevant provisions of the Framework Convention on Tobacco Control. Now that just over 3 years have passed, it is time for an overall assessment of the implementation of the FSPTCA.

The law is built around a public health standard that represents a departure from the traditional 'safety and efficacy' standard in the Food, Drug and Cosmetic Act. This standard obligates FDA to regulate tobacco products in a manner that 'is appropriate for the protection of the public health.'<sup>2</sup> Equally important, the public health decisions FDA makes must take into account key population-level behavioural considerations, including the

impact of regulation on initiation, cessation and re-initiation of tobacco use.<sup>3</sup>

FDA faced the daunting task of building an entire regulatory program while simultaneously meeting various mandatory deadlines in the FSPTCA. The agency has done an admirable job of creating a new regulatory infrastructure and deserves high marks for meeting all its Congressionally-imposed deadlines. Some of the most significant actions the Congress required the agency to take included a ban on descriptors like 'light' and 'low tar,' reinstatement of most of the marketing and sales restrictions in FDA's original 1996 final rule designed to reduce the number of new, young smokers and completion of a rulemaking requiring graphic warning labels on all cigarette packs.

In addition to the mandated actions, the agency has also launched several important initiatives that deserve praise. These include commissioning a major longitudinal study of tobacco use and behaviour,<sup>4</sup> and releasing a detailed statement of research priorities.<sup>5</sup>

Nonetheless, many in the tobacco control community expected FDA to have made more progress to date in two areas: (1) interpreting the public health standard and population-level behavioural criteria, and (2) applying those analyses when actually using the key regulatory tools contained in the FSPTCA. FDA did issue non-binding guidance covering what should be included in various industry submissions. But the agency has yet to issue any policy articulating binding standards and criteria in three important areas that fall under its regulatory authority:

- The agency needs to issue mandatory 'product standards' that would limit the allowable levels of ingredients and constituents in finished tobacco products and the smoke of combusted products. It has been well over a year since FDA's advisory committee

concluded that the marketing of menthol cigarettes contributes to youth initiation. FDA has not taken any action towards a menthol product standard other than to announce a second, completely discretionary review of the relevant scientific evidence.

- FDA must promulgate binding policy explaining the criteria it will use to determine whether an application for a new product will be subjected to a more robust premarket evaluation, or a shortened process because the product is 'substantially equivalent' to an older tobacco product that had been on the market as of 15 February 2007. These criteria will determine whether new or altered products can be sold.
- The agency must decide what criteria will be employed to determine whether a manufacturer is able to make an exposure reduction or risk reduction claim under the provisions of the law governing so-called 'modified risk tobacco products.'

Another area where FDA inaction has created a void involves e-cigarettes. FDA sought to regulate e-cigarettes as a drug or drug delivery device. But in early 2011, the agency acquiesced to a court ruling that e-cigarettes can only be regulated as tobacco products as long as they do not make any therapeutic treatment claims.<sup>6</sup> FDA's current rules only govern cigarettes, smokeless tobacco, and roll-your-own tobacco. The rules do not automatically apply to e-cigarettes or other products containing nicotine derived from tobacco, including certain dissolvable tobacco products.

When it acquiesced to the court decision, FDA announced that it would create a regulatory framework for these products. Unfortunately, FDA has not yet acted. As a result, e-cigarettes and several other products reside in a regulatory 'no man's land,' where the products continue to be marketed and sold without any regulatory oversight. This has spawned entirely new non-e-cigarette products brought directly to market as tobacco products under the court ruling, but without any premarket review and approval by FDA. One recent example of this is 'Verve,' a 'tobacco-derived nicotine product' that Altria is selling in outlets in Virginia.<sup>7</sup>

FDA has not shared a strategic vision of how it will interpret and apply the FSPTCA and expand its authority over e-cigarettes and other tobacco-based products. The tobacco control community

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remains supportive of the agency's efforts, but many are concerned by the lack of an adequate strategic dialogue with FDA.

The tobacco industry has been strangely silent as pending applications at FDA pile up. According to a recent FDA response to a Freedom of Information Act request by Greg Connolly from the Harvard School of Public Health, at least 3293 industry applications for substantial equivalence determinations by FDA were pending at the end of April 2012.<sup>8</sup> Interestingly, that same Freedom of Information Act response reveals that tobacco companies have not filed a single *new* product application. It is not unreasonable to conclude that the industry's strategy is to bring all new products to market employing the substantial equivalence short-cut.

The agency has offered no public explanation of why it has not ruled on any of the thousands of applications. We are left to wonder about the actual nature of the review process, and the current status and timing for action on those applications. On a related point, the FSPTCA mandates the public disclosure of applications for modified-risk tobacco products. To date, not one of those applications has been made public.

Having worked on FDA-related issues for 30 years, including time as a senior FDA official, I will hypothesise that part of the challenge at FDA is, in fact, FDA itself.

FDA is a regulatory agency with an ingrained culture of painstaking, process-oriented deliberation. This institutional mindset historically served the agency well. But when confronted with public health challenges such as HIV/AIDS in the 1980s, or the 2009 grant of authority over tobacco products, action is sometimes sacrificed to process. In this environment internal service entities (legal, economic analysis, budget, contract and human resources) can dominate and slow progress. It falls to the leadership of FDA to ensure the requisite level of public health urgency and a commitment to doing business differently as it tackles its FSPTCA responsibilities.

Fortunately, these are still 'early days' for tobacco product regulation in the USA. At the 1994 world tobacco control

conference in Paris, Nigel Gray said the yardstick for measuring the success or failure of major tobacco control initiatives is a decade. With 3 years down, and seven to go, FDA must begin to confront the critical issues now. This is especially important given the expected impact that FDA action, or inaction, will have on product regulation efforts to be undertaken in other countries. FDA must be seen as a decisive leader willing to take the regulatory actions needed to protect the public health.

As we envision the next 7 years of FSPTCA implementation, here are some key principles for FDA to embrace:

- ▶ A significantly greater commitment to transparency and genuine strategic engagement with the tobacco control and public health communities than have existed so far. Philip Morris International is apparently quite happy with its recent substantive discussions with FDA.<sup>9</sup> The same cannot be said for many who work to reduce the death and disease from tobacco use.
- ▶ Dedication to whatever internal reforms are needed so that all parts of FDA work together and with appropriate urgency to maximise the positive public health impact that can come from science-based tobacco product regulation under the FSPTCA.
- ▶ Recognition that FDA has a historic opportunity to forge a comprehensive nicotine regulatory policy that cuts across the agency's Tobacco and Drugs Centres. Experts agree that there is a distinct 'continuum of risk' when it comes to products that deliver nicotine.<sup>10</sup> FDA is uniquely poised to shift current tobacco users away from the deadliest form of nicotine delivery (conventional cigarettes) to the cleanest and safest (currently medicinal nicotine products). Designing agency-wide nicotine regulatory policy will help establish the strategic priorities that need to drive the work of the Tobacco Centre.

On behalf of all of those who launched the first FDA tobacco regulatory efforts in the 1990s, and those who worked to get the FSPTCA enacted, let us pause at this

3-year milestone to rededicate ourselves to doing all that we can to support effective implementation of this important law. Along with that support, however, there is both the hope and expectation that the needed actions highlighted here will occur quickly.

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