A Dangerous Loophole in the Process for FDA Approval of New Tobacco Products

The Family Smoking Prevention and Tobacco Control Act gives the U.S. Food and Drug Administration unprecedented authority to regulate tobacco products.\(^1\) One of the most powerful tools available to the FDA under the Tobacco Control Act is to decide whether or not a new tobacco product can be introduced to the market.\(^2\) In theory, this gatekeeping role for the FDA should allow it to prevent those products with the most potential to harm public health from ever making it to retail store shelves.

However, the tobacco industry has exploited a loophole that allowed it to introduce thousands of new addictive and deadly products without FDA authorization and the FDA has done very little thus far to stop this manipulation. In fact, while the FDA has publicized its actions on some product applications, it has failed to prioritize the removal of non-compliant, loophole-exploiting products from the market. At the same time, it has continued to authorize new products for sale, allowing the tobacco product market to grow.

This problem is mostly hidden from the public health community. The FDA has not made it a priority to explain the fairly technical application approval process – or how the agency is implementing this process – in sufficient depth, using terms that the general public can understand. This fact sheet will explain the process for authorizing the marketing of new products and provide information on FDA’s actions to date.

FDA Authority over New Products

The Tobacco Control Act creates three pathways by which the tobacco industry can receive FDA authorization to put additional products on the market: 1) Premarket Tobacco Product Applications, 2) Substantial Equivalence Reports, and 3) Exemptions from Substantial Equivalence Reports. Each pathway has its own review process.

1) **Premarket Tobacco Product Applications (PMTA)**

The “Premarket Tobacco Product Application” pathway for new products is what most would imagine when they learn that the Tobacco Control Act requires the FDA to decide whether or not new products can enter the market. The FDA often refers to the pathway by the acronym, “PMTA.” The pathway is intended to be the primary process for the FDA to decide whether it is
appropriate for new tobacco products to enter the market. This pathway should be used for any products that are different from all other products marketed before February 15, 2007. An application should be denied by the FDA if: 1) the product does not appropriately protect public health, considering the product’s impact on initiation and cessation; 2) the manufacturing process for the product does not meet established standards; 3) the labeling of the product is false or misleading; or 4) the product does not meet a product standard set by the FDA.

Little information is available regarding how the FDA reviews these applications because the tobacco industry did not submit any applications of this type until August 2013 and then only submitted four. The FDA had 180 days to approve or deny these applications, and in February 2014, the agency announced that it rejected the submissions because they were deficient. Because they were rejected and could be modified and then resubmitted, the FDA did not disclose their contents.

2) *Substantial Equivalence Reports (SE)*

The “Substantial Equivalence Report” pathway, or the “SE” pathway, is the review process for new products that are similar to products already on the market. This process is intended to be used for products that have the same characteristics as products marketed as of February 15, 2007, or that have different characteristics that do not raise different questions of public health.

This product pathway requires a comparison between an existing product, which the FDA calls a predicate product, and the new product yet to be marketed. If the FDA finds that the existing product was commercially marketed (not test marketed) in the United States on February 15, 2007, it can be named as a predicate product on this type of application. A product that is authorized for sale under this pathway can also serve as a predicate product on another application even if the authorized product was not on the market until after February 15, 2007, as long as the product is compliant with any product standards established by the FDA.

3) *Substantial Equivalence Exemption (SE Exemption)*

The third method the industry can use to seek FDA authorization a new product is to file a request for exemption from Substantial Equivalence stating that, for example, a new product is so similar to a predicate product (described above) that the difference between the two is minor and the submission of a full report demonstrating substantial equivalence is not necessary to protect public health. The Tobacco Control Act provides an example of a product that might be exempt from the SE report process: a product that is only different from an existing product because an additive was deleted or added or where the level of an existing additive was increased or decreased.
The Loophole that Allows Thousands of Products to Avoid Premarket Review

Under the first and third pathways listed above – the pathways for products that are entirely different from products already on the market (PMTA) or for the products that the industry claims should be exempt from the SE report process due to their similarity to products already on the market (SE Exemption) – no products can be introduced to the market until after the FDA has reviewed and approved the industry’s applications.

Similarly, for any industry applications filed after March 22, 2011, under the second pathway – seeking FDA approval to sell new tobacco products because they are similar to other products already on the market (SE) – the new products cannot be sold until the FDA grants permission.

However, industry applications that were filed under the SE pathway by March 22, 2011 are treated differently. The Tobacco Control Act states that the new products listed in these
applications can be introduced to the market and stay on the market until the FDA reviews the applications and decides to require that the product be removed from the market. The applications that fall within this category are called “Provisional Substantial Equivalence” or “Provisional SE” reports, all other SE reports are called “Regular” SE reports.

With its sophisticated knowledge of the Tobacco Control Act and instinct for profit-seeking at the expense of public health, the tobacco industry orchestrated a massive exploitation of this loophole in the new product authorization process. The industry flooded the FDA with Provisional SE reports just before the March 22, 2011 deadline, bringing the total number of Provisional SE reports to 3,517.\(^\text{18}\) This activity is striking considering that the industry filed only 959 Regular SE reports after March 22, 2011,\(^\text{19}\) and only 63 total product applications under the pathways that are entirely subject to premarket review (4 PMTAs and 59 SE Exemption requests).\(^\text{20}\) This means that 77% of the 4,539 applications that the FDA has received to allow new products to enter the market were submitted through the loophole that allows the industry to sell the products before they can be reviewed by the FDA.\(^\text{21}\) Figure 2 attempts to put this tactic into perspective.

**Figure 2.**

![Tobacco Product Applications](image)

While the FDA publicizes its actions on pending SE reports, even considering the actions taken on Regular SE reports, the total amount of FDA action in the context of all SE reports is very small. The agency’s action with respect to Provisional SE reports is even smaller. In the four years since the vast majority of the Provisional SE reports were submitted, the FDA has only acted on 11 Provisional SE reports.\(^\text{22}\) After 181 industry withdrawals, 3,325 reports remain, representing products that can be sold to consumers even though they have not been subject to any federal oversight. In addition, only 142 of these reports are currently under scientific...
review. The FDA’s stated commitment to prioritizing Regular rather than Provisional SE reports perpetuates this problem caused by the loophole. Figure 3 shows FDA action for Regular and Provisional SE reports separately as well as all both categories combined.

**Figure 3.**

**Provisional SE Reports - 3,517 total**
( can enter the market without preapproval)

**Regular SE Reports - 959 total**
(preapproval required)

**All SE Reports - 4,476 total**

Because Regular SE reports represent products that are not yet on the market, delayed review of these reports poses no threat to public health. However, delaying action on Provisional SE reports, as the FDA continues to commit to doing, allows the tobacco industry to continue to sell deadly and addictive products that have not been scrutinized by the FDA.

**The Proposed Deeming Regulation Multiplies the Problem**

The public health threat caused by the FDA’s continued delay on Provisional SE reports will be multiplied if the FDA finalizes the Deeming Regulation as it is currently proposed. The proposed regulation will bring additional classes of tobacco products under the FDA’s regulatory authority. According to the agency’s proposal, the FDA expects to receive 54 PMTAs, 4,208 SE reports, and 1,402 SE Exemption requests in the first two years after the regulation takes effect. These estimates may be low because the FDA expects that the regulation will result in over 13,000 new products being brought under its authority and long delays in the finalization and implementation of this rule will allow more tobacco products to be introduced in the interim. All of these new product applications will need to be reviewed, as will the FDA’s existing backlog of applications. That problem cannot be avoided.
However, the FDA has proposed to defer enforcement of premarket review of all new products that would now fall within its jurisdiction – regardless of the pathway – for 24 months following the regulation’s implementation. While a delay in the FDA’s approval or denial of the sale of new products may not normally be a grave concern of the public health community, the FDA proposes to establish that 24-month window as a new provisional period, meaning that the FDA would allow the tobacco industry to market even more new products until the FDA reviews the applications for those products and decides whether to order the products removed from the market.

The FDA can solve this problem and best protect public health by taking two steps. First, it must prioritize its review of existing Provisional SE reports filed under the loophole created by the Tobacco Control Act. Second, the FDA’s Deeming Regulation must not create another loophole in the premarket review process by allowing a provisional period for new tobacco product applications for the products that will fall under its jurisdiction in the future.

For more in-depth information on the FDA’s review of tobacco product marketing applications, see the Consortium’s Tobacco Product Applications webpage with other resources on this topic, including our FDA Premarket Review Video Series.

Last updated: April 2015

The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health. The Consortium does not provide legal representation or advice. This document should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.

Notes

8 U.S. FOOD AND DRUG ADMIN., Total Number of Product Submission Received or Filed in the Month, http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all (last visited December 3, 2014).
An applicant may also indicate that a report “is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health,” or that “an exemption is otherwise appropriate.” 21 U.S.C. § 387e(j)(3)(A)(ii)-(iii).

FDA data on incoming applications is current through September 30, 2014, while the number of industry withdrawals and FDA actions is current through November 30, 2014.