New FDA Policy Puts Industry Interests Before Public Health

On March 4, 2015, the U.S. Food and Drug Administration announced a policy change that will have big repercussions for public health. After rescinding this policy in the face of an industry lawsuit, the agency reinstated the policy on September 8, 2015.

The Tobacco Control Act requires tobacco companies to receive authorization from the FDA before they can begin to market a new product. For decades, manufacturers manipulated tobacco products to increase their addictiveness and attractiveness. As a result of these industry practices, many products sold today are far more deadly than those sold in the past.

That was supposed to end when the Tobacco Control Act was passed in 2009. This law makes the FDA the gatekeeper of the tobacco product retail market. Because all tobacco products marketed after the passage of the Tobacco Control Act require authorization from the FDA before they can be marketed, all regulated products fall into one of a few categories.

1) **Grandfathered Products** – These are products that were commercially marketed in the United States on February 15, 2007. They can stay on the market as long as they comply with any new regulations issued by the FDA.

2) **SE Products** – These are products that were not on the market on February 15, 2007, but which have been authorized to market by the FDA because the agency found them to be substantially equivalent to products already on the market. There are 101 such products currently on the market as of March 2015.

3) **Pending Provisional SE Products** – These are products for which manufacturers are seeking authorization to sell as substantially equivalent but the FDA has not yet made a decision. Under the Act, so long as manufacturers introduced these products to the market by March 22, 2011, and applied for a provisional SE authorization, the products are allowed to stay on the market until the FDA makes a decision. More than 3,500 applications for provisional SE products were submitted to the FDA. The agency has issued orders removing only eleven of these products from the market and some of the applications have been voluntarily withdrawn by manufacturers. Unfortunately, that means thousands of these products remain on the market without a decision from the FDA that their sale is appropriate for the protection of public health.
The Pending Provisional SE Product category has an additional twist that is at the heart of the problem with the new FDA guidance document issued on March 4. In order to market a new product in the third category, a manufacturer’s application must identify a Grandfathered Product or an SE Product in addition to the new product that it wishes to sell. The Grandfathered Product or the SE Product is called a predicate product. The manufacturer’s application to the FDA must explain how the differences between the predicate product and the new product will not have a negative impact on public health.

Until the FDA’s new policy was issued, the three categories listed above were the only categories of products that could be sold in the U.S. Of these, the first and third categories contain products which the FDA has not yet evaluated. The public health danger caused by these products is significant and the Consortium has been urging the FDA to prioritize the review of the Pending Provisional SE Products. Many of them should be removed from the market. The Consortium has more resources about this problem.

Not only has the FDA failed to take swift action on Pending Provisional SE Products, but also its new policy will establish a fourth category of products that can be marketed without any oversight, like Grandfathered Products and Pending Provisional SE Products.

The FDA’s new policy allows a tobacco product manufacturer to name a Pending Provisional SE Product as a predicate product and then make a modification that creates an entirely new product. That means that for the more than 3,000 currently marketed Pending Provisional SE Products, the tobacco industry can create dozens, or even hundreds of permutations, potentially leading to thousands of new products. Federal law prohibits this practice. The Tobacco Control Act states that only Grandfathered Products and SE Products are allowed to be used as predicates. The practice of allowing the tobacco industry to list a Pending Provisional SE Product as a predicate product is an abuse of the FDA’s discretion.

In addition, the FDA’s decision to allow the tobacco industry to market these products before the agency has a chance to review the applications is also outside of the FDA’s discretion. The law requires the agency to issue an order before a product can be marketed, except for Grandfathered Products and Pending Provisional SE Products. Allowing the introduction of new products under other circumstances is not allowed by the Tobacco Control Act. It is impossible to justify this action from a public health perspective, as the agency is required to do when it takes action.

This new FDA policy only serves the interests of the tobacco industry; it does not protect public health. Please take the time to submit a comment so that the FDA knows that the public health community will not stand on the sidelines while it makes decisions that jeopardize public health.