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Commentary

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FDA deeming rules for e-cigs are now in effect: what does this mean?

Commentary

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With the rapid popularity of electronic cigarettes, many in tobacco control have been urging the FDA for years to jump in and regulate these new devices. It has been a long nine-step process[1] that started in April 2014 and finally became effective on Monday, August 8, 2016.

These new regulations are not only for electronic cigarettes but also a wide variety of tobacco products that were not included in the 2009 Family Smoking Prevention Tobacco Control Act (TCA). Originally only cigarettes, smokeless and roll-your-own tobacco were subject to FDA regulation.

However, within the TCA, the FDA was granted the authority to extend regulation to other tobacco products. In other words the FDA could "deem" other tobacco products to fall within the guidelines of the TCA and subject to regulation. Which is what happened last week. The expansion of the FDA regulation now includes: electronic cigarettes, cigars, hookahs, pipe tobacco, cigarillos (little cigars), nicotine gels and dissolvable.

Effective immediately these tobacco products join cigarettes, smokeless and roll-your-own tobacco in that they cannot be sold to anyone under the age of 18 and a photo ID is required. Free samples can no longer be distributed and vending machines sales are limited to adult only facilities. Any new tobacco product introduced will be required to submit a Pre-Market Tobacco Application (PMTA).

These additional tobacco products will also be subject to other requirements of the TCA:

i. Registering manufacturing establishments and providing product listings to the FDA (by June 30, 2017);

ii. Reporting ingredients (by February 8, 2017), and harmful and potentially harmful constituents (by August 8, 2019);

iii. Placing health warnings on product packages and advertisements (by August 8, 2017);

iv. Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA (by August 8, 2017).[2,3]

"The actions being taken today will help the FDA prevent misleading claims by tobacco product manufacturers, evaluate the ingredients of tobacco products and how they are made, as well as communicate their potential risks." (2)

What has caused the most controversy is the requirement for a PMTA. Within the TCA, tobacco products are divided into two categories:

1. "Tobacco products as customarily marketed" which were on the market prior to February 15, 2007. While this term has not be defined, it is generally recognized as any tobacco product that has been marketed to the public prior to this date are "eligible for grandfather status".[4] An example would be traditional cigarettes that have been on the market for decades.

2. Any tobacco product introduced after February 15, 2007 is considered to be a new product and subject to submitting a lengthy Pre-Market Tobacco Application (PMTA) to the FDA.[5] An exception would be if a manufacturer claimed that their new product is "substantially equivalent" to an existing product and there are no significant changes to the tobacco product.

An example of this is Camel Crush cigarettes, manufactured by R.J. Reynolds, which contained a bead of menthol in the filter. The user could "crush" the filter to release the flavor. It went on sale in August 2008. Reynolds submitted an application that held that Crush cigarettes were substantially equivalent to other cigarettes. However, the FDA deemed Crush to be a new tobacco product and not something that was substantially equivalent to other grandfathered tobacco products and therefore would need to have a PMTA to be filed and approved by the FDA before Camel Crush could be available for sale to the public. In September 2015 the FDA ordered that sales and distribution of Camel Crush be stopped.[6]

The controversy with electronic cigarettes is that few were commercially available prior to February 15, 2007, so almost all would require a PMTA which could be expensive. Many small manufacturing companies may not be able to handle the cost, thereby effectively putting them out of business while the larger traditional tobacco companies do have the financial resources to cover the costs. The FDA estimates the cost for a PMTA to be between $117,000 to $466,000,[4] while manufacturers and others put the figure at costing millions of dollars.

Traditional tobacco companies largely manufacture first generation closed systems called a "cig-a-like" or "one-n-done" which are not as effective in delivering nicotine as second and third generation open systems called "mods" or "personal vaporizers". Opponents to the deeming rule are concerned that innovation will be stifled since it

is these other electronic cigarette manufacturers that have expanded the variety of devices including mods which are more efficient at delivering nicotine to the user. Since people smoke for the nicotine, the argument is made that it is these newer devices that are effective at helping smokers stop cigarettes and the FDA is condemning smokers to continue smoking instead of offering an alternative because of the financial and regulatory burden of filing a PMTA. Plus, there is also a risk that even after filing an application, it could be rejected by the FDA.

Recognizing that these newly deemed tobacco products are already on the market, the FDA is postponing enforcement for submitting a PMTA for up to 24months. There are different time periods depending on whether the manufacturer is submitted an application for a substantially equivalent product or a PMTA for a new product.

Opponents of these new deeming rules want the grandfather date for these newly regulated products to be changed. But according to the FDA: "Only an Act of Congress can change the grandfather date. In the proposed rule, the FDA stated it lacks the legal authority to change the grandfather date and specifically asked for the public to comment on this legal interpretation. The agency received a large number of comments in response to this statement, but none provided a legal theory that would support changing the date".[4]

The Cole Bill (H.R. 2058 - FDA Deeming Authority Clarification Act of 2015) is currently in Congress to change the grandfather date. It basically says that a tobacco product is not a tobacco product until it is deemed a tobacco product. This would move the grandfather date for all these new products to August 8, 2016 instead of February 15, 2007.[7] Similar wording has been included as amendments to other bills in Congress but so far the effort has not been successful.

It is important to remember that changing the grandfather date would affect not only electronic cigarettes but all the other newly deemed tobacco products, which will affect the regulation of future tobacco products as well. Instead of submitting a PMTA, a manufacturer could file a substantially equivalent application meaning that the new product is the similar enough to another product on the market as of August 8, 2016 with a minor change that would not make it a new product (See Camel Crush example above which took 7years from introduction into the market until a cease and desist letter was issued).

Changing the grandfather date would substantially change how the FDA regulates these newly deemed tobacco products. In the TCA besides the items listed above (registration of manufacturing facilities etc), for products grandfathered in (such as traditional cigarettes), the TCA:

i. "Allows FDA to implement standards for tobacco products to protect public health. For example, FDA has the authority to regulate nicotine and ingredient levels".[8]

It is this vague guideline that would let the FDA make rules and regulations regarding any grandfathered tobacco products. The difference is that this would put the onus on the FDA to set the regulatory standards for a product to meet instead of the manufacturer being required to do the necessary product testing and research for a PMTA.

Complicating the matter is an exception to a PMTA. If a manufacturer wants to make the claim that a product could be used to stop smoking, this would be a "therapeutic use". Then an application would be for a different division of the FDA. Instead of the being under the Center for Tobacco Products, an application would be submitted to the Center for Drug Evaluation and Research or the Center for Devices and Radiological Health[5] Each would have different requirements.

Because many claims have been made by electronic cigarette manufacturers about cessation, within these deeming rules the FDA sought to clarify the difference between "tobacco products as customarily marketed" (ie. for recreational use) and tobacco products with a "therapeutic use" (i.e. for the use in cessation products). The intended purpose of a product would dictate which agency within the FDA would have jurisdiction over the tobacco product.[9]

It is expected for lawsuits to be filed against the FDA and/or Congress could amend the TCA (i.e. Cole Bill or amendment) which could cause many years to pass before any significant regulation on electronic cigarettes or the other variety of newly deemed tobacco products to actually go into effect.

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None.

Conflict of interest

The author declares no conflict of interest.

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