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FDA Finalizes Ruling on E-Cigarettes

By Hank Campbell — May 5, 2016

In November of 2015, the American Council on Science and Health was called on to testify at the White House on the proposed deeming regulations, making all tobacco products subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

This was six years in the making so we dismissed concern about some of the rules, like stronger regulations on cigars and pipes. We recognize that tobacco regulation was being geared toward potential future products like a nasal spray, so we limited our key recommendation to changing the "grandfathered" date for products.

The FDA issued its final ruling today [1] and is going to stick with its early date for when products will not have to undergo approval as a new product.

In 2009, a 2007 substantial equivalence date was quite reasonable, but by 2015 the popularity of e-cigarettes and other "vaping" devices had really taken off, and some 100,000 products existed. A 2007 date was positively archaic. To put that in broader technology terms, people were still using a Blackberry in 2007. The Samsung Galaxy, arguably the best phone on the market today, didn't even exist.

It seemed arbitrary and punitive to effectively ban so may products unless they could survive a daunting regulatory approval process. Obviously, popularity means some regulation is a good thing. New rules will prohibit the sale of e-cigarettes to children and will allow the government to regulate the contents of the products for safety -- we can only wish they would do the same thing with supplements and nonsense like homeopathy -- but with a 2007 date, a number of products will sudden become illegal.

This may be just regulatory maneuvering because the FDA knows Reps. Tom Cole, R-Okla. and Sanford Bishop, D-Ga., have amended the Fiscal Year 2017 House Agriculture Appropriations bill to move the predicate date until the effective date of the final regulations, which will be summer of 2016.

If that does not happen, companies will have to show substantial equivalence of their product, exemption from substantial equivalence, or undergo premarket tobacco product review, the last of

which can be quite expensive.

E-cigarettes seem to be primarily used for tobacco harm reduction and smoking cessation, so if the market is impacted it could be a real negative for public health, but the free market is quite resilient. We'll have to see how this ends up in final form before making judgments.

Links
[1] https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-10685.pdf