

health; set standards manufacturers must meet before they are allowed to make health-related claims; and authorize the FDA to regulate the content of tobacco products.¹¹⁵

However, the deeming rule did not extend the prohibition on characterizing flavors to these newly regulated products despite the substantial evidence that flavors play a critical role in youth use of these products. The FDA itself proposed removing these flavored products from the marketplace in the version of the rule that it sent to the White House Office of Management and Budget (OMB) for review, but OMB deleted this provision from the final rule. This key change was revealed in a [“redline” version of the rule](#) published on May 27, 2016, which showed changes made by OMB.



The deleted provision would have removed flavored e-cigarettes, cigars, hookah and other newly regulated products from the market by November 2016 and required those products to receive pre-market authorization from the FDA before re-entering the marketplace. This provision would also have affected menthol-flavored products. The deleted portion of the rule provided 17 pages of scientific evidence to support removing flavored products from the market, concluding that these products should be removed “given the attractiveness of flavors, especially to youth and young adults, and the impact flavored tobacco products may have on youth initiation.”¹¹⁵

Despite this change in the final rule, the FDA retains another pathway for reviewing and removing flavored tobacco products from the market. The rule requires all new tobacco products introduced after February 15, 2007, to undergo FDA scientific review to determine their impact on public health, including their appeal to kids (products can remain on the market for up to three years from the rule’s effective date – until August 2019 – while undergoing this review). The FDA has the authority to remove from the market products that it determines are harmful to public health, including the many sweet-flavored e-cigarettes and cigars that have been introduced during this time period.



However, two bills introduced in Congress would significantly weaken the FDA's authority over these newly regulated products and make it much more difficult, if not impossible, for the FDA to remove sweet-flavored products from the market. One bill (H.R.1136) would "grandfather" e-cigarettes, cigars and other newly deemed tobacco products already on the market (those introduced between February 15, 2007, and August 8, 2016, when the FDA's rule took effect) and exempt these products from the critical FDA review needed to determine their impact on public health. Tobacco companies would also be able to introduce similarly flavored products in the future. In short, this bill would allow existing flavored tobacco products to stay on the market and make it easier for tobacco companies to introduce new ones.

In September 2016, The New York Times reported that Altria drafted the legislation to change the "grandfather" date for e-cigarettes, cigars and other newly-regulated products and that it was endorsed by R.J. Reynolds. The Times reported that the legislation as introduced "pulled verbatim from the industry's draft."¹¹⁷ Reynolds and Altria make two of the best-selling e-cigarette brands in the U.S. (Vuse and MarkTen).

A second bill (S.294/H.R.564) would exempt what the tobacco industry calls "traditional large and premium cigars," but defines such cigars so broadly that it could also exempt some cheap, machine-made, flavored cigars that are widely used by kids. This legislation invites manufacturers to manipulate their products to qualify for the exemption and continue targeting kids, as they have done before.

In addition to being introduced as stand-alone legislation, such measures have also been added in recent years to the U.S. House appropriations bill that funds the FDA. They could be considered again this year as Congress finalizes appropriations for the rest of Fiscal Year 2017 and considers appropriations bills for Fiscal Year 2018. A large coalition of public health and medical groups has repeatedly urged Congress to reject these measures.

Given the strong evidence summarized in this report that flavored tobacco products such as e-cigarettes and cigars are attracting and addicting a new generation of kids, Congress must reject any proposals to weaken FDA oversight of these products. In fact, the FDA should strengthen its new rule by prohibiting all flavored tobacco products, including menthol products. As the FDA itself has demonstrated and as this report documents, there is more than sufficient scientific evidence to support such a prohibition. Eliminating all flavored tobacco products is a critical step in preventing tobacco companies from addicting another generation of kids and reversing our nation's progress in the fight against tobacco.

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