THE FDA'S NEW TOBACCO REGULATORY PLAN:

What You Need to Know

On July 28, 2017, U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb announced a new plan for the FDA's regulation of tobacco products.

The plan has several facets, some of which have the potential to dramatically decrease the death and disease caused by tobacco products in the U.S., while other aspects of the plan may result in increased harm. The FDA emphasized this plan is one unified path forward, not a series of unconnected policies. To participate effectively in the regulatory process, the public health community needs to understand how all parts of the plan fit together. As with any policy, benefits depend upon successful implementation. At this point, many important implementation details have not been disclosed or even decided. The following information is based on what is currently known about the FDA's plan.

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What's in the plan?

1. Reducing nicotine in cigarettes

The most well-known part of the plan is the FDA's intent to implement a product standard that mandates lowering nicotine content in cigarettes to a minimally addictive level.

Best Possible Outcomes	• Youth experimentation with combustible products may not lead to physiological addiction and regular use. • Many adults who are addicted to nicotine will likely either quit using tobacco products entirely or switch to non-cigarette tobacco products. • As many smokers quit, fewer people will be exposed to secondhand smoke.
Potential Concerns	• A product standard that only addresses cigarettes without also covering other combustible products will see its benefits severely compromised, as many smokers may switch to little cigars, which pose health harms and risks similar to cigarettes, and would retain highly addictive levels of nicotine. • While cigarettes will no longer be addictive, people who continue to smoke will still be exposed to hundreds of highly toxic and carcinogenic chemicals that are not associated with the nicotine level of the product. • Secondhand smoke continues to pose a dangerous risk to the health of non-smokers, regardless of the nicotine level in the products. • Public misconceptions about a product standard may lead to a mistaken belief that no tobacco products are addictive or that a standard makes products less harmful.

2. Increasing access to and use of FDA-approved therapeutic nicotine products

A nicotine-reduction product standard's potential to reduce tobacco use significantly, rather than simply cause product switching, will depend greatly on widespread access to effective, FDA-approved therapeutic nicotine. At this point, the FDA has provided few details on how it intends to improve access to and use of therapeutic nicotine, although the agency has begun to gather information from the public.

Best Possible Outcomes	• Even without a nicotine product standard, improved access to and higher usage rates of therapeutic nicotine should decrease rates of tobacco use.
Potential Concerns	• Significant changes to the drug approval processes could affect the safety and efficacy of cessation treatments.

3. Considering the role of flavors in tobacco products

The FDA has said that it intends to collect information on both the role that flavors play in attracting youth and in helping smokers switch to potentially less harmful products. The FDA has specifically called out menthol as a flavor that it will examine and consider prohibiting.

Best Possible Outcomes	• A prohibition on menthol as a characterizing flavor in cigarettes would likely lead to significant reductions in youth initiation into cigarette use and significant cessation by adult menthol smokers, and would likely have an especially beneficial effect on vulnerable populations with high rates of menthol use. • A prohibition on all characterizing flavors in all tobacco products would likely go even further to reduce initiation and increase cessation.
Potential Concerns	• The FDA already has sufficient data to act on menthol and the additional optional regulatory step that the agency has said it will take only serves to delay action.

4. Potentially deregulating premium cigars

The FDA plans to reexamine data related to the public health impact of premium cigars, repeating a process conducted recently with the promulgation of the Deeming Regulation.

Best Possible Outcomes	• No public health benefits.
Potential Concerns	• Even if premium cigars are not a youth-initiation product and are mostly used by adults, FDA regulation still benefits adult users. No evidence suggests that health harms and risks differ significantly between premium cigars and other cigars; thus, rolling back existing regulations would harm public health.

5. Changing premarket review

Undoubtedly the quickest change to FDA policy following the July announcement was a major change to premarket review for products regulated by the deeming rule. The FDA has long delayed the full implementation of premarket review, which is designed to prevent new products from entering the market without FDA authorization. The latest change allows products marketed as of August 8, 2016, to remain on the market without even submitting a marketing application until August 8, 2021, for combustible products and until August 8, 2022, for non-combustible products. With a timely application, these products can remain on the market indefinitely until the FDA orders their removal.

Best Possible Outcomes	• No public health benefits.
Potential Concerns	• Millions of tobacco products will remain on the retail market without proper oversight by the FDA for three to four years longer than under previously adopted guidelines. • Delaying application deadlines and allowing products to remain on the market indefinitely after the deadlines encourages the submission of deficient marketing applications.

When will the plan be implemented?

Changes to the implementation of premarket review took effect just a week after the FDA's announcement. Most of the other policies in the FDA's plan will require notice-and-comment rulemaking, a process that usually takes several years. In addition to the delays as a result of the rulemaking process, the following barriers will likely further delay or potentially prevent some of the FDA's proposed policies from taking effect:

1. Executive Order 13771

Shortly after President Trump took office, he signed an order requiring all federal executive branch agencies to revoke two rules for every new rule that it promulgates. The order also

instructs agencies to ensure that in this one-in-two-out process, the net economic costs are at least neutral. This process does not allow agencies to consider the economic benefits of their actions. The order has been challenged in federal court but until the case is resolved, the order remains in effect. Commissioner Gottlieb has stated that many of the actions he wishes to see the FDA take are deregulatory in nature, which would allow the FDA to simultaneously move forward with new regulations such as the ones proposed in the tobacco regulatory plan. However, under this executive order, the FDA would still be obligated to find cost savings to offset new rules, even though the overall impact of the rule will likely create an economic benefit as a result of the lives saved.

2. Office of Information and Regulatory Affairs

Most of the proposed FDA policies will be reviewed by the Office of Information and Regulatory Affairs, a sub-agency of the Office of Management and Budget within the White House. This office serves as a gatekeeper for significant regulatory actions, with the ability to rewrite or entirely reject agency rules. If the White House does not approve of the FDA's actions, it can hold back the new regulations or significantly weaken them.

There is precedence for this type of action. When the FDA issued the final deeming regulation, it had planned to exercise its enforcement discretion to significantly reduce the availability of flavored tobacco products. The White House stripped that policy from the final rule, preventing any FDA action on flavors at that time.

3. Litigation

Tobacco product manufacturers have challenged every major FDA tobacco regulatory action and have even tried to preemptively stop others. Despite supportive public statements about the FDA's regulatory plan, a litigation challenge to most FDA actions seems likely. Even with an FDA victory, industry litigation could delay the implementation of these policies for years.

This publication was prepared by the Tobacco Control Legal Consortium, a program of the Public Health Law Center at Mitchell Hamline School of Law, St. Paul, Minnesota.