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FDA Retrospective: The Comprehensive Plan for Tobacco and Nicotine Regulation at One Year

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On August 2, 2018, just over one year since FDA announced its "Comprehensive Plan for Tobacco and Nicotine Regulation"[1] (hereinafter, the "Comprehensive Plan"), FDA Commissioner, Scott Gottlieb, M.D., and Center for Tobacco Products (CTP) Director, Mitch Zeller, J.D., authored a post on the Agency's *FDA Voice* blog, which reviewed the progress made to date and outlined several new initiatives related to the Comprehensive Plan.[2] Among other things, these initiatives included a potential e-cigarette product standard and also proposed foundational rules on various topics related to premarket applications. The authors note that the Comprehensive Plan is a multi-year roadmap for the future of tobacco regulation and "provides a framework for regulating nicotine and tobacco."[3]

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Recent Actions Implementing FDA's Comprehensive Plan

The *FDA Voice* blog post recounts the FDA's actions over the first year of the Comprehensive Plan. For instance, the authors note that FDA recently issued three advanced notices of proposed rulemaking (ANPRMs) that have the "potential to reframe the tobacco landscape."[4] These ANRPMs focus on: (i) the potential development of a product standard to lower nicotine in cigarettes to minimally or no-addictive levels; (ii) the role that flavors – including menthol – play in initiation, use and cessation of tobacco products; (iii) the patterns of use and resulting public health impacts from "premium" cigars. While the comment period for each of these ANPRMs has closed, FDA is currently in the process of reviewing the comments that the Agency has received. In addition, the authors note the Agency's efforts to re-evaluate and modernize its approach to the development of nicotine replacement therapy products, including, among other things, by establishing a Nicotine Steering Committee and issuing a draft guidance related to the nonclinical testing of orally inhaled nicotine-containing drug products.[5]

Establishing a Rigorous, Science-Based Framework for Premarket Review of Tobacco Products

The FDA also announced that a key part of its Comprehensive Plan involves issuing foundational rules and guidance to help industry better understand what is required to submit premarket applications. Indeed, "[e]stablishing a rigorous, predictable, science-based framework for the premarket review of tobacco products is a key element of [FDA's] program."[6] With that in mind, the FDA announced several steps to achieve these goals. First, the Agency announced that it plans to propose new rules in the coming months to aid industry on topics including Substantial Equivalence, Premarket Tobacco Product Applications, Modified Risk Tobacco Product Applications, and Tobacco Product Manufacturing Practices. Second, FDA plans to hold a public meeting on the premarket application and review process on October 22-33, 2018.[7] Third, FDA plans to explore opportunities for premarket review efficiencies through rulemaking and guidance as well as new administrative steps to modernize and improve the review process.

FDA did not mention whether it might consider further extending its compliance policy deadlines, which are currently being challenged by several public health groups, that permit deemed tobacco products on the market as of August 8, 2016 (the effective date of the Deeming Rule) to remain on the market until applications are due by August 8, 2021 (for combustible products) or August 8, 2022 (for non-combustibles). Considering that FDA is

only now, exactly two years after the Deeming Rule went into effect, announcing potential new guidance documents, rulemakings and public hearings "within the coming months," additional time for industry to comply would seem warranted.

New Initiatives to Address Youth Use of Tobacco Products

The *FDA Voice* blog post elucidates a bedrock principle: No kids should be using any tobacco or nicotine-containing products, including e-cigarettes.[8] With that in mind, the authors summarize FDA's recent actions aimed at addressing youth use of nicotine, and e-cigarettes specifically. Among other things, the FDA has recently sent warning letters to companies for selling e-liquids resembling juice boxes, candies, and cookies[9]; sent warning letters to retailers for selling JUUL e-cigarettes to youth[10]; and worked with eBay to remove internet listings for JUUL.[11]

However, the blog post also outlines three additional new initiatives to address these concerns. Among other things, the *FDA Voice* blog post announced that FDA has "begun exploring a product standard for e-cigarettes."[12] As part of this standard, the FDA plans to consider, among other things, levels of toxicants and impurities in propylene glycol, glycerin, and nicotine in e-liquids.[13] Additionally, FDA announced that it plans to expedite the Agency's review and analysis of comments on the flavors ANPRM so that the Agency can pursue policy solutions, should the science support further action. Lastly, the FDA explained that it is exploring ways that FDA can act more efficiently when the Agency becomes aware of violations affecting youth use of e-cigarettes, such as illegal product marketing to youth.[14]

Enforcement of New Products Without Premarket Authorization

While deemed tobacco products on the market as of August 8, 2016 can take advantage of the premarket application compliance policy noted above, new products intended to be introduced for the first time after August 8, 2016 must first obtain FDA premarket authorization. Regarding new products that have allegedly been introduced without such authorization, the blog authors note: "We've also become aware of reports that some companies may be marketing new products that were introduced after the FDA's compliance period and have not gone through premarket review. These products are being marketed both in violation of the law and outside of the FDA's announced compliance policies. We take these reports very seriously. Companies should know that the FDA is watching and we will take swift action wherever appropriate."

Potential Impact on Vapor Industry

While the *FDA Voice* blog post largely outlines previously known regulatory initiatives, the Agency's discussion of FDA initiatives to address youth use of tobacco products outlines several new proposals of interest to the vapor industry. Indeed, an e-cigarette product standard could dramatically impact the design and production of future e-cigarettes. Likewise, any action regulating the marketing of flavored tobacco products, including flavored e-cigarettes and e-liquids, could shape the vapor industry for years to come. From an administrative perspective, the FDA's initiatives to propose foundational rules, hold a public meeting on premarket review, and explore opportunities for premarket review efficiencies, offer the potential to greatly improve the premarket review process, if companies are given enough time to comply.

Looking back, the FDA's Comprehensive Plan brought a much-needed revamp to the Agency's approach to tobacco and nicotine regulation. Only time will tell whether the Agency is able to translate its regulatory plan into effective regulatory policy.

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[1] FDA News Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease and Death (July 28, 2017),

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm.

[2] FDA Voice Blog, Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine (Aug. 2, 2018), https://blogs.fda.gov/fdavoice/index.php/2018/08/advancing-tobacco-regulation-to-protect-children-and-families-updates-and-new-initiatives-from-the-fda-on-the-anniversary-of-the-tobacco-control-act-and-fdas-comprehensive-plan-for-nicotine/.

[3] *Id.*

[4] *Id.*

[5] FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps the Agency is Taking to Support the Development of Novel Nicotine Replacement Drug Therapies to Help Smokers Quit Cigarettes (Aug. 3, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615740.htm

[6] *Id.*

[7] FDA Website, Tobacco Product Application Review – A Public Meeting (Oct. 22-23, 2018), https://www.fda.gov/TobaccoProducts/NewsEvents/ucm615443.htm.

[8] FDA Voice Blog, Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine (Aug. 2, 2018).

[9] FDA News Release, FDA, FTC Take Action Against Companies Misleading Kids with E-Liquids That Resemble Children's Juice Boxes, Candies, and Cookies (May 1, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm.

[10] FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on New Enforcement Actions and a Youth Tobacco Prevention Plan to Stop Youth Use of, and Access to, JUUL and Other E-Cigarettes (Apr. 24, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm.

[11] FDA Voice Blog, Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine (Aug. 2, 2018).

[12] *Id.*

[13] *Id.*

[14] *Id.*