December 4, 2020

Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Docket No. HHS-OS-2020-0012: Securing Updated and Necessary Statutory Evaluations Timely: Notice of Proposed Rulemaking

Comments on Proposed Rule and Request for Extension of Comment Period under 21 C.F.R. § 10.40(b)(3); RIN 0991-AC24

Dear Sir or Madam:

The undersigned organizations, committed to protecting and promoting the public health by reducing the use of tobacco products, respectfully submit comments on the proposed rule, "Securing Updated and Necessary Statutory Evaluations Timely." 85 Fed. Reg. 70,096 (Nov. 4, 2020) (the "Proposed Rule").

HHS should withdraw the Proposed Rule because it violates the Administrative Procedure Act ("APA"). In addition, if adopted it would force the Food and Drug Administration ("FDA"), and its Center for Tobacco Products ("CTP") in particular, to dedicate substantial resources and attention to the required "Reviews" and "Assessments" rather than focusing on its mission of protecting Americans from harmful tobacco products. If HHS declines to withdraw the Proposed Rule, it should at minimum extend the comment period by at least another 90 days. For a proposed rule that effectively amends 18,000 regulations and may significantly impair CTP's ability to perform its regulatory role, the unjustifiably short comment period flouts the APA's requirement that interested parties be given a meaningful opportunity to assess and comment on the proposal.

A. The Proposed Rule Violates the APA.

The Proposed Rule is subject to the rulemaking requirements imposed by the APA as interpreted by the courts over the more than seventy years since Congress enacted the APA. In section 701(a) of the Federal Food, Drug and Cosmetic Act, Congress authorized FDA to adopt regulations which, once adopted, have the force of law. When developing a regulation, the APA requires that FDA issue a proposed rule explaining what the proposal would accomplish and its impact, to allow a meaningful opportunity for public comment, and to consider all relevant comments. 5 U.S.C. § 553(b)-(c).[1]

[1] It is notable that, at the November 23, 2020 public hearing on the Proposed Rule, every one of the approximately twenty participants—representing public health organizations, industry trade

The Proposed Rule effectively amends 18,000 regulations to add a date on which each regulation will automatically expire unless the agency has completed the resource-intensive review. According to the Proposed Rule, 12,400 rules would have to undergo review in the first two years the rule is effective or expire automatically. This blanket amendment in the Proposed Rule would violate the APA, because it violates the statute's procedural requirements by not allowing an adequate opportunity for comment and is substantively arbitrary and capricious. The mandatory sunset provision inevitably will vary in its impact for each of the thousands of rules promulgated by HHS and covered by the Proposed Rule. Yet the Proposed Rule asserts that, as to *every* covered regulation—no matter how important to the public health—"the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review." 85 Fed. Reg. at 70,106. The Proposed Rule offers no analysis of specific rules and thus no reasoned assessment as to each of the thousands of regulations impacted by the proposal. But that is what the APA requires when a regulation is revoked or amended. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983) (in revoking a rule "the agency must examine the relevant data and articulate a satisfactory explanation for its action").

Thus, if the Proposed Rule were finalized, the APA would be violated every time a rule automatically expires because the expiration will occur without the required notice and comment opportunity and without an examination by FDA of whether expiration of the rule is justified by the relevant science and in light of public health considerations. Moreover, the ensuing litigation could clog the courts and paralyze the agency.

B. The Proposed Rule Will Divert FDA and CTP from Their Public Health Activities.

Instead of allowing CTP to focus on protecting Americans from deadly tobacco products, this rule, if finalized, would divert FDA's and CTP's attention and resources.

Cigarette smoking is the leading cause of preventable disease and death in the United States, killing more than 480,000 Americans every year.[2] Over 16 million Americans suffer from tobacco-related disease.[3] According to the most recent CDC data, 34.1 million U.S. adults still smoke cigarettes.[4] And over the last several years, e-cigarette use among youth has reached epidemic proportions, with about 1 in 5 American kids now using these highly-addictive

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associations, physician organizations, and consumer groups—opposed the Proposed Rule and urged HHS to withdraw it and at minimum to extend the comment period.

[2] Office of the Surgeon General (OSG), U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General* 2 (2014), https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf.

[3] Center for Disease Control and Prevention (CDC), *Smoking & Tobacco Use*, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#toll (last visited Nov. 30, 2020).

[4] CDC, *Tobacco Product Use Among Adults – United States, 2019*, 69 Morbidity & Mortality Wkly. Rep. 1736, 1737 (Nov. 20, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6946a4.htm.

products.[5] It is essential that FDA be allowed to focus on its critical task of protecting the American people from addictive and deadly tobacco products.

Since the enactment of the Family Smoking Prevention and Tobacco Control Act (the "TCA") in 2009, CTP has issued 11 final regulations and 14 proposed regulations.[6] While several of those rules were statutorily mandated, and thus would be exempt under the Proposed Rule, others would be subject to its automatic repeal provisions. At this point, more than 10 years after enactment of the TCA, the story of tobacco product regulation is not one of unnecessary regulatory burdens on small businesses, but rather of FDA's failure to use its regulatory authority to protect public health and, particularly, to protect our kids. For example, FDA has had the authority to establish tobacco product standards to make tobacco products less harmful, less addictive, and less appealing, especially to kids. *Yet FDA has yet to finalize a single product standard.*

The youth e-cigarette epidemic resulted in significant measure from FDA's failure to take timely action on e-cigarettes. In April 2011, FDA first announced its intention to regulate e-cigarettes as tobacco products.[7] But FDA did not extend its authority to e-cigarettes until May 2016.[8] During this five-year delay, e-cigarettes gained a foothold in the American market, with a particular appeal to kids. Youth use of e-cigarettes then accelerated dramatically beginning in 2017, after FDA suspended its public health review of these products.

FDA has issued several advanced notices of proposed rulemaking on important issues, including a product standard on nicotine in combusted cigarettes and the regulation of flavors in tobacco products. The public health of the nation, particularly its youth, would be far better served by CTP dedicating its finite resources to make progress on those initiatives, rather than on the "Assessments" and "Reviews" described in the Proposed Rule. These "Assessments" and "Reviews" would impose unjustifiable costs on the regulatory process, and if subject to legal challenge under the APA as the rule envisions, would further distract FDA from its public health mission.

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[5] CDC, *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Wkly. Rep. Surveillance Summaries (Sept. 9, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf.

[6] FDA, Rules and Regulations, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations (last visited Nov. 30, 2020).

[7] FDA, *Regulation of E-Cigarettes and Other Tobacco Products* (Apr. 25, 2011), http://web.archive.org/web/20110530152010/http:/www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm.

[8] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 29,037 (May 20, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) ("Deeming Rule").

Therefore, because the Proposed Rule would impose extraordinary burdens on FDA and its regulation of tobacco products, with no benefits to the public health, and because it violates the APA, the undersigned organizations urge HHS to withdraw the Proposed Rule.

C. At Minimum, HHS Should Extend the Comment Period.

Under HHS and FDA regulations, the agency ordinarily allows 60 days for public comment on a proposed rule. *See, e.g.*, 21 C.F.R. § 10.40(b)(2). While HHS and FDA can shorten the time for "good cause," the Proposed Rule offers no justification for such an abbreviated comment period. In fact, a longer comment period is required given (i) the potential impact of the Proposed Rule on thousands of existing rules and on HHS/FDA/CTP's ability to perform its public health mission, and (ii) the abbreviated comment period falls in the midst of the novel coronavirus pandemic. Accordingly, the Proposed Rule's 30-day comment period itself violates the APA because it denies meaningful "opportunity to participate in the rule making" required by 5 U.S.C. § 553(c). *See N. Carolina Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012) (APA requires "meaningful" opportunity to comment); *Petry v. Block,* 737 F.2d 1193, 1201 (D.C. Cir. 1984) (relying on Administrative Conference of the United States's view that 30-day comment period is inadequate and 60-day comment period is the reasonable minimum time for comment). In light of the far-reaching scope of the Proposed Rule and the ongoing COVID-19 public health crisis, HHS should extend the comment period by at least 90 days beyond the current December 4, 2020 deadline.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative