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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, ACTION ON SMOKING AND HEALTH, AMERICAN MEDICAL ASSOCIATION, and NATIONAL MEDICAL ASSOCIATION, Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the U.S. Dep't of Health and Human Services; U.S. FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration; CENTER FOR TOBACCO PRODUCTS; MITCH ZELLER in his official capacity as the Center for Tobacco Products Director, Defendants.	**Case No.: 4:20-cv-4012-KAW** **Judge Kandis A. Westmore** **BRIEF OF *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S SECOND MOTION TO DISMISS**

TABLE OF CONTENTS

TABLE OF AUTHORTIES

Cases

Statutes

Rules

Regulations

INTRODUCTION AND INTEREST OF THE AMICUS CURIAE

The U.S. Food & Drug Administration ("FDA") has stated time and time again that it will initiate a rulemaking to prohibit menthol in cigarettes. But words are just that—words—unless they are followed up by concrete, discrete, and of most interest to the judicial system, reviewable action.

The Public Health Law Center ("Center") is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For over twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws.[1] This work is evidence-based, informed by leading empirical research on policy interventions.

Most relevant to this case, the Center is a national leader with deep expertise in the FDA's implementation of the Family Smoking Prevention and Tobacco Control Act ("TCA"). The Center is the lead petitioner of the 2013 citizen petition at issue in this case, which is part of the Center's ongoing effort to ensure that the FDA's regulation of commercial tobacco is evidence-based and protects the public health of *all* people—most critically, those historically and disproportionately impacted by past policy decisions. In the eight years since filing the citizen petition, the Center has worked to advance menthol cigarette regulation at the federal, state, and

[1] The Center has long worked in partnership with a consortium of legal centers providing legal technical assistance to communities working on effective commercial tobacco control policy. The Center's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts.

local level. As such, the Center is uniquely well-suited to discuss the FDA's failure to regulate the deadliest consumer product ever created.

At the heart of this case is the TCA's requirement that the FDA set product standards that are protective of public health and reflect the latest scientific and medical data. And yet, the FDA has never acted on one of the most pernicious threats to public health. The Center has a strong interest in supporting the Plaintiffs in their opposition to the government's efforts to dismiss this case and in ensuring that the FDA cannot continue to delay promulgation of a rule prohibiting menthol in cigarettes.

SUMMARY OF ARGUMENT

The TCA's requirement to reevaluate product standards and the FDA's regulations governing the citizen petition process make clear that the FDA must complete the rulemaking process to satisfy its legal obligations and render this case moot. The FDA has not yet even proposed a rule, let alone published and implemented a final rule, meaning there is no reason for the Court to dismiss this litigation. In fact, doing so will almost certainly result in additional years of foot-dragging by the FDA, as evidenced by its twelve-year history of delay and inaction with respect to menthol. The FDA has not acted on menthol on its own and has further shown that it cannot act within a reasonable timeframe without a court overseeing the process. For this reason, the judiciary has the power and authority to impose equitable remedies to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). As one Maryland District Court has already recognized in the context of the FDA's lassitude in regulating tobacco products, district courts have "discretion to exercise [their] equitable powers to tailor a remedy" in light of an agency's "'long-standing failure to meet [its statutory] obligations.'" *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019) (quoting *Thompson v. U.S. Dep't of Hous. &*

Urban Dev., Civil Action No. MJG-95-309, 2006 U.S. Dist. LEXIS 9416, at *21, *37 (D. Md. Jan. 10, 2006)). Accordingly, the Court should deny the government's Motion to Dismiss because it can grant relief in the form of ongoing oversight over this case.

Part I of this brief discusses the statutory and regulatory obligations applicable to the FDA requiring the *concurrent* issuance of product standards via rulemaking when granting citizen petitions like the one at issue here. Part II provides factual history that underscores the importance of this Court maintaining jurisdiction by describing FDA's numerous promises to act on menthol in the past—none of which ever resulted in a final rule or even a proposed rule. Part III adds additional context by describing other tobacco control regulatory efforts where the FDA stated its intent to pursue rulemaking but ultimately failed to follow through on its promised action.

Although there is no district court rule describing the standard for the participation of an *amicus curiae*, district courts have "broad discretion to appoint amici curiae." *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982), *abrogated on other grounds by Sandin v. Conner*, 515 U.S. 472 (1995). Whether to allow an amicus to file a brief "is solely within the Court's discretion, and generally courts have exercised great liberality in permitting amicus briefs." *California v. United States DOI*, 381 F. Supp. 3d 1153, 1164 (N.D. Cal. 2019) (Armstrong, J.) (citing *Woodfin Suite Hotels, LLC v. City of Emeryville*, No. C 06-1254 SBA, 2007 U.S. Dist. LEXIS 4467, at *8 (N.D. Cal. Jan. 9, 2007) (Armstrong, J.)). "'The touchstone is whether the amicus is helpful.'" *Earth Island Inst. v. Nash,* No. 1:19-cv-01420-DAD-SAB, 2019 U.S. Dist. LEXIS 214578, at *3 (E.D. Cal. Dec. 11, 2019) (citations omitted). The information presented below is helpful, "desirable and…relevant to the disposition of the case" because of its direct relevance to the need for continued judicial oversight and involvement in this case. Fed. R. App. P. 29 (a)(3)(B).

DISCUSSION

The FDA's position in the Motion to Dismiss currently before the Court is that the African American Tobacco Control Leadership Council ("AATCLC") and its co-Plaintiff public health groups are simply confused by a difficult and lengthy rulemaking process. Specifically, the government maintains that the groups "mistakenly" assume that the rulemaking process begins with the publication of a Notice of Proposed Rulemaking ("NPRM") in the Federal Register. FDA 2d Mot. to Dismiss, at 6. In its Reply, the government doubles down on this point, asserting that the Plaintiffs "continue to maintain an overly simplistic view of rulemaking." FDA Reply in Supp. of Mot. to Dismiss ("FDA Reply"), at 1. Rather, the government asserts, the rulemaking process is "complex, with the publication of the NPRM occurring in the middle—not the beginning—of the rulemaking process." FDA 2d Mot. to Dismiss, at 6-7. However, other than a confusing graphic from the Government Accountability Office, the government points to no authority on its central point.

The government's position is misguided at best, and blatant obfuscation at worst. By painting a picture of a long and complicated process, the government argues that the agency is making forward progress when there is none. Indeed, the FDA's graphic suggests that it has been in the "middle" of a rulemaking for eight years, perpetually stuck at the stage entitled, "identify issues and gather data" ever since publishing reports in 2011 and 2013 and issuing two Advanced Notices of Proposed Rulemaking ("ANPRMs") in 2013 and 2018. According to the government's representations, the FDA is still in the "[d]evelop proposed action" step of its graphic; the grant of the citizen petition did not actually move the process forward. At the same time, the agency argues that its announcement was significant enough to satisfy the citizen petition and conclude this Court's jurisdiction over the matter. Essentially, the government's argument suggests that its

decision to "grant" the citizen petition was little more than a paper exercise intended to sidestep legal accountability for the agency's failure to issue a rule.

Moreover, contrary to the government's arguments, the public health groups' position is grounded in statutory and regulatory requirements imposed by the TCA at 21 U.S.C. § 387g and by regulation at 21 C.F.R. § 10.30(e). Together, these authorities require that the agency "publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard," 21 U.S.C. § 387g(c)(1); and that any response to a citizen petition be accompanied by "concurrent […action… implementing the approval." 21 C.F.R. § 10.30(e)(emphasis added). In short, the FDA cannot simply assert that it has begun the rulemaking process internally, with no publicly available information to share. Indeed, in light of the agency's repeated delays, missed deadlines, and failures to fulfill statutory mandates in other contexts, it has fallen to the public and the courts to ensure that the FDA does its job.

I. The FDA is required by statute and by rule to initiate a rulemaking.

Two primary sources of legal authority are relevant to the instant motion: the TCA itself and the regulation governing the agency's response to the citizen petition. Both require the agency to engage in the public-facing rulemaking process.

A. The TCA requires that once the FDA has made a determination that a standard should be updated, it must engage in a rulemaking in order to implement that determination.

The government's arguments with respect to how the FDA is required to periodically reevaluate product standards would create an exception that swallows the rule. The government is correct that the language quoted at 21 U.S.C. § 387g(a)(5) does not dictate what form a "determin[ation] whether such standards should be changed" should take. However, the government's brief completely ignores the corollary statutory requirements in that section, which

require the FDA to "publish in the Federal Register a notice of proposed rulemaking for the establishment, *amendment*, or revocation of any tobacco product standard." 21 U.S.C. § 387g(c)(1) (emphasis added). In case there was any doubt as to what the FDA must do, Congress made it clear: product standards require a properly promulgated rule. Subsections (c) and (d) of 21 U.S.C. § 387g go on to lay out all of the rulemaking requirements, most of them fairly common throughout federal statutes, including a minimum 60-day comment period, 21 U.S.C. § 387g(c)(4), and a minimum of 1 year before the effective date, 21 U.S.C. § 387g(d)(2). But most importantly, (d)(4), entitled "Amendment; Revocation," specifies that "the Secretary, upon the Secretary's own initiative *or upon petition* of an interested person, *may by a regulation*, promulgated in accordance with the requirements of subsection (c) and paragraph (2), *amend* or revoke a tobacco product standard." 21 U.S.C. § 387g(d)(4)(A) (emphasis added). In other words, if the "determination" made under 21 U.S.C. § 387g(a)(5) takes the form of a response to a citizen petition, as the government acknowledges it has here, then 21 U.S.C. § 387g(d) explicitly requires a rule promulgated in accordance with notice-and-comment rulemaking procedures in order to amend a product standard.

Further, if a legally sufficient "determination" allows the agency to simply write a letter expressing its intent to someday initiate a rulemaking, the TCA's periodic reevaluation provision becomes meaningless. If a letter is sufficient, the FDA is then free to reevaluate product standards and make unimplemented determinations infinitely without ever actually amending any product standards at all. This cannot be what Congress intended in enacting a public-health-focused federal statute that requires the FDA to regulate tobacco products in light of the most current science and medical research. To the contrary, the FDA must reevaluate its tobacco product

standards, and when it determines that a standard needs updating in light of scientific data, the FDA must promulgate a rule making that change. *Id.*

B. The FDA's own regulations mandate the timing of the agency's next steps by requiring concurrent action when responding to the citizen petition.

The government's reading of its regulations governing citizen petitions is similarly tortured. The government does not dispute the plain meaning of the language at 21 C.F.R. § 10.30, which requires that when a petition is granted, "the Commissioner shall concurrently take appropriate action." Rather, the government again disputes the action's appropriate form. The government's position is that a memorandum from the Acting FDA Commissioner Janet Woodcock instructing FDA staff to "promptly begin drafting a proposed rule was an appropriate action." FDA Reply, at 6.

What is required by regulation, however, is not just *any* action that FDA deems appropriate—it is an "appropriate action . . . *implementing the approval*." 21 C.F.R. § 10.30(e) (emphasis added). Indeed, Acting Commissioner Woodcock's memo no more implements approval of the petition than any other past FDA statement about the importance of acting on menthol. The citizen petition process is explicitly a petition to undertake rulemaking pursuant to 5 U.S.C. §553(e) and 21 C.F.R. § 10.30, meaning the petitioners expect the agency to finalize a rule. The Acting Commissioner's memo to FDA staff similarly asks the agency to begin a rulemaking, which doesn't fulfill the regulatory requirement that the "appropriate action…implement[] the approval" of the petition. 21 C.F.R. § 10.30(e). A final regulatory action by the agency is the only "action" that will implement the approval, and thus, the only one that is appropriate in this context. At this point, *no* concurrent implementation action has been taken.

It is also critical that here, 21 C.F.R. § 10.30(e) specifies that the action be *concurrent*. The regulation could have been entirely silent on the timing of the implementation of an action

granting a citizen petition. The FDA, in its own wisdom, has decided that the agency ought to act swiftly upon citizen petitions by acting "concurrently." *Id*. Even if, *arguendo,* the initiation of rulemaking procedures by noticing a proposed rule (rather than by promulgating a final rule) constitutes "appropriate action" under the regulation, the FDA estimates that it will propose a menthol tobacco product standard by April 2022 at the earliest. *See* Office of Information and Regulatory Affairs ("OIRA") Spring 2021 Tobacco Product Standard for Menthol in Cigarettes.[2] Two events that are one year apart from one another are not "concurrent." *See Concurrent*, Merriam-Webster.com Dictionary (defining "concurrent" to mean "operating or occurring at the same time"; "acting in conjunction"); *Concurrent*, Black's Law Dictionary (11thd ed. 2019) ("operating at the same time; covering the same matters.").)

Finally, the FDA's argument that the Acting Commissioner's memo somehow moots Plaintiffs' claims is inconsistent with the agency's position that the memo also represents the "middle" of its rulemaking process. Either the agency is engaging in an ongoing rulemaking process, in which case there is no reason to believe that the Commissioner's memo has legal significance sufficient to remove this Court's jurisdiction over the underlying controversy, or the memo marks the "consummation of the agency's decisionmaking process" from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 157 (1997) (citations omitted) (defining "final agency action"). Clearly, both cannot be true.

The Commissioner's memo does not implement the approval of the citizen petition because the FDA has taken no step to initiate a public-facing rulemaking. As explained below, the FDA has expressed its intent to act on menthol in the past, but it has never published a rule.

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[2] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-ai60&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

The Commissioner's memo in the instant case is no different than the agency's past statements. Only a properly promulgated final rule will implement the request in the citizen petition.

II. The FDA has repeatedly stated its intent to remove menthol from the market, but has yet to do so, at the cost of hundreds of thousands of human lives.

Upon passage of the TCA, Congress established several deadlines for various actions by the FDA. Among the actions with the most immediate deadlines was the requirement that the FDA's Tobacco Product Scientific Advisory Committee ("TPSAC") submit a report and recommendations on "the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." 21 U.S.C. § 387g(e)(1). In 2011, TPSAC issued a thorough report, detailing the health impacts of menthol, and concluding that the "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States." 2011 TPSAC Report, at 225; 2d Am. Compl. (1st Suppl.) ¶¶ 4-6. Of course, as underscored by the lawsuit at bar, the FDA has never implemented TPSAC's recommendation. In 2013, almost two years after the TPSAC report, the Center and many of its partners, including Plaintiff AATCLC, filed the citizen petition at issue in this case, seeking to compel the FDA to take the action recommended by TPSAC. Shortly thereafter, the agency appeared to move in the direction of prohibiting menthol by issuing an ANPRM in 2013. 2013 ANPRM, 78 Fed. Reg. 44484 (Sept. 23, 2013). Five years later, it did the same thing. 2018 ANPRM; 2d Am. Compl. (1st Suppl.) ¶ 10. Neither of the ANPRMs led to a rulemaking. The April 29, 2021 announcement in response to the citizen petition continues in this vein, merely stating an intention to hopefully begin a rulemaking within the next year.

Yet, this is far from the first time the FDA has acknowledged the harm caused by menthol and the need for action without taking any steps to reduce that harm through regulation. For example, in 2017, former Commissioner Scott Gottlieb announced a renewed focus on tobacco

product regulation at the FDA. The plan included several components, one of which was supposed to result in the removal of flavors from combustible tobacco products (which would have included removal of menthol cigarettes.) The archive of Gottlieb's statements and speeches is filled with comments about the problems associated with the presence of menthol and the FDA's intentions to solve it:

- "One focus of my attention is the characterizing flavors that remain in some combustible tobacco products, including menthol in cigarettes and fruity flavors we increasingly see in cigarillos." Statement of Scott Gottlieb, Keynote Address 2018 FDLI Annual Conference (May 3, 2018).[3]
- "[W]e need to address the impact that menthol in cigarettes has on the public health." "I can think of no more impactful action the FDA could possibly take on my watch to help American families." Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes (Nov. 15, 2018).[4]

Gottlieb continued to make regular statements about menthol cigarettes, eventually labeling them "pernicious" (a word he used frequently in this context):

- "[W]e are also setting out to advance the notice of proposed rulemaking that would seek to ban menthol in the combustible products. I think the menthol in the combustible products has long been a pernicious problem." Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce tobacco use, especially among youth, by exploring options to address the role of flavors—including menthol—in tobacco products (Mar. 19, 2018).[5]
- "[M]enthol in and of itself is pernicious. Menthol is an on-ramp to smoking for kids. I quoted statistics fully, 54 percent of kids who use cigarettes, use mentholated cigarettes. We know that the menthol itself has features that mask some of the undesirable aspects of smoking, so it makes it easier for

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[3] *Available at* https://www.fda.gov/news-events/speeches-fda-officials/keynote-address-2018-fdli-annual-conference-05032018 (last visited Aug. 31, 2021).

[4] *Available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access (last visited Aug. 31, 2021).

[5] *Available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-reduce-tobacco-use-especially-among-youth (last visited Aug. 31, 2021).

> someone who is uninitiated to smoking to begin smoking. The burning, the coughing that comes with that first cigarette or starting on tobacco is masked by the menthol, and so the menthol becomes a very pernicious tool by which it becomes easier for children to start smoking. And we see a very disproportionate impact of menthol on the African-American community and underserved communities. Transcript of FDA Media Availability on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018).[6]

Despite the perniciousness of menthol and Gottlieb's statements that the FDA would "advance the notice of proposed rulemaking," such a rule was never published in the Federal Register. In fact, the FDA has yet to even send a rule for review by OIRA, the final step before such publication (and the fifth step in the government's overly complicated chart on page 7 of its Motion to Dismiss). Under Gottlieb, the agency published another ANPRM but failed to move past the ANPRM stage in its process. The issuance of a second ANPRM rather than an NPRM brings into question the agency's commitment to acting on menthol. If the purpose of an ANPRM is to gather information to inform future policy, the agency had already gathered that information in the 2011 TPSAC report and the agency's own report in 2013. Based on the former commissioner's own statements, it is clear that the level of harm caused by menthol was well known in 2018. When seen through this light, the 2018 ANPRM is clearly another attempt to give the appearance of forward progress without having to actually move the process forward.

Beyond the actions surrounding the 2013 and 2018 ANPRMs, there are additional reasons to question the sincerity of the FDA's commitment to acting on menthol. Not only has the FDA failed to initiate a rulemaking related to menthol, but in its adjudicatory procedures to authorize the sale of tobacco products, the FDA continues to authorize *new* menthol cigarettes. These authorizations have continued even while the agency publicly recognizes the products' harm. In

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[6] *Available at* https://www.fda.gov/media/123932/download (last visited Aug. 31, 2021).

fact, the FDA has issued marketing orders for menthol-flavored cigarettes as recently as August 10, 2020—nearly two months after this litigation was filed and more than two years after the agency issued its second ANPRM on menthol.[7] If the FDA is truly committed to removing all menthol cigarettes from the market, then why is the agency allowing more of the same into the market?

The letter sent to the citizen petitioners on April 29, 2021 bears no real distinction from all these previous statements by the FDA and its representatives. The letter no more effects a ban on menthol cigarettes than any of the ANPRMs, scientific reports, or past statements by FDA officials. The fact of the matter remains: menthol cigarettes are available for sale, and the FDA has not acted to change that fact in the twelve years it has had the authority to do so. As has been the case in the past, the Acting Commissioner's memo here does not compel future FDA staff and leadership to act any more than any statement made by a previous Commissioner. If the Court agrees with the government's position that the letter response is sufficient for purposes of the agency's legal obligations, the citizen petition process will be rendered meaningless. The citizen petition cannot not be "granted" until a menthol ban is implemented through notice-and-comment rulemaking.

III. The FDA has a chronic problem of failing to meet deadlines—whether aspirational or statutorily imposed.

Without a court overseeing its process, the FDA has a dismal track record of failing to meet deadlines for action, even those imposed by Congress. It is particularly telling that the government points to a Spring 2021 Unified Regulatory Agenda ("URA") item related to menthol

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[7] *See e.g. August 2020 Substantial Equvalence Marketing Orders for: Marlboro Menthol Special Select Box, Marlboro Menthol Special Select 100's Box, and Marlboro Menthol Black Special Blend Box*, FDA, *available at* https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se (last visited Aug. 31, 2021).

as evidence that the Commissioner's instructions to start the process are being followed. FDA Reply, at 7. The court should look skeptically upon the government's argument that an URA item related to menthol is more meaningful than any previous statements on menthol that have also not resulted in action. In fact, *Amici* are aware of no cases where the FDA has placed a new intended tobacco regulatory action on the URA with a proposed deadline and then met that deadline on the first try. Rather, it has always been the case that upon publication of the next URA, an initial deadline will be pushed back, and the process may repeat itself many times over while years pass. In fact, the agency itself recently acknowledged in a news release related to premium cigars that the URA is essentially a regulatory wish list, stating, "The [URA] is published twice a year and provides information about regulations that the Federal government is considering or reviewing. ***It does not create a legal obligation on agencies to adhere to published schedules or to confine their regulatory activities to regulations that appear within the Unified Agenda."*** CTP Statement on Withdrawal of the Unified Agenda Entry Pertaining to the Advance Notice of Proposed Rulemaking for Premium Cigars and Related Request for Information, June 11, 2021, at n.2 (emphasis added).[8] There is no reason to believe the FDA will treat this new menthol item any differently than it has all other URA items in the past.

The FDA's most recent failure to meet statutory obligations began on December 20, 2019, when the Further Consolidated Appropriations Act, 2020 was signed into law. Pub. L. No. 116-94. In this law, Congress gave the FDA 180 days–or, until June 17, 2020–to publish a rule in the Federal Register that would update the FDA's regulations changing the minimum legal sales age for tobacco products from 18 to 21. More than a year past that deadline, no such rule has been

[8] *Available at* https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-statement-withdrawal-unified-agenda-entry-pertaining-advance-notice-proposed-rulemaking-premium (last visited Aug. 31, 2021).

promulgated. The FDA did submit a rule to OIRA for review several months after its deadline, but it was withdrawn with the change in administrations in January 2021. *See* OIRA Jan. 21, 2021 OIRA Conclusions of EO 12866 Regulatory Review.[9] Since that time, no new rule has been submitted to the Office of Management and Budget ("OMB") for review, yet it has been repeatedly listed in the URA. In fact, the agency first included this rule in the Spring 2020 URA with a final rule expected in June 2020. *See* OIRA Spring 2020 Prohibition of the Sale of Tobacco Products to Persons Younger Than 21 Years of Age.[10] When it missed that date, the item was listed on the Fall 2020 URA with a rule expected November 2020. *See* OIRA Fall 2020 Prohibition of the Sale of Tobacco Products to Persons Younger Than 21 Years of Age.[11] After another missed deadline, the rule was listed most recently on the Spring 2021 URA with a rule expected in May 2021—there is still no rule. *See* OIRA Spring 2021 Prohibition of the Sale of Tobacco Products to Persons Younger Than 21 Years of Age.[12] One should expect this item to appear on the Fall 2021 URA as well, perhaps with a date later this year or early next year. The FDA is out of compliance with this statutory requirement and has been for over a year. It is highly likely that it will remain out of compliance for many more months to come.

Additional examples include:

- The TCA required the FDA to issue regulations governing the non-face-to-face sale of tobacco products by October 2011 and regulations governing marketing and promotion by March 2012. 21 U.S.C. § 387f(d)(4)(A). The agency listed this item on the URA from Spring 2010 through Fall 2011.

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[9] *Available at* https://www.reginfo.gov/public/do/eoDetails?rrid=131094 (last visited Aug. 31, 2021).
[10] *Available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202004&RIN=0910-AI51 (last visited Aug. 31, 2021).
[11] *Available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202010&RIN=0910-AI51 (last visited Aug. 31, 2021).
[12] *Available at* https://www.reginfo.gov/public/do/eAgendaViewRule? pubId=202104&RIN=0910-AI51 (last visited Aug. 31, 2021).

See OIRA Unified Agenda and Regulatory Plan Search Results.[13] The FDA published an ANPRM on September 9, 2011, but never followed through on this statutorily required rule. 76 Fed. Reg. 55835 (Sept. 9, 2011). Indeed, after no meaningful updates for six years, the agency placed this item on the list of "Completed Actions" for the Spring 2017 URA and classified the item as "Withdrawn," despite never finalizing, or even proposing, the required rule. *See* OIRA Spring 2017 Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products.[14]

- The FDA has also expressed interest in establishing "requirements for the testing and reporting of tobacco product constituents, ingredients, and additives" as early as the Spring 2011 URA. 76 Fed. Reg. 40062 (July 7, 2011). After numerous delays, the rule was converted to a "Long-Term Action" item and was ultimately withdrawn from the URA in the Spring 2017 agenda without any regulatory documents ever being published. *See* OIRA Unified Agenda and Regulatory Plan Search Results.[15]
- Beginning in 2012, the FDA included a rule for "Establishment Registration and Product Listing for Tobacco Products" in every URA it has issued. *See* OIRA Unified Agenda and Regulatory Plan Search Results.[16] Although the item was withdrawn in Spring 2017, it reappeared in the Fall of 2017 with a different RIN. *See* OIRA Unified Agenda and Regulatory Plan Search Results [17] It has been published in every URA since then and was eventually downgraded to a long-term action. *Id.*
- Beginning with the Spring 2015 URA, the FDA began listing a rule respecting "Requirements for Tobacco Product Manufacturing Practice." OIRA Unified Agenda and Regulatory Plan Search Results.[18] After five URA publications, the item was "withdrawn" but then published under a different RIN. OIRA Unified Agenda and Regulatory Plan Search Results.[19]

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[13] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AG43&Image61.x=14&Image61.y=12 (last visited Aug. 31, 2021).

[14] *Available at* https://www.reginfo.gov/public/do/eAgendaViewRule? pubId=201704&RIN=0910-AG43 (last visited Aug. 31, 2021).

[15] *Available at* https://www.reginfo.gov/public/do/eAgendaViewRule? pubId=201704&RIN=0910-AG59 (last visited Aug. 31, 2021).

[16] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AG89&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[17] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AH59&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[18] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AH22&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[19] The item appeared did appear in the next URA under a different RIN, though that new agenda item did not reference the prior ANPRM docket at all. *See* https://www.reginfo.gov/

The most recent publication of this item was in Spring 2021, though the FDA has yet to propose a rule.

- A rule for "Investigational Tobacco Product Applications and General Information Regarding Submission of Information to Support Legal Marketing" was first published in the Fall 2013 URA. OIRA Unified Agenda and Regulatory Plan Search Results.[20] After sixteen URA publications, the FDA has yet to propose a rule and this item eventually shifted to a long-term action.
- A rule governing the "Formant and Content of Reports Intended to Demonstrate Substantial Equivalence," which would govern the flow of information between the agency and the regulated industry, first appeared on the URA in Spring 2013. 78 Fed. Reg. 44259 (July 23, 2013). Similar to the other items, it was withdrawn in Spring 2017 and republished under a different RIN. OIRA Unified Agenda and Regulatory Plan Search Results.[21] The rule was finally proposed April 2, 2019, and the final rule was submitted to OIRA on December 31, 2020. 84 Fed. Reg. 12740 (Apr. 2, 2019); OIRA Jan. 13, 2021 OIRA Conclusions of EO 12866 Regulatory Review.[22] The rule was placed on public inspection for publication in the Federal Register but was not published before it was withdrawn due to the change in administration. The new version of the final rule was submitted to OIRA on April 5, 2021 and is still pending review.
- A rule governing "Premarket Tobacco Product Applications and Recordkeeping Requirements" followed a similar trajectory, first appearing in the URA in Fall 2016. OIRA Unified Agenda and Regulatory Plan Search Results.[23] An NPRM was published September 25, 2019, 84 Fed. Reg. 50566, and a final rule was submitted to OIRA on December 31, 2020. OIRA Jan. 13, 2021 OIRA Conclusions of EO 12866 Regulatory Review.[24] It also was removed from the public inspection before publication in the

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public/Forward?SearchTarget=Agenda&textfield=0910-AH91 &Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[20] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AH06&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[21] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AH89&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[22] *Available at* https://www.regulations.gov/document/FDA-2016-N-3818-0001(last visited Aug. 31, 2021).

[23] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield=0910-AH44&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

[24] *Available at* https://www.reginfo.gov/public/do/eoDetails?rrid=131911 (last visited Aug. 31, 2021).

Federal Register and resubmitted to OIRA on April 5, 2021 with review still pending. OIRA Pending EO 12866 Regulatory Review.[25]

- An item related to nicotine reduction was first published in the Fall 2017 URA. OIRA Unified Agenda and Regulatory Plan Search Results.[26] In the Fall 2018 URA, it was downgraded to a long-term action and by Fall 2019 the item was withdrawn. If inclusion in the URA is a signal as to the agency's regulatory priorities, then apparently, the FDA has all but abandoned the idea of attempting to reduce nicotine.
- The FDA also included an item in the Fall 2017 URA linked to its 2018 ANPRM covering menthol cigarettes and flavors in cigars. OIRA Unified Agenda and Regulatory Plan Search Results [27] Curiously, the Fall 2018 version of that item was retitled "Tobacco Product Standard for Characterizing Flavors in Cigars," possibly to acknowledge that a rule related to cigars would be separate from a rule related to menthol cigarettes. The item for cigar flavors had a change to the RIN and has been published in the URA six additional times. OIRA Unified Agenda and Regulatory Plan Search Results.[28] FDA has still not proposed a rule.

It is not surprising, then, given this long list of URA-related delays and inaction, that *Amici* question the agency's assertion of the URA as a meaningful stage in its rulemaking process. Rather, given the FDA's history, a single URA item appears to represent no more of a step forward than any other aspirational statement expressed by the agency in other fora. Neither an item in the URA nor a memo from the FDA Commissioner has any meaningful regulatory significance when it comes to actually removing menthol cigarettes from stores.

Importantly, this is not the first time public health groups have stepped in to force the FDA to act in other statutorily required contexts. Two other examples are worth highlighting not only because of the similarity of the issues, but also because of the remedies imposed. In both

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[25] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget= RegReview&textfield =0910-AH44&Image61.x=17&Image61.y=10 (last visited Aug. 31, 2021).
[26] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield =0910-AH86&Image61.x=0&Image61.y=0) (last visited Aug. 31, 2021).
[27] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield =0910-AH60&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).
[28] *Available at* https://www.reginfo.gov/public/Forward?SearchTarget=Agenda&textfield =0910-AI28&Image61.x=0&Image61.y=0 (last visited Aug. 31, 2021).

cases, the American Academy of Pediatrics, joined by a coalition of other public health groups, filed suit over the FDA's delay in fulfilling its statutory obligations under the TCA. In the first case, the groups filed a lawsuit in the District of Massachusetts over the FDA's delay in issuing a rule requiring graphic warning labels on cigarette packages and advertisements. *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin.,* No. 1:16-cv-11985 (D. Mass. Oct. 4, 2016). In that case, the public health groups, as they did here, pointed to the existence of a clear statutory mandate and the very slow pace at which the agency was acting to implement that mandate. Recognizing the important public health interests involved, the court found that the agency had unreasonably delayed issuing the graphic warning label rule at issue and imposed a remedy that set a deadline by which the agency was required to issue a final rule. *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin.*, 330 F. Supp. 3d 657, 667 (D. Mass. 2018), Mem. and Order Granting Injunctive Relief, Dkt. 56 (Mar. 5, 2019).

In the second case, *Am. Acad. of Pediatrics v. U.S. Food & Drug Admin*, No. 8:18-cv-00883 (D. Md. Mar. 27, 2018), the public health groups filed suit in the District of Maryland, alleging that the agency had unreasonably delayed its implementation and enforcement of the premarket review process applicable to certain tobacco products. In that case, the court also found that the agency had unreasonably delayed acting and imposed deadlines on the agency's review of new products in light of the important public health interests at stake. *Am. Acad. of Pediatrics,* 399 F. Supp. 3d at 487, *appeal dismissed sub nom. In re Cigar Ass'n of Am.,* 812 F. App'x 128 (4th Cir. 2020). In short, this is not the first time the FDA has dragged its feet in the context of fulfilling its statutory duties under the TCA, and it has fallen squarely within the purview of the courts to issue remedies sufficient to right the wrongs. The public health interests at play in this case are similarly grave and warrant judicial intervention.

CONCLUSION

This case is not moot because the FDA has not acted to fulfill its obligations under the Tobacco Control Act and administrative procedure regulations. Accordingly, the government's Second Motion to Dismiss should be denied.

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Respectfully submitted,

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