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### No. 25-1780

## UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

State of New York, et al.,

Plaintiffs - Appellees,

v.

Robert F. Kennedy, Jr., et al., Defendants - Appellants.

On Appeal from the U.S. District Court for the District of Rhode Island, Case No. 1:25-cv-00196; Hon. Melissa R. DuBose

# MOTION OF CAMPAIGN FOR TOBACCO-FREE KIDS FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES' OPPOSITION TO EMERGENCY MOTION FOR STAY PENDING APPEAL

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## **MOTION**

Under Rule 27 of the Federal Rules of Appellate Procedure, the Campaign for Tobacco-Free Kids ("Tobacco-Free Kids") hereby moves the Court for leave to file a brief *amicus curiae* in support of Plaintiffs-Appellees' Opposition to Defendants-Appellants' Emergency Motion for Stay Pending Appeal. Tobacco-Free Kids proposes filing its brief no later than Thursday, August 21, 2025. Plaintiffs-Appellees and Defendants-Appellees both consent to the proposed *amicus* brief.

Tobacco-Free Kids is a 501(c)(3) nonprofit organization and a leading advocacy organization working to reduce tobacco use and its deadly consequences in the United States and around the world. Tobacco-Free Kids regularly partners with various medical, public health, and community organizations that work on a daily basis to reduce the devastating health harms of tobacco products. From pediatricians who counsel their young patients and their parents about the hazards of tobacco use, to organizations with formal programs to urge users to quit, to groups representing parents and families struggling to free young people from nicotine addiction, Tobacco-Free Kids and these organizations have direct and immediate interests in protecting the lifesaving programs and activities of agencies within the U.S. Department of Health and Human Services directed at reducing tobacco-related disease and mortality, including the Office on Smoking and Health (OSH) and the Center for Tobacco Products (CTP). A stay of the Preliminary Injunction would seriously undermine federal and state efforts to prevent the death and suffering caused by tobacco products, including the addiction of millions of young people. Tobacco-Free Kids is actively soliciting participation in its proposed brief from some of these partner organizations and anticipates that its submitted brief will be joined by several of these groups.

This *amicus* brief is desirable because Tobacco-Free Kids and its partner organizations have substantial expertise in the health harms of tobacco products, as well as a deep understanding of the programs and activities of OSH and CTP that are critical components of national and state efforts to address the myriad health harms of tobacco. *Amici* can address not only the harm to the Plaintiff States from the requested stay, but also the harm to young people and their families.

The proposed brief would comply with Rule 27(d) and be no longer than 20 pages and 5,200 words.

For these reasons, Tobacco-Free Kids urges the Court to grant this motion for leave to file a brief *amicus curiae*.

## Respectfully submitted,

## /s/ Christina S. Marshall

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Dated: August 21, 2025

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### **CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing motion complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because the motion contains 389 words. The motion complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface using Microsoft Office 365 in 14-point Times New Roman font.

August 21, 2025

/s/ Christina S. Marshall

Christina S. Marshall

### **CERTIFICATE OF SERVICE**

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on August 21, 2025.

I hereby certify that participants in the case are represented by registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system, except the following who will be served by electronic and First Class mail:

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No. 25-1780

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## BRIEF OF VARIOUS MEDICAL, PUBLIC HEALTH AND COMMUNITY ORGANIZATIONS AS AMICI CURIAE IN OPPOSITION TO STAY PENDING APPEAL

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## **CORPORATE DISCLOSURE STATEMENT**

Amici curiae American Academy of Pediatrics, American Cancer Society

Cancer Action Network, American Heart Association, American Lung

Association, American Medical Association, American Thoracic Society,

Campaign for Tobacco-Free Kids, Parents Against Vaping E-cigarettes, Rhode

Island Medical Society, and Truth Initiative are all non-profit medical, public

health or community organizations committed to reducing disease and mortality

caused by tobacco products. No party to this filing has a parent corporation, and

no publicly held corporation owns 10% or more of the stock of any of the parties to

this filing.

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Amici curiae medical, public health and community organizations submit this brief in opposition to the defendants' motion to stay the preliminary injunction issued by the District Court. Granting defendants' stay motion would seriously undermine federal and state efforts to prevent the death and suffering caused by tobacco products, including the addiction of millions of young people.<sup>1</sup>

### STATEMENT OF INTEREST OF AMICI CURIAE

Amici are ten national and state medical, public health, and community organizations working to reduce tobacco-related disease and mortality: American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Medical Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Parents Against Vaping E-cigarettes, Rhode Island Medical Society, and Truth Initiative. They include organizations with programs to assist individuals to quit the use of tobacco products, those representing physicians who counsel young patients and their families about the hazards of tobacco use, and parents struggling to free young people from nicotine addiction. These organizations have unquestionable expertise in the health harms of tobacco products, as well as a deep

<sup>&</sup>lt;sup>1</sup> No person or entity other than *amici* and their counsel authored this brief in whole or in part or contributed money intended to fund preparing or submitting this brief.

understanding of the programs and activities of agencies within the Department of Health and Human Services ("HHS"), including the Office on Smoking and Health ("OSH") within the Centers for Disease Control and Prevention ("CDC") and the Center for Tobacco Products ("CTP") within the Food and Drug Administration ("FDA"), that are critical to the nation's efforts to address the devastating health harms of tobacco. *Amici* have strong and continuing interests in protecting these lifesaving programs and activities, and the statutory mandates giving rise to them, against the arbitrary, capricious and illegal action taken by Secretary Kennedy through the widespread reductions in force ("RIFs") which quickly followed his March 27 Communiqué.

## BACKGROUND: THE DEVASTATING EFFECTS OF TOBACCO PRODUCTS ON PUBLIC HEALTH

A quarter century ago, the U.S. Supreme Court recognized that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). Despite considerable progress reducing smoking prevalence, today tobacco use remains the leading cause of preventable death in the U.S., with smoking alone killing approximately 490,000 Americans each year<sup>2</sup> – more than alcohol, AIDS, car accidents, illegal

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<sup>&</sup>lt;sup>2</sup> U.S. DEP'T OF HEALTH & HUM. SERVS., Surgeon General's Report: *Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the* 

drugs, murders and suicides combined.<sup>3</sup> Smoking is a primary driver of chronic disease, causing 30% of all cancer deaths,<sup>4</sup> at least 25% of deaths from cardiovascular disease, including heart attack and stroke,<sup>5</sup> and 80% of all deaths from COPD.<sup>6</sup> It increases the risk of developing Type 2 Diabetes by 30-40%.<sup>7</sup>

In recent years, a new kind of tobacco product, e-cigarettes, has emerged as a serious threat to the health of young people. In its unanimous opinion in FDA v.

Surgeon General (2024),

https://archive.cdc.gov/#/details?url=https://www.cdc.gov/tobacco-surgeon-general-reports/about/2024-end-tobacco-disparities.html.

<sup>&</sup>lt;sup>3</sup> U.S DEP'T OF HEALTH & HUM. SERVS., *The Health Consequences of Smoking* – 50 Years of Progress: A Report of the Surgeon General (2014), <a href="https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\_-">https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncbi.nlm.nih.gov/bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncbi.nlm.nih.gov/bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncbi.nlm.nih.gov/bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncbi.nlm.nih.gov/bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncbi.nlm.nih.gov/bookshelf\_-</a> <a href="https://www.ncbi.nlm.nih.gov/bookshelf\_-">https://www.ncb

<sup>&</sup>lt;sup>4</sup> 7 Islami F. et al., Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States, 2019, 74 CA Cancer J. Clin. 405 (2024), https://doi.org/10.3322/caac.21858.

<sup>&</sup>lt;sup>5</sup> CNTRS. FOR DISEASE CONTROL & PREVENTION, Health Effects of Cigarettes: Cardiovascular Disease, 2025, <a href="https://www.cdc.gov/tobacco/about/cigarettes-and-cardiovascular-disease.html">https://www.cdc.gov/tobacco/about/cigarettes-and-cardiovascular-disease.html</a> (last visited Aug. 15, 2025).

<sup>&</sup>lt;sup>6</sup> U.S. DEP'T OF HEALTH & HUM. SERVS., Let's Make the Next Generation Tobacco-Free: Your Guide to the 50th Anniversary Surgeon General's Report on Smoking and Health (2014) (citing U.S. Dep't of Health & Hum. Servs., The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General (2014)), <a href="http://www.surgeongeneral.gov/library/reports/50-years-of-progress/consumer-guide.pdf">http://www.surgeongeneral.gov/library/reports/50-years-of-progress/consumer-guide.pdf</a>.

<sup>&</sup>lt;sup>7</sup> U.S. Dep't of Health & Hum. Servs., *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General* 544 (2014).

Wages and White Lion Investments, LLC, 604 U.S. , 145 S.Ct. 898 (2025), addressing FDA's public health review of flavored e-cigarettes, the Supreme Court noted that "e-cigarettes . . . pose their own health risks," including the concern that their use could lead young non-smokers to smoke conventional cigarettes. *Id.* at 909. The Court cited data showing that youth usage of these highly addictive nicotine products at one point reached 3.6 million middle-and high-school students, due in part to "[t]he kaleidoscope of flavor options" contributing to "the allure of e-cigarettes" creating "the booming demand for such products among young Americans." Id. at 910. The most recent data from CDC's National Youth Tobacco Survey ("NYTS") shows that youth e-cigarette use remains a persistent public health concern, with over 1.6 million youth, including 7.8% of high schoolers, reporting current e-cigarette use in 2024.8 Of those, 38.4% reported frequent use, and 26.3% reported daily use. FDA Commissioner Dr. Martin Makary recently commented on the continuing problem of youth addiction to ecigarettes, saying he personally has "observed kids . . . who have become addicted to vaping": "They know they're addicted, they want to stop and they can't stop." 10

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<sup>&</sup>lt;sup>8</sup> Eunice Park-Lee et al., *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students* — *United States*, 2024, 73 *Morbidity & Mortality Wkly. Rep.* 774 (Sept. 5, 2024), <a href="https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf">https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf</a>.

<sup>&</sup>lt;sup>9</sup> *Id*.

<sup>&</sup>lt;sup>10</sup> Video posted by Dr. Marty Makary (@DrMakaryFDA), X, This illegal importation stops today. I personally have observed kids from good families who

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## **SUMMARY OF THE ARGUMENT**

As the District Court found, Plaintiff States have demonstrated the widespread, harmful effects of the March 27 Communiqué on a vast array of mandatory activities of HHS that are essential to public health. *Amici* here focus on the impact of the Communiqué on the activities mandated by Congress to protect the public – particularly youth – from the health harms of tobacco products. From the Comprehensive Smoking Education Act of 1984, intended to make Americans "more aware of any adverse health effects of smoking," to the Family Smoking Prevention and Tobacco Control Act of 2009, 12 giving FDA broad regulatory authority over tobacco products and finding that the use of tobacco products by children is a "pediatric disease of considerable proportions," Congress has mandated multifaceted federal actions to prevent tobacco-related disease.

Although the Secretary attempts to justify the RIFs which followed the March 27 Communiqué as efforts to refocus HHS on "ending Americans"

have become addicted to vaping. They know they're addicted, they want to stop, and they can't stop. The FDA will continue to monitor and take necessary actions to prevent these illegal products from entering the United States. (May 22, 2025), https://x.com/DrMakaryFDA/status/1925552991618076684.

<sup>&</sup>lt;sup>11</sup> Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 2, 98 Stat. 2200, 2201 (1984) (codified at 15 U.S.C. § 1331 note).

<sup>&</sup>lt;sup>12</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(1) Publ, 123 Stat. 1776, 1777 (2009) (codified at 21 U.S.C. § 387 note).

epidemic of chronic illness" and to save taxpayer money, they have effectively eliminated OSH and seriously impeded mandatory functions of CTP. The impact on tobacco-related programs highlights how the Secretary has flouted the commands of Congress and is among the most compelling reasons for this Court to accept the District Court's conclusion that the March 27 Communiqué is likely contrary to law, as well as arbitrary and capricious, and deny the requested stay of the District Court's preliminary injunction.

### **ARGUMENT**

I. THE CHALLENGED "DRAMATIC RESTRUCTURING" OF HHS THROUGH THE MARCH 27 COMMUNIQUÉ DEFIES THE AGENCY'S STATUTORY OBLIGATIONS AND UNDERCUTS EFFORTS TO PREVENT TOBACCO-RELATED DISEASE AND MORTALITY.

Congress enacted the Comprehensive Smoking Education Act in 1984 "to provide a new strategy for making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings and to enable individuals to make informed decisions about smoking." 15 U.S.C. § 1331. The Act directs the Secretary of Health and Human Services to both "establish" and "carry out" "a program to inform the public of any dangers to human health presented by cigarette smoking." 15 U.S.C. § 1341(a). The statute grants the Secretary some discretion. The Secretary shall undertake "information

<sup>&</sup>lt;sup>13</sup> ECF No. 1-1 at 2 (the March 27 Communiqué).

and research activities" not specifically enumerated in the statute that the Secretary "determines necessary and appropriate." Id. § 1341(a)(6). But Congress took pains to enumerate actions that the Secretary *must* take in connection with this important health mandate. The Secretary "shall . . . develop materials for informing the public" of the effect of cigarette smoking on human health. *Id*. § 1341(a)(1). The Secretary "shall . . . establish and maintain a liaison with . . . State and local public agencies respecting activities relating to the effect of cigarette smoking on human health . . ." Id. § 1341(a)(3). And the Secretary "shall ... collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health..." Id. § 1341(a)(4) As the District Court found, the uncontroverted evidence shows that the Secretary is defying these statutory duties at the expense of public health. See, e.g., ROA 67-68.

Prior to the April 1 RIFs which followed the March 27 Communiqué, the Secretary carried out much of these mandated functions through OSH. *See generally* Compl. (ECF No. 1) ¶¶ 164-72; Jane Doe 4 Decl. (ECF No. 55-5) ¶¶ 6-19. As CDC's website astonishingly continues to proclaim:

CDC's Office on Smoking and Health (OSH) is the lead federal agency for comprehensive tobacco prevention and control. OSH saves lives and money by preventing and reducing the use of commercial tobacco products—the leading cause of preventable disease, disability, and death in the United States.<sup>14</sup>

But on April 1, 2025, "[a]ll [OSH] employees who had not already filed for retirement or early retirement received a RIF notice." Jane Doe 4 Decl. ¶ 22. "The RIFs effectively shut down OSH." *Id.* All OSH work has been "effectively halted" as "there is no one left in the Office to carry it out and because OSH-funded contracts have been terminated." *Id.* ¶ 23. Thus, various "statutorily mandated functions and activities" are not being carried out. *Id.* 

The undisputed evidence presented to the District Court shows that HHS's "materials for informing the public" of the dangers of cigarette smoking, required by 15 U.S.C. § 1341(a)(1), have been removed. *See, e.g.*, Davis Decl. (ECF No. 44-37) ¶ 26 (New York's public health agency "no longer has access to OSH education ads through the Media Campaign Resource Center," a "clearinghouse" for tobacco educational materials. including "hundreds of videos, radio, print, outdoor (billboard), digital ads, and social media materials"); Strandridge Decl. (ECF No. 44-50) ¶ 53 (Wisconsin's public health agency lacks the same). "Liais[ing]" with State public health agencies on the dangers of smoking, *see* 15 U.S.C. § 1341(a)(3), has entirely ceased. *See, e.g.,* Jane Doe 4 Decl. ¶ 24 ("[T]here

<sup>14</sup> CNTRS. FOR DISEASE CONTROL & PREVENTION, *About the Office on Smoking and Health*, <a href="https://www.cdc.gov/nccdphp/divisions-offices/about-the-office-on-smoking-and-health.html">https://www.cdc.gov/nccdphp/divisions-offices/about-the-office-on-smoking-and-health.html</a> (last visited Aug. 15, 2025).

is no one left within OSH to provide ... national technical assistance on the best available science."); Davis Decl. ¶ 24 (New York's public health agency has "not been able to receive answers or guidance..."). The "[c]ollect[ion], analy[sis], and disseminat[ion]" of data on smoking dangers, mandated by 15 U.S.C. § 1341(a)(4), has also ended. See, e.g., Standridge Decl. ¶ 54 (Wisconsin's public health agency "has lost access to . . . Behavioral Risk Factor Surveillance System, National Health and Nutrition Examination Survey, NYTS," and other data sets). <sup>15</sup> The evidence further shows that HHS is now refusing to accept "list[s] of the ingredients added to tobacco in the manufacture of cigarettes" that 15 U.S.C. § 1335a(a) requires be submitted to the Secretary. See ECF No. 44-9 at 2 (email from CDC to manufacturer stating that "[d]ue to the impact of the HHS Reduction in Force and reorganization, CDC is pausing any ingredient submissions . . . "); ECF No. 44-15 at 2 (CDC website confirming the same).

The District Court was also presented with uncontroverted evidence that "OSH will not be able to provide funding to the states for the Tips [from Former Smokers] Campaign." Jane Doe 4 Decl. ¶ 27. OSH provided millions of dollars in

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<sup>&</sup>lt;sup>15</sup> Data from the NYTS first established that youth e-cigarette use had reached, in the words of the Surgeon General, "epidemic" levels, by 2018. *Surgeon General's Advisory on E-Cigarette Use Among Youth* (December 18, 2018), <a href="https://stacks.cdc.gov/view/cdc/153187">https://stacks.cdc.gov/view/cdc/153187</a> (last accessed August 19, 2025). The NYTS has enabled health authorities to track the level of youth e-cigarette use since that time. *See, e.g.*, Park-Lee, E., *et al.*, *supra* note 8.

funding to the National and State Tobacco Control Program in all 50 states and the District of Columbia. *Id.* ¶ 7. New Jersey's "Quitline and Quit Centers are already dealing with the consequences of the loss of resources . . ." Brown Decl. (ECF No. 44-26) ¶ 21. To keep the state's programs running at all, New Jersey reallocated available funds, which has "reduce[d] the number of subgrants it provides to community-based services" causing "a disruption and deterioration of services offered . . .." *Id.* <sup>16</sup> These OSH-supported activities have been proven to be effective in leading current smokers to quit and in preventing non-smokers from starting. Indeed, CDC estimated that in just a six-year span, the Tips Campaign motivated over 16.4 million individuals who smoke to attempt to quit, and led about a million people to give up smoking. Jane Doe 4 Decl. ¶ 8. <sup>17</sup>

As the District Court found, the March 27 Communiqué is also impeding the functions of the statutorily mandated CTP. *See* ROA 67-68. When it passed the Family Smoking Prevention and Tobacco Control Act in 2009, Congress found that "[a] consensus exists within the scientific and medical communities that

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<sup>&</sup>lt;sup>16</sup> See also ECF No. 44-24 at 4-5 (Larkin Decl. ¶ 10) (Rhode Island's Tobacco Control Program lost \$1,383,858 in grant funding, amounting to 80% of staff funding and 67% of quitline funding).

<sup>&</sup>lt;sup>17</sup> See also R. Murphy-Hoefer, et al., Association Between the Tips From Former Smokers Campaign and Smoking Cessation Among Adults, United States, 2012-2018. Preventing Chronic Disease, 17 (Aug. 27, 2020): E97, <a href="https://pubmed.ncbi.nlm.nih.gov/32857030/">https://pubmed.ncbi.nlm.nih.gov/32857030/</a>.

tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." P.L. 111-31, § 2(2); 21 U.S.C. § 387 note. To combat the scourge of tobacco, Congress for the first time gave FDA the authority to regulate tobacco products. 21 U.S.C. § 387a. To enable FDA effectively to do so at no expense to the taxpayers, Congress mandated the creation of the CTP, responsible for the implementation of the Act, 21 U.S.C. § 387e, and provided that its sole source of funding would come from user fees to be paid by manufacturers and importers of tobacco products. 21 U.S.C. § 387s(c)(2)(A)-(B). 18

Within CTP, the Office of Health Communication and Education develops and administers "The Real Cost" campaign, a tobacco prevention advertising campaign that provides current information on the harms of tobacco products. ECF No. 55-8 at 8 (John Doe 7 Decl. ¶ 24); see also 15 U.S.C. § 1341(a) (requiring "a program to inform the public of any dangers to human health presented by cigarette smoking."). The campaign prevented an estimated 444,252 American youth from starting e-cigarettes between 2023 and 2024. Davis Decl. ¶ 22; see also Davis Decl. Ex. D. Not only is it funded entirely at no cost to taxpayers, see supra, but for each dollar spent, it saves an estimated \$180 in

For the current fiscal year, Congress provided for user fees of \$712,000,000. *See* 21 U.S.C. § 387s(b)(1)(K).

medical, productivity, and other costs. ECF No. 55-9 at 8 (Sloss Decl. ¶ 34).

Despite this, the campaign can no longer "continue its mission…" as "[a]ll of the employees working on the [c]ampaign were RIFed on April 1…" John Doe 7

Decl. ¶ 24; see ROA 67-68. Other crucial CTP offices have been harmed by the March 27 Communiqué, as well.

The Office of Science is central to the CTP. It collaborates with OSH in administering the NYTS and "employs scientists to review premarket tobacco product applications" concerning "any new tobacco product seeking an FDA marketing order." John Doe 7 Decl. ¶ 15. Millions of such applications have been filed. By statute, CTP must review these applications "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application . . .."

21 U.S.C. § 387j(c)(1)(A). CTP also must issue an order finding a tobacco product "appropriate for the protection of the public health" before the proposed product "may be introduced" into the market. 21 U.S.C. § 387j(c)(2)(A). Nevertheless, throughout CTP's history, a vast number of e-cigarette products have remained on the market "without premarket review" and without a finding that they have met the statutory public health standard. See generally Am. Acad. of Pediatrics v. Food

<u>product/tobacco-product-applications-metrics-reporting</u> (last visited Aug. 15, 2025)].

<sup>&</sup>lt;sup>19</sup> U.S. FOOD & DRUG ADMIN., Tobacco Product Applications: Metrics & Reporting, , <a href="https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-products/market

& Drug Admin., 379 F. Supp. 3d 461, 470, 490 (D. Md. 2019), appeal dismissed sub nom. In re Cigar Ass'n of Am., 812 F.App'x 128 (4th Cir. 2020). On the heels of 80 terminations in the Office of Science in February, 20 the March 27 Communiqué has had the effect of removing the leader of the Office of Science, 21 which has undermined the ability of CTP to satisfy its statutory mandate to review every new tobacco product before it reaches the market and to allow no new products to remain on the market without a marketing authorization order.

## II. THE CHALLENGED "DRAMATIC RESTRUCTURING" OF HHS THROUGH THE MARCH 27 COMMUNIQUÉ IS ARBITRARY, CAPRICIOUS AND NOT IN ACCORDANCE WITH LAW

As the District Court properly found, Plaintiffs are likely to succeed on their claims that the department-wide RIFs at HHS implementing the March 27 Communiqué were unlawful in numerous ways. *See* ROA 65-74. The illegality of the Secretary's actions is undeniable in the context of the OSH and CTP for at least two reasons.

First, the Secretary cannot reasonably claim to have any discretion to strip the OSH or CTP of their ability to comply with unambiguous statutory mandates.

<sup>&</sup>lt;sup>20</sup> See Sarah Todd, What FDA cuts could mean for the future of tobacco, STAT, April 3, 2025, <a href="https://www.statnews.com/2025/04/03/trump-fda-cuts-raise-questions-tobacco-control-regulation-stop-smoking-efforts/">https://www.statnews.com/2025/04/03/trump-fda-cuts-raise-questions-tobacco-control-regulation-stop-smoking-efforts/</a> (last visited Aug. 15, 2025).

<sup>&</sup>lt;sup>21</sup> *Id*.

Yet that is exactly what the Secretary has done — even though the Secretary was instructed to comply with statutory mandates in conducting RIFs within HHS.<sup>22</sup> OSH has effectively been abolished, and the undisputed evidence shows that HHS is now incapable of satisfying its obligations under the Comprehensive Smoking Education Act. While the CTP continues to exist, its ability to fulfill its statutory responsibilities under the Tobacco Control Act has been hamstrung by the removal of its scientific leadership.

Second, even if the Secretary has some discretion to restructure HHS or shift its priorities, his striking departure from the Department's longstanding commitment to combat tobacco-related chronic disease was plainly arbitrary and capricious. The Secretary claims that the "overhaul" of the Department he announced on March 27 "will implement the new HHS priority of ending America's epidemic of chronic illness." ECF 1-1 at 3. Given the scientific and medical consensus that tobacco products are a major source of chronic disease, as recognized by both the Supreme Court and Congress, the Secretary's abrupt decision to undermine well accepted, highly effective and Congressionally

<sup>&</sup>lt;sup>22</sup> See U.S. Office of MGMT. & Budget & U.S. Office of Pers. MGMT., Guidance on Agency RIF and Reorganization Plans Requested by Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative' (Feb. 26, 2025), <a href="https://www.opm.gov/policy-data-oversight/latest-memos/guidance-on-agency-rif-and-reorganization-plans-requested-by-implementing-the-president-s-department-of-government-efficiency-workforce-optimization-initiative.pdf">https://www.opm.gov/policy-data-oversight/latest-memos/guidance-on-agency-rif-and-reorganization-plans-requested-by-implementing-the-president-s-department-of-government-efficiency-workforce-optimization-initiative.pdf</a>.

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mandated public information and tobacco control initiatives cannot be reconciled with the Secretary's stated objectives. Further, because statutorily mandated user fees are the source of CTP's funding, nor can any the Secretary's decisions concerning CTP be explained by a desire to save taxpayer money.

As the Supreme Court explained many years ago, an agency acts arbitrarily and capriciously when it offers an explanation for its decision that "runs counter to the evidence before the agency" or "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs.*Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983). This Circuit has followed a similar approach. See, e.g., Associated Fisheries of Maine, Inc. v. Daley, 127 F.3d 104, 109 (1st Cir. 1997). It is difficult to imagine how the Secretary could possibly have concluded that handcuffing the ability of HHS to combat the scourge of tobacco would somehow promote the fight against chronic disease. There is no reason for the Court to defer to such a plainly implausible judgment.

## **CONCLUSION**

For all these reasons, the Court should deny the Secretary's motion for a stay pending appeal.

Respectfully submitted,

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### **CERTIFICATE OF COMPLIANCE**

This brief complies with the type-volume limitation of Fed. Rs. App. P. 29(a)(5) and 32(a)(7)(B) because the brief contains 3,467 words, excluding the parts of the brief exempt by Fed. R. App. P. 32(f).

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August 21, 2025

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#### **CERTIFICATE OF SERVICE**

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system on August 21, 2025.

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