

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

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

Scott P. Lewis (Cir. Bar No. 21119)
Christina S. Marshall (Cir. Bar No. 1197627)
Anderson & Kreiger LLP
50 Milk Street, Floor 21
Boston, MA 02109
T: 617-621-6500
E: slewis@andersonkreiger.com
E: cmarshall@andersonkreiger.com

Dennis A. Henigan
Andrew R. Tardiff
Campaign for Tobacco-Free Kids
1400 I Street NW, Suite 1200
Washington, DC 20005
T: 202-304-9928
E: dhenigan@tobaccofreekids.org
E: atardiff@tobaccofreekids.org

Counsel for Amici Curiae

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.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

STATEMENT OF INTEREST OF *AMICI CURIAE* 1

BACKGROUND: THE DEVASTATING EFFECTS OF TOBACCO
PRODUCTS ON PUBLIC HEALTH.....2

SUMMARY OF THE ARGUMENT5

ARGUMENT6

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.6

II. THE CHALLENGED “DRAMATIC RESTRUCTURING” OF HHS
THROUGH THE MARCH 27 COMMUNIQUÉ IS ARBITRARY,
CAPRICIOUS AND NOT IN ACCORDANCE WITH LAW13

CONCLUSION15

TABLE OF AUTHORITIES

Cases

Am. Acad. of Pediatrics v. Food & Drug Admin., 379 F. Supp. 3d 461 (D. Md. 2019).....13

Associated Fisheries of Maine, Inc. v. Daley, 127 F.3d 104 (1st Cir. 1997)15

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. (2000).....2

FDA v. Wages and White Lion Investments, LLC, 145 S.Ct. 898 (2025).....4

In re Cigar Ass’n of Am., 812 F.App’x 128 (4th Cir. 2020).....13

Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29 (1983)15

Statutes

15 U.S.C. § 13315, 6

15 U.S.C. § 1335a(a).....9

15 U.S.C. § 1341(a) 6, 7, 8, 9, 11

21 U.S.C. § 387 note11

21 U.S.C. § 387a11

21 U.S.C. § 387e11

21 U.S.C. § 387j(c)(1)(A)12

21 U.S.C. § 387s(b)(1)(K)11

21 U.S.C. § 387s(c)(2)(A)-(B).....11

Other Authorities

CNTRS. FOR DISEASE CONTROL & PREVENTION, *About the Office on Smoking and Health*8

CNTRS. FOR DISEASE CONTROL & PREVENTION, Health Effects of Cigarettes: Cardiovascular Disease, 2025	3
Dr. Marty Makary (@DrMakaryFDA), X (formerly Twitter)	4
Eunice Park-Lee et al., <i>E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024</i> , 73 <i>Morbidity & Mortality Wkly. Rep.</i> 774 (Sept. 5, 2024)	4
Farhard Islami et al., <i>Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States, 2019</i> , 74 <i>CA Cancer J. Clin.</i> 405 (2024)	3
R. Murphy-Hoefer, et al., <i>Association Between the Tips From Former Smokers Campaign and Smoking Cessation Among Adults, United States, 2012-2018</i> . 17 <i>Preventing Chronic E</i> 97 (Aug. 27, 2020)	10
Sarah Todd, <i>What FDA cuts could mean for the future of tobacco</i> , STAT, April 3, 2025	13
U.S DEP’T OF HEALTH & HUM. SERVS., <i>The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General</i> (2014)	3
U.S. DEP’T OF HEALTH & HUM. SERVS., <i>Let’s Make the Next Generation Tobacco- Free: Your Guide to the 50th Anniversary Surgeon General’s Report on Smoking and Health</i> (2014)	3
U.S. DEP’T OF HEALTH & HUM. SERVS., <i>Surgeon General’s Report: Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the Surgeon General</i> (2024)	3
U.S. DEP’T OF HEALTH & HUM. SERVS., <i>The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General</i> (2014)	3
U.S. FOOD & DRUG ADMIN., <i>Tobacco Product Applications: Metrics & Reporting</i>	12
U.S. OFFICE OF MGMT. & BUDGET & U.S. OFFICE OF PERS. MGMT., <i>Guidance on Agency RIF and Reorganization Plans Requested by Implementing the President’s ‘Department of Government Efficiency’ Workforce Optimization Initiative</i> ” (Feb. 26, 2025)	14

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.¹

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

¹ 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 year² – more than alcohol, AIDS, car accidents, illegal

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

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>.

³ U.S DEP'T OF HEALTH & HUM. SERVS., *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General* (2014),
https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_-_NBK179276.pdf.

⁴ 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>.

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

⁶ 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)), <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/consumer-guide.pdf>.

⁷ 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.⁹ FDA Commissioner Dr. Martin Makary recently commented on the continuing problem of youth addiction to e-cigarettes, 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

⁸ 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), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf>.

⁹ *Id.*

¹⁰ Video posted by Dr. Marty Makary (@DrMakaryFDA), X, *This illegal importation stops today. I personally have observed kids from good families who*

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,”¹¹ 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>.

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

¹² 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”¹³ 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

¹³ 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.¹⁴

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

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

¹⁵ 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), <https://stacks.cdc.gov/view/cdc/153187> (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.*¹⁶ 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. ¶ 8.¹⁷

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

¹⁶ *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).

¹⁷ *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, <https://pubmed.ncbi.nlm.nih.gov/32857030/>.

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

¹⁸ 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.¹⁹ 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*

¹⁹ U.S. FOOD & DRUG ADMIN., Tobacco Product Applications: Metrics & Reporting, , <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting> (last visited Aug. 15, 2025)].

& 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.

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

²¹ *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.²² 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

²² 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), <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>.

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,

/s/ Christina S. Marshall
Scott P. Lewis (Cir. Bar No. 21119)

Christina S. Marshall (Cir. Bar No. 1197627)
ANDERSON & KREIGER LLP
50 Milk Street, Floor 21
Boston, MA 02109
T: 617-621-6500
E: slewis@andersonkreiger.com

Dennis A. Henigan
Andrew R. Tardiff
Campaign for Tobacco-Free Kids
1400 I Street NW, Suite 1200,
Washington, DC 20005
T: 202-304-9928
E: dhenigan@tobaccofreekids.org
E: atardiff@tobaccofreekids.org

Counsel for *Amici Curiae*

Dated: August 21, 2025

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).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(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:

Alexa Gabriela Salas
AZ Attorney General's Office
2005 N Central Ave.
Phoenix, AZ 85004

Elleanor H. Chin
162 Court St., NE
Salem, OR 97301
E: Elleanor.chin@doj.oregon.gov

E: alexa.salas@azag.gov

Justine M. Longa
NJ Attorney General's Office
25 Market St.
Trenton, NJ 08625
E: Justine.longa@law.njoag.gov

Jessica L. Palmer
NJ Attorney General's Office
25 Market Street
Trenton, NJ 08625
E: Jessica.palmer@law.njoag.gov

Margaret Machaiek
ME Attorney General's Office
6 State House Station
Augusta, ME 04333-0006
E: margaret.machaiek@main.gov

Andrew C. Mendrala
DC Office of the Attorney General
400 6th St., NW
Washington, DC 20001
E: Andrew.mendrala@dc.gov

Lindsey E. Middlecamp
MN Attorney General's Office
445 Minnesota St., Suite 600
St. Paul, MN 55101
E: linsey.middlecamp@ag.state.mn.us

August 21, 2025

/s/ Christina S. Marshall
Christina S. Marshall