IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civ. No. 1:25-cv-00196
ROBERT F. KENNEDY, JR., *et al.*,	)	
Defendants.	)	

BRIEF OF AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AMERICAN THORACIC SOCIETY, CAMPAIGN FOR TOBACCO-FREE KIDS, PARENTS AGAINST VAPING E-CIGARETTES, AND TRUTH INITIATIVE AS *AMICI CURIAE* IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

CORPORATE DISCLOSURE STATEMENT

Amici curiae American Academy of Family Physicians, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Parents Against Vaping E-cigarettes, 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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With the consent of the parties, *amici curiae* medical, public health and community organizations submit this brief in opposition to the defendants' October 14, 2025, motion to dismiss. Granting defendants' 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.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are eight national and state medical, public health, and community organizations working to reduce tobacco-related disease and mortality: American Academy of Family Physicians, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Parents Against Vaping E-cigarettes, 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 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 AND SUMMARY OF THE ARGUMENT

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[1] – more than alcohol, AIDS, car accidents, illegal drugs, murders and suicides combined.[2] Smoking is a primary driver of chronic disease, causing 30% of all cancer

[1] U.S. DEP'T OF HEALTH & HUM. SERVS., Surgeon General's Report: *Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the Surgeon General* (2024), https://archive.cdc.gov/#/details?url=https://www.cdc.gov/tobacco-surgeon-general-reports/about/2024-end-tobacco-disparities.html.

[2] 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.

deaths,[3] at least 25% of deaths from cardiovascular disease, including heart attack and stroke,[4] and 80% of all deaths from COPD.[5] It increases the risk of developing Type 2 Diabetes by 30-40%.[6]

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. Wages and White Lion Investments, LLC,* 604 U.S. 542 (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 554. 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 555. The most recent data from CDC's National Youth Tobacco Survey ("NYTS") shows that youth e-cigarette use remains a persistent public

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[3] Farhad Islami *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.

[4] 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 November 14, 2025).

[5] 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 (last visited November 14, 2025).

[6] 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).

health concern, with over 1.6 million youth, including 7.8% of high schoolers, reporting current e-cigarette use in 2024.[7] Of those, 38.4% reported frequent use, and 26.3% reported daily use,[8] a strong sign of addiction. FDA Commissioner Dr. Martin Makary has 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."[9]

The March 27 Communiqué is having widespread, harmful effects on a vast array of HHS's mandatory activities that are essential to public health. *Amici* here focus on the impact of the Communiqué on the activities expressly 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,"[10] to the Family Smoking Prevention and Tobacco Control Act of 2009,[11] giving FDA broad regulatory authority over tobacco products and finding that the use of tobacco products by

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[7] 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.

[8] *Id.*

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

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

[11] 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, *et seq.*).

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' epidemic of chronic illness" and to save taxpayer money, they have effectively eliminated OSH and seriously impeded mandatory functions of CTP. The impacts on tobacco-related programs highlight the Secretary's violation of the commands of Congress and are among the most compelling reasons for this Court to deny Defendants' motion to dismiss.

ARGUMENT

I. This Court Has Jurisdiction Over Plaintiff States' Claims

a. Plaintiff States Have Pled Article III Standing for Their Tobacco Control Claims

Defendants' various challenges to Plaintiffs' standing to bring their tobacco control claims should be summarily rejected. The "irreducible constitutional minimum of standing contains three elements": (1) an "injury in fact"; (2) "causal connection between the injury and the conduct complained of"; and (3) "redress[ability]." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992) (quotations omitted). At the pleading stage, standing is not a particularly exacting test. "[G]eneral factual allegations of injury resulting from the defendant's conduct may suffice." *Id.* at 561 (1992). That is, plaintiffs need only "plausibly plead[]" such facts. *Tyler v. Hennepin Cnty., Minnesota*, 598 U.S. 631, 637 (2023). Those factual averments "must" be "accept[ed] as true," and the court must "indulge all reasonable inferences therefrom." *In re Fin. Oversight & Mgmt. Bd. for Puerto Rico*, 110 F.4th 295, 308 (1st Cir. 2024) (*quoting Katz v. Pershing, LLC*, 672 F.3d 64, 70 (1st Cir. 2012)). Further, when considering jurisdiction, a court may consider materials outside the pleadings. *Gonzalez v. United States*, 284 F.3d 281, 288 (1st Cir. 2002), as corrected (May 8,

2002). Plaintiff States' detailed factual averments—supported by substantial evidence relied on by this Court in issuing a preliminary injunction—more than satisfy this relatively low bar.

i. Plaintiffs Have Properly Pleaded Cognizable "Informational Injury," Including from the Secretary's Refusal to Disseminate Data on the Dangers of Cigarettes

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 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).[12] The Act separately specifies

[12] Similarly, the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401, *et seq.*, requires the Secretary to "establish and carry out a program to inform the public

actions that the tobacco industry must take in connection with this health program. Specifically, "[e]ach person who manufactures, packages, or imports cigarettes shall annually provide the Secretary with a list of the ingredients added to tobacco in the manufacture of cigarettes . . ." *Id.* § 1335a(a). These reports "permit the federal government to initiate the toxicologic research necessary to measure any health risk posed by the addition of additives and other ingredients to cigarettes during the manufacturing process." H.R. Rep. No. 805, 98th Cong., 2d Sess. 21 (1984).

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* Am. Compl. ¶¶ 172-180); *see also* ECF No. 55-5 at 3-7 (Jane Doe 4 Decl. ¶¶ 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.[13]

The lifesaving importance of OSH is reiterated in Defendants' Motion to Dismiss: "[T]he Office on Smoking and Health (OSH) … works to protect the public's health from the harmful effects of tobacco use by seeking to reduce tobacco-related health disparities, death and disease." ECF No. 98 (Mot.) at 3. 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; *see also* Am. Compl.

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of any dangers to human health resulting from the use of smokeless tobacco products." 15 U.S.C. § 4401(a)(1).

[13] 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 November 10 2025).

¶ 192. "The RIFs effectively shut down OSH." Jane Doe 4 Decl. ¶ 22. Directly after the RIFs, all OSH work had 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 complaint alleges that "[t]he implementation of the March 27 [Communiqué] has also kept CDC from fulfilling its obligations to," *inter alia*, "'collect, analyze and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health …' under the Comprehensive Smoking Education Act …." Am. Compl. ¶ 199 (*quoting* 15 U.S.C. § 1341(a)(4)). And while Plaintiffs can "rest on 'mere allegations'" at this stage of the case, they have already "'set forth' by affidavit or other evidence 'specific facts'" relevant to this injury. *Lujan*, 504 U.S. at 561 (citing Fed. R. Civ. P. 56(e)); *see also Gonzalez*, 284 F.3d at 288. That evidence demonstrates that the "[c]ollect[ion], analy[sis], and disseminat[ion]" of data on smoking dangers, mandated by 15 U.S.C. § 1341(a)(4), has been significantly curtailed. *See, e.g.*, ECF No. 44-50 at 16 (Standridge Decl. ¶ 54) (certain data has not been updated).[14] For instance, the Complaint alleges – and evidence demonstrates – that HHS is 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. Am. Compl. ¶ 194; ECF No. 44-9 at 2 (email from CDC to manufacturer stating that "[d]ue to the impact of the HHS

[14] Data from the NYTS first established that youth e-cigarette use had reached, in the words of the Surgeon General, "epidemic" levels by 2018. *U.S. Surgeon General's Advisory on E-Cigarette Use Among Youth* (December 18, 2018), https://stacks.cdc.gov/view/cdc/153187 [last accessed June 4, 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 7.

Reduction in Force and reorganization, CDC is pausing any ingredient submissions…"); ECF No. 44-15 at 2 (CDC website confirming the same). Defendants cite to regulations concerning *smokeless* tobacco ingredient reporting (governed by a different statute)[15] to argue reports are not yet due, but HHS's own website declares that at least importers' reports are "due upon initial importation into the United States" – not annually.[16] These required reports "permit the federal government to initiate the toxicologic research necessary to measure any health risk posed by the addition of additives and other ingredients to cigarettes during the manufacturing process." H.R. Rep. No. 805, 98th Cong., 2d Sess. 21 (1984). Indeed, given the purpose of the statutorily mandated ingredient reports, it is reasonable to infer that HHS's inability to continue to analyze health risks posed by cigarettes will harm Plaintiff States, including by preventing their access to up-to-date research. Hence, Plaintiff States reasonably allege that they use "these data to inform their program and policy interventions." Am. Compl. ¶ 193.

Defendants characterize these types of injuries as "informational injuries" and invite this Court to follow a Fourth Circuit case requiring Plaintiffs show (1) that they "lack access to information to which [they are] legally entitled" and (2) "that the denial of that information creates a 'real' harm with an adverse effect." Mot. at 16 (citing *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016))). But *Spokeo* is clear: "[T]he violation of a procedural right granted by statute can be sufficient in some

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[15] Mot. at 17-18 (citing 64 Fed. Reg. 14,086 (Mar. 23, 1999); *compare* 15 U.S.C. § 1335a(a) *with* 15 U.S.C. § 4403(a).

[16] CNTRS. FOR DISEASE CONTROL & PREVENTION, *Tobacco Ingredient and Nicotine Reporting*, https://www.cdc.gov/tobacco/php/state-and-community-work/reporting.html (last visited November 10, 2025).

circumstances to constitute injury in fact," and "a plaintiff in such a case need not allege any *additional* harm beyond the one Congress has identified." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 342 (2016) (emphasis original). Hence, there are many instances where a plaintiff suffers an "injury in fact" when she "fails to obtain information which must be publicly disclosed pursuant to a statute." *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998) (citing cases). This is such a case. As a result of the Secretary's actions, Plaintiff States have been unable to obtain data relating to the effect of cigarette smoking on human health that HHS is obligated, by statute, to disseminate. Under *Akins* and its progeny, nothing more is required. But to the extent this Court holds that something more is required, the Plaintiff States nevertheless have pled both a legal entitlement to this data and resulting harm. On the former, 15 U.S.C. § 1341(a)(4) mandates that HHS "collect, analyze, and *disseminate* … information, studies, and other data …." The statute is expressly concerned with "State and local public health agencies." *Id.* § 1341(a)(3). And on the latter, the Plaintiff States have alleged real harm. *See, e.g.*, Am. Compl. ¶ 193. Plaintiff States have thus properly pled standing on these claims.

ii. Plaintiffs Have Properly Pleaded Cognizable Injury Resulting from Cuts in "Services," Including for Liaison Services

The Plaintiff States allege concrete harm stemming from the loss of information critical to their programs aimed at diminishing the harmful effects of cigarette smoking on public health. They allege that the March 27 Communiqué has kept CDC from complying with mandate under the Comprehensive Smoking Education Act to "'establish and maintain a liaison with … State and local public agencies respecting activities relating to the effect of cigarette smoking on public health ….'" Am. Compl. ¶ 199 (*quoting* 15 U.S.C. § 1341(a)(3)). And, like many of their other allegations, they have since put forth specific evidence that functioning as liaison with State public health agencies on the dangers of smoking has entirely ceased. *See, e.g.*, Jane Doe 4 Decl. ¶ 24

("[T]here is no one left within OSH to provide … national technical assistance on the best available science."); ECF No. 44-37 at 10 (Davis Decl. ¶ 24) (New York's public health agency has "not been able to receive answers or guidance….").

Defendants characterize these types of harms as impacts to "services" previously provided by HHS and argue that States lack standing for "service"-related harms. *See* Mot. at 25-27 (*citing United States v. Texas*, 599 U.S. 670, 674 (2023)). But *Texas*, which concerned the challenge of two States to the arrest policies of a federal agency, simply reaffirmed the Supreme Court's "long held" view that "a citizen lacks standing to contest the policies of the prosecuting authority when he himself is neither prosecuted nor threatened with prosecution." 599 U.S. at 674 (quoting *Linda R. S. v. Richard D.*, 410 U.S. 614, 619 (1973)). Further, *Texas* involved alleged increased monetary costs resulting from those arrest policies, which the Court considered to be "more attenuated," "indirect effects on state revenues or state spending." 599 U.S. at 681 fn. 3. Here, the States' tobacco-related "service" harms are direct, as Plaintiff States cannot use resources that OSH previously provided them *directly*, and that HHS is required by statute to provide. *See* 15 U.S.C. § 1341(a)(3). Indeed, whatever discretion HHS has regarding the level of service to provide, it is indisputable that, by statute, must provide at least *some*. Plaintiffs thus have properly pled standing on these claims.

iii. Plaintiffs Have Properly Pleaded Particularized Injuries for their Tobacco Control Claims

Defendants argue that Plaintiff States have failed to "explain their 'personal stake' in certain actions about which they complain," Mot. at 28, but this is unequivocally not the case for the Plaintiff States' tobacco control allegations. The complaint alleges that OSH, which was "destroyed," "is responsible for maintaining the national network of tobacco cessation quitlines to encourage people to quit tobacco use by supporting quitline services in fifty states, two U.S.

territories, and Washington, D.C.," and "also provides millions in funding to the National and State Tobacco Control Program … in fifty states, the District of Columbia," and more. Am. Compl. ¶¶ 178-79, 192. "Participating states used OSH funds to," among other things, "prevent kids from using tobacco …." *Id.* ¶ 179. No speculation is necessary to connect the dots between the destruction of a program office and the inability to carry out that office's programs.

The same is true for less direct injuries, like those the Plaintiff States will suffer from the loss of the Tips from Former Smokers campaign, a long-running media campaign that "encourages smokers to quit by featuring real people with serious health conditions caused by smoking and secondhand smoke exposure." Am. Compl. ¶ 176. The Tips Campaign has been proven to be effective in leading current smokers to quit and in preventing non-smokers from starting. 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] These are concrete health and economic benefits to smoking cessation. Smoking cessation reduces the risk of developing various cancers, as well as cardiovascular diseases, respiratory diseases, and other health conditions.[18] Smoking cessation can improve health outcomes even after diagnosis of cancer and other health conditions.[19] Thus, smoking cessation interventions

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[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/.

[18] *Smoking Cessation: A Report of the Surgeon General*, Ch. 4: The Health Benefits of Smoking Cessation, U.S. DEP'T OF HEALTH & HUM. SERVS. (2020), https://www.ncbi.nlm.nih.gov/books/NBK555590/.

[19] *Id.*

ultimately reduce system-wide healthcare costs.[20] It is eminently reasonable to infer that the loss of the Tips Campaign resulting from the destruction of OSH will harm the States' efforts to reduce tobacco use and increase their health care costs.

At bottom, federal courts "may resolve only 'a real controversy with real impact on real persons.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021) (quoting *American Legion v. American Humanist Ass'n*, 588 U.S. 29, 87 (2019). That is emphatically the case here. Plaintiff States have alleged—and established—that the March 27 Communiqué has a "real impact" on them. Plaintiffs therefore have Article III standing.

b. The March 27 Communiqué Constitutes Final Agency Action

Defendants' argument that the March 27 Communiqué cannot be challenged as "final agency action" because it is neither "final" nor "discrete," but rather "preliminary" and "programmatic," *see* Mot. at 33-37, misconstrues the law and the challenged agency action.

First, an agency action is "final" if it (1) "mark[s] the consummation of the agency's decisionmaking process" and (2) determines "rights or obligations" or if "legal consequences will flow" from it. *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (*quoting Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal citations omitted)). Both prongs are satisfied here.

As to the "consumption" prong, the Secretary's decision-making process has been completed with respect to dozens of HHS components that have been effectively destroyed because personnel have been removed from their positions. *See generally* Am. Compl. ¶ 3. An

[20] *Smoking Cessation: A Report of the Surgeon General*, Ch. 5: The Benefits of Smoking Cessation on Overall Morbidity, Mortality, and Economic Costs, U.S. DEP'T OF HEALTH & HUM. SERVS. (2020), https://www.ncbi.nlm.nih.gov/books/NBK555593/.

agency action does not lack finality merely because the agency "will continue to look for further ways to streamline its operations and agencies," as Defendants argue. Mot. at 36. Such a statement simply advises the public that there may be more final agency action coming down the pike. Nor does an agency action lack finality because the agency might "reverse" its decision. Mot. at 36-37. Indeed, this suit is premised on the Secretary's action being arbitrary and capricious—which suggests the Secretary may change his mind once the effects of his arbitrary actions become clear. Hence, a "final agency action" does not require finality until the end of time. It is "final" if it is a "definitive statement of the agency's position." *Ass'n of Int'l Auto. Mfrs., Inc. v. Comm'r, Mass. Dep't of Env't Prot.*, 208 F.3d 1, 5 (1st Cir. 2000) (cleaned up).

The plain language of the March 27 Communiqué demonstrates that it is. It discusses what the restructuring "will" do—namely, "save taxpayers $1.8 billion per year through a reduction in workforce of about 10,000 full-time employees who are part of this most recent transformation," "consolidate [the 28 divisions of the HHS] into 15 new divisions," and reduce "[r]egional offices … from 10 to 5." If the Secretary's decision were preliminary, it could not speak in such certain terms. *See, e.g., U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 595 (2016) (comparing an agency's "preliminary" jurisdictional determinations, which advise a property owner that there "*may* be" regulated waters on a property and do not constitute "final agency action," with determinations that "state the presence or absence" of regulated waters and do constitute "final agency action" (*citing* 33 C.F.R. §§ 320.1(a)(6), 331.2)). To the extent there remains a material dispute about finality, that dispute should be resolved with Defendants' lodging of the administrative record or discovery. But Plaintiffs have certainly sufficiently *pled* a final agency action with respect to components like OSH—and that is the question currently before the Court.

As to the "legal consequences" prong, Defendants misconstrue this suit as concerning a mere "press release." *See* Mot. at 35. But as the Amended Complaint clarifies, the March 27 Communiqué, which the Complaint refers to as the "March 27 Directive," is the Secretary's directive as reflected in the press release—not necessarily the press release itself. *See* Am. Compl. ¶ 3. According to the Complaint, the RIFs and reorganization "implemented the March 27 Directive." *Id.* Legal consequences directly impacted HHS components like OSH, which as a direct result, was effectively shut down and can no longer carry out its statutory duties. Were the Secretary's decision formalized in a record of decision or a Federal Register notice, that might have permitted Plaintiffs to frame their complaint differently. However, the Secretary's failure to be more transparent or formal in his decision-making has no impact on whether this final agency action has occurred. To find otherwise would only discourage transparency in government.

Finally, the Plaintiffs are not bringing a "wholesale," "programmatic" challenge in this suit. Mot. at 34-35. Plaintiffs are not challenging a generalized policy, but "discrete agency actions." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62 (2004). To be sure, the March 27 Communiqué emphasizes policy goals, including saving taxpayers' money, reducing redundancies, and ending America's epidemic of chronic illness. *See generally* ECF No. 1-1. Plaintiffs do not challenge those general policies. Consistent with *Lujan*, Plaintiffs argue that the discrete actions the agency has taken are utterly inconsistent with those policy rationales. *Compare* Am. Compl. *with Sierra Club v. Peterson*, 228 F.3d 559, 567 (5th Cir. 2000) ("Rather than limit their challenge to individual sales, they merely used these sales as evidence to support their sweeping argument that the Forest Service's 'on-the-ground' management of the Texas forests over the last twenty years violates the NFMA."). Likewise, Defendants conflate the size of an agency action with its discreteness. The Secretary's action that resulted in the reorganization and staffing cuts is

obviously a large and significant agency action, but it is nevertheless a single, discrete agency action—and its size alone does not allow the Secretary to defeat APA review. Were it otherwise, APA review would be precluded for agency actions of the greatest significance. This cannot be the law.

As the Supreme Court recently reaffirmed, "the APA's 'basic presumption' [is] that anyone injured by agency action should have access to judicial review." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 824 (2024) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967)). Plaintiff States have been injured by HHS action and should have access to judicial review.

II. The March 27 Communiqué Is Arbitrary, Capricious, and Contrary to Law Because It Will Prevent HHS from Carrying Out Its Mandatory Statutory Functions and Because the Agency Entirely Failed to Consider the Serious Public Health Consequences of Its Actions

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. 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.[21] OSH has effectively been abolished and the undisputed

[21] *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.

evidence shows that HHS is now incapable of satisfying its obligations under the Comprehensive Smoking Education Act.[22] While the CTP continues to exist, its ability to fulfill its statutory responsibilities under the Tobacco Control Act has been seriously compromised by the removal of its scientific leadership.

Second, the Secretary's 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-mandated public information and tobacco control initiatives cannot be reconciled with the Secretary's stated objectives.

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[22] Plaintiffs seek to reverse a final action that is preventing agencies within HHS from meeting their statutory obligations. Although Plaintiffs have expressly ground their APA claims in 5 U.S.C. § 706(2), *see* Am. Compl. (Counts III, IV, and V), Defendants assert that Plaintiffs are in fact seeking to "compel agency action unlawfully withheld" under § 706(1). *See* Mot. at 35-36 (*citing* 5 U.S.C. § 706(1)). Defendants rely on *Sheldon v. Vilsack*, 538 F. App'x 644, 649 n.3 (6th Cir. 2013), and *Hells Canyon Pres. Council v. U.S. Forest Serv.*, 593 F.3d 929, 933 (9th Cir. 2010), for this proposition, but these cases are inapposite. *Sheldon* affirms that § 706(2) is the appropriate provision when the complaint concerns "specific, affirmative agency action" (as the operative complaint here does). 538 F. App'x at 649 n.3. And *Hells Canyon* affirms that a claim based on an agency action (as this one is) is "better phrased" as an "arbitrary and capricious" claim under § 706(2). 593 F.3d at 933. Indeed, a final agency action can be arbitrary, capricious, and contrary to law *because* it fails to consider its statutory duties, without seeking an order compelling the agency to carry out particular obligations. *See Nat'l Urb. League v. Ross*, 489 F. Supp. 3d 939, 982 (N.D. Cal. 2020), order clarified, 491 F. Supp. 3d 572 (N.D. Cal. 2020) (an agency's "statutory obligations" are "important aspects" of a problem for the agency to consider) (citing cases).

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). The First 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 – or how dramatic reductions in staffing at the CTP would save taxpayers money, when the CTP is entirely funded by user fees paid by the tobacco industry.

The March 27 Communiqué is impeding the functions of the statutorily mandated CTP. 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 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).[23]

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

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." ECF No. 55-8 at 5 (John Doe 7 Decl. ¶ 15). Millions of such applications have been filed.[24] 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 & 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,[25] the March 27 Communiqué has had the effect of removing the Director of CTP,[26] as well as a leadership position in the Office of Science, which has undermined the ability of CTP to satisfy the statutory mandate that the applications be reviewed and decided within 180 days. While Defendants assert that review "continues as

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[24] 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 November 10, 2025].

[25] *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 November 10, 2025].

[26] *Id.* CTP now has an Acting Director.

required," Mot. at 21, HHS's own website demonstrates that review has been significantly hindered. FDA has announced only three PMTA actions this year (one of which was under the prior Administration), compared with eight announced the year prior.[27] Because most of these products remain on the market while FDA review is pending, these continuing violations will only exacerbate the unique health risks posed by "the allure of e-cigarettes" to young people. *Wages and White Lion*, 145 S.Ct. at 909-10.

[27] U.S. FOOD & DRUG ADMIN., Tobacco Products Marketing Orders, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders [Last visited November 10, 2025].

CONCLUSION

For all these reasons, the Court should deny the Secretary's motion to dismiss.

Respectfully submitted,

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Dated: November 18, 2025

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Rhode Island by using the CM/ECF system on November 18, 2025.

I hereby certify that all participants in the case are registered CM/ECF users and that services will be accomplished by the appellate CM/ECF system.

November 18, 2025

/s/ Christina S. Marshall
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