UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK; STATE OF WASHINGTON; STATE OF RHODE ISLAND; STATE OF ARIZONA; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF ILLINOIS; STATE OF MAINE; STATE OF MARYLAND; THE PEOPLE OF THE STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF OREGON; STATE OF VERMONT; STATE OF WISCONSIN,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SUSAN MONAREZ, in her official capacity as ACTING DIRECTOR, FIRST ASSISTANT TO THE DIRECTOR, PRINCIPAL DEPUTY DIRECTOR OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION: CENTERS FOR DISEASE CONTROL AND PREVENTION; MARTIN A. MAKARY in his official capacity as COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION; U.S. FOOD AND DRUG ADMINISTRATION; ANDREW GRADISON, in his official capacity as ACTING ASSISTANT SECRETARY OF THE ADMINISTRATION FOR CHILDREN AND FAMILIES: ADMINISTRATION FOR CHILDREN AND FAMILIES; MARY LAZARE in her official capacity as PRINCIPAL DEPUTY ADMINISTRATOR OF THE ADMINISTRATION FOR COMMUNITY LIVING; ADMINISTRATION FOR COMMUNITY LIVING; ARTHUR KLEINSCHMIDT, in his official capacity as PRINCIPAL DEPUTY ASSISTANT SECRETARY OF THE SUBSTANCE ABUSE AND MENTAL

Case No.

HEALTH SERVICES ADMINISTRATION; SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION,

Defendants.

INTRODUCTION

1. The core mission of the Department of Health and Human Services (HHS, or the Department) is to enhance the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. HHS, its many agencies, divisions, offices, and programs are the manifestation of Congress's interest in protecting and improving the well-being of our citizens. Congress has passed dozens of laws for HHS to enforce and authorized HHS to spend \$2.5 trillion in Fiscal Year 2024 alone because, in Congress's judgment, the work of the Department is that critical. Over the course of a few days in late March and early April, HHS Secretary Robert F. Kennedy, Jr. (Secretary Kennedy) dismantled the Department in violation of Congress's instructions, the U.S. Constitution, and the many statutes that govern the Department's programs and appropriate funds for it to administer.

2. In its first three months, this administration systematically deprived HHS of the resources necessary to do its job. Their plan escalated significantly on March 27, 2025, when HHS announced it would send termination notices to 10,000 HHS employees and shutter dozens of agencies as part of Secretary Kennedy's directive to "Make America Healthy Again" (the March 27 Directive).

3. On April 1, 2025, when the termination notices went out and employees were immediately expelled from their work email, laptops, and offices, work across the vast and complicated Department came to a sudden halt. Throughout HHS, critical offices were left unable

to perform statutory functions. There was no one to answer the phone, factories went into shutdown mode, experiments were abandoned, trainings were cancelled, site visits were postponed, application portals were closed, laboratories stopped testing for infectious diseases such as hepatitis, and partnerships were immediately suspended. The Food and Drug Administration missed a vaccine application deadline and cancelled a critical test for the bird flu virus, suspending that testing program for the year. Office closures and layoffs left Head Start and Low-Income Home Energy Assistance Program left grantees abandoned with no one to answer their questions. The World Trade Center Health Program had no doctors to certify new illnesses for coverage, a necessary part of caring for the responders and survivors of the 9/11 attacks under the Zadroga Act, and programs aimed at monitoring maternal and newborn health were abruptly shuttered. These early failures are only the beginning. According to a leaked budget memo, the administration is seeking to zero out even more agencies and departments.

4. The layoffs affected every type of HHS worker, yet the layoffs did not fall evenly across the Department and in fact targeted disfavored work and programs at the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Administration for Children and Families (ACF), and the Administration for Community Living (ACL). Ultimately, Defendants terminated 10,000 full-time employees, collapsed twenty-eight agencies into fifteen (shuffling and splitting several subagencies), created three new agencies, and closed half of HHS's ten regional offices.

5. Abandoning the Department's core functions was not an unintended side effect, but rather, the intended result of the March 27 Directive. Incapacitating one of the most sophisticated departments in the federal government implicates hundreds of statutes, regulations, and programs.

But Secretary Kennedy refused to undertake this restructuring legally or carefully. In fact, Secretary Kennedy has since said that he knew that possibly twenty percent of the reductions in force (RIFs) were going to be "mistakes" even before the RIFs were executed. He agreed that he forewent a careful line-by-line review of who should be fired because "it takes too long" and he would lose "political momentum"—making plain that the process used to determine layoffs was arbitrary and capricious. The March 27 Directive came after scores of probationary employees were laid off and many employees took a buy-out offer. None of these layoffs were necessary to accommodate a funding shortfall—Congress's appropriations have remained steady, or in many cases, grown in recent years. All told, 20,000 full-time employees—almost twenty-five percent of HHS headcount—would be terminated in a few months to save, by Defendants' own estimate, less than one percent of HHS expenditures.

6. The terminations and reorganizations happened quickly, but the consequences are severe, complicated, and potentially irreversible. Plaintiff States are already suffering consequences of these terminations and reorganizations. Those employees who remain at HHS have been prevented from collecting and reviewing new applications; designing, distributing, and implementing new policies and guidance; collecting and distributing scientific data; issuing obligated funds to the Plaintiff States and others; investigating for program integrity; and responding to any manner of public inquiry. Dismantling HHS by terminating the people necessary for it to meet its own mandates, and paralyzing it by means of a confusing reorganization, is an unlawful effort to undercut the will of Congress who ordered the agencies and programs to run. It is an agency action that contravenes not only the laws that created the Department, its agencies, and the appropriated funds it administers, but also the laws that the Department and agencies regulate and enforce. Congress created HHS and has invested enormous sums into it every year

without interruption, and the congressional mandates remain in place today. Much of that investment was lost in a day through the massive firings of HHS's leaders and staff. More will be lost if nothing is done.

7. As a result, Plaintiff States seek declaratory and injunctive relief to prevent the unconstitutional and illegal dismantling of the Department.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States). Jurisdiction is also proper under the judicial review provisions of the Administrative Procedure Act (APA). 5 U.S.C. §§ 702, 704. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201, 2202 and 5 U.S.C. §§ 705, 706.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)(2) and (e)(1). Defendants are United States agencies or officers sued in their official capacities. Plaintiff State of Rhode Island is a resident of this district, and a substantial part of the events or omissions giving rise to this Complaint occurred and continues to occur within the District of Rhode Island.

PARTIES

I. Plaintiffs

10. Plaintiff State of New York is a sovereign state of the United States of America. As a body politic and a sovereign entity, it brings this action on behalf of itself and as trustee, guardian, and representative of all residents, and political subdivisions of New York. Attorney General Letitia James is the chief law enforcement officer for New York.

11. Plaintiff State of Washington is a sovereign state in the United States. Washington is represented by Attorney General Nicholas W. Brown. The Attorney General of Washington is

the chief legal adviser to the State and is authorized to act in federal court on behalf of the State on matters of public concern.

12. Plaintiff State of Rhode Island is a sovereign state in the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief law enforcement officer of Rhode Island.

13. Plaintiff State of Arizona is a sovereign state in the United States of America. Arizona is represented by Attorney General Kris Mayes, who is the chief law enforcement officer of Arizona.

14. Plaintiff State of California is a sovereign state in the United States of America. California is represented by Rob Bonta, the Attorney General of California and the chief law officer of California.

15. Plaintiff State of Colorado is a sovereign state in the United States of America. Colorado is represented by Phil Weiser, the Attorney General of Colorado. The Attorney General acts as the chief legal representative of the state and is authorized by Colo Rev. Stat. § 24-31-101 to pursue this action.

16. Plaintiff State of Connecticut is a sovereign state of the United States of America. Connecticut is represented by and through its chief legal officer, Attorney General William Tong, who is authorized under General Statutes § 3-125 to pursue this action on behalf of the State of Connecticut.

17. Plaintiff State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941).

Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

18. Plaintiff the District of Columbia is a municipal corporation organized under the Constitution of the United States. It is empowered to sue and be sued, and it is the local government for the territory constituting the permanent seat of the federal government. The District is represented by and through its chief legal officer, Attorney General Brian L. Schwalb. The Attorney General has general charge and conduct of all legal business of the District and all suits initiated by and against the District and is responsible for upholding the public interest. D.C. Code. § 1-301.81.

19. Plaintiff State of Hawai'i is a sovereign state of the United States of America. Hawai'i is represented by Attorney General Anne E. Lopez, Hawai'i's chief legal officer and chief law enforcement officer, who is authorized by Hawai'i Rev. Statutes § 28-1 to pursue this action.

20. Plaintiff State of Illinois is a sovereign state in the United States of America. Illinois is represented by Kwame Raoul, the Attorney General of Illinois, who is the chief law enforcement officer of Illinois and authorized to sue on the State's behalf. Under Illinois law, the Attorney General is authorized to represent the State's interests by the Illinois Constitution, article V, section 15. See 15 Ill. Comp. Stat. 205/4.

21. Plaintiff State of Maine is a sovereign state of the United States of America. Maine is represented by Aaron M. Frey, the Attorney General of Maine. The Attorney General is authorized to pursue this action pursuant to 5 Me. Rev. Stat. § 191.

22. Plaintiff State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

23. The People of the State of Michigan are represented by Attorney General Dana Nessel. The Attorney General is Michigan's chief law enforcement officer and is authorized to bring this action on behalf of the People of the State of Michigan pursuant to Mich. Comp. Laws § 14.28.

24. Plaintiff State of Minnesota is a sovereign state of the United States. Minnesota is represented by and through its chief legal officer, Minnesota Attorney General Keith Ellison, who has common law and statutory authority to sue on Minnesota's behalf.

25. Plaintiff State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the State's chief law enforcement officer.

26. Plaintiff State of New Mexico is a sovereign state in the United States of America. New Mexico is represented by Attorney General Raúl Torrez, who is the chief law enforcement officer of New Mexico authorized by N.M. Stat. Ann. § 8-5-2 to pursue this action.

27. Plaintiff the State of Oregon, represented by and through Attorney General Dan Rayfield, is a sovereign state of the United States. The Oregon Attorney General is Oregon's chief law enforcement officer and authorized to pursue this action by Oregon Revised Statutes Chapter 180.

28. Plaintiff the State of Vermont is a sovereign state of the United States of America. Vermont is represented by Attorney General Charity R. Clark, who is Vermont's chief legal officer and is authorized to pursue this action on behalf of the State. Vt. Stat. Ann. tit. 3, § 159.

29. The State of Wisconsin is a sovereign state of the United States. Wisconsin is represented by Attorney General Josh Kaul, who is the State's Chief Law Officer.

II. Defendants

30. Defendant Robert F. Kennedy, Jr., is the Secretary of the Department of Health and Human Services, and that agency's highest ranking official. He is charged with the supervision

and management of all decisions and actions of that agency. He is sued in his official capacity. 42 U.S.C. §§ 3501a, 3502.

31. Defendant the United States Department of Health and Human Services is a cabinet agency within the executive branch of the United States government. 42 U.S.C. §§ 3501, 3501a.

32. Defendant Susan Monarez is the Acting Director, First Assistant to the Director, Principal Deputy Director of the Centers for Disease Control and Prevention. She is charged with the supervision and management of all decisions and actions of that agency. She is sued in her official capacity.

33. Defendant the Centers for Disease Control and Prevention is an executive branch agency within the federal government and a component of HHS, headquartered in Atlanta, Georgia. 44 U.S.C. § 3502(1); 5 U.S.C. § 551(1).

34. Defendant Martin A. Makary is the Commissioner of the U.S. Food and Drug Administration. He is charged with the supervision and management of all decisions and actions of that agency. He is sued in his official capacity.

35. Defendant U.S. Food and Drug Administration is an executive branch agency within the federal government and a component of HHS, headquartered in Silver Spring, Maryland. 44 U.S.C. § 3502(1); 5 U.S.C. § 551(1).

36. Defendant Andrew Gradison is the Acting Assistant Secretary of the Administration for Children and Families. He is charged with the supervision and management of all decisions and actions of that agency. He is sued in his official capacity.

37. Defendant Administration for Children and Families is an executive branch agency within the federal government and a component of HHS, headquartered in Washington, D.C.

38. Defendant Mary Lazare is the Principal Deputy Administrator of the Administration for Community Living. She is charged with the supervision and management of all decisions and actions of that agency. She is sued in her official capacity.

39. Defendant Administration for Community Living is an executive branch agency within the federal government and a component of HHS, headquartered in Washington, D.C.

40. Defendant Arthur Kleinschmidt is the Principal Deputy Assistant Secretary of the Substance Abuse and Mental Health Services Administration. He is charged with the supervision and management of all decisions and actions of that agency. He is sued in his official capacity.

41. Defendant Substance Abuse and Mental Health Services Administration is an executive branch agency within the federal government and a component of HHS, headquartered in Rockville, Maryland.

FACTUAL ALLEGATIONS

42. Congress created HHS to enhance and protect the health and well-being of all Americans. Since its inception, Congress has charged HHS with more and more responsibilities and granted it more and more authorities to fulfill those responsibilities. Congress also entrusted HHS with the financial resources necessary to fulfill those obligations and, over seventy-two years, HHS has grown to manage a complex portfolio of work.

43. The Secretary of HHS advises the President on health, welfare, and income security plans, policies, and programs of the federal government; directs Department staff in carrying out the programs and activities of the Department; and promotes general public understanding of the Department's goals, programs, and objectives.

III. The Department's Origins and Structure

44. The modern Department of Health and Human Services was created through a succession of acts of Congress. Pursuant to the Reorganization Act of 1939, 53 Stat. 561 (1939),

and the Reorganization Plan No. 1 of 1939 promulgated thereunder to redistribute the functions of existing and newly created agencies, 4 Fed. Reg. 2727 (1939), Congress issued a joint resolution creating the Federal Security Agency in 1939, 53 Stat. 813 (1939). The new agency would bring together related federal activities in health, education, and social insurance. Among other subagencies, the agency would contain the Public Health Service (PHS), headed by the Surgeon General, which had previously been housed in the Treasury Department.

45. In the years following the creation of the Federal Security Agency, the Food and Drug Administration (FDA) was transferred from the Department of Agriculture to the Federal Security Agency, and the Communicable Disease Center—the predecessor to today's Centers for Disease Control and Prevention (CDC)—was established within the PHS. In 1953, Congress created the cabinet-level Department of Health, Education, and Welfare (HEW). 42 U.S.C. § 3501 (1953). The new Department encompassed all functions of the former Federal Security Administration, including the PHS, the Office of Education, the FDA, the Social Security Administration, and the Office of Vocational Rehabilitation.

46. In 1979, Congress enacted the Department of Education Organization Act to remove the Department of Education from HEW, creating two separate cabinet-level departments: the Department of Education and HHS. 20 U.S.C. §§ 3411, 3508 (1979).

47. In 1994, Congress removed the Social Security Administration from HHS, establishing the Social Security Administration as an independent agency. 108 Stat. 1465 (1994).

48. In Fiscal Year 2024, HHS committed to spending roughly \$2.5 trillion—twenty-six percent of all federal spending. A majority of the HHS budget is comprised of mandatory spending for Medicare and Medicaid.

49. At the end of 2024, HHS employed 82,000 people across its many agencies and offices, which, themselves, were spread across the Department's headquarters and ten regional offices. In Fiscal Year 2024, approximately seventy percent of all federal health spending was mandatory and eleven percent was discretionary. Salaries and payroll are entirely discretionary spending.

IV. Secretary Kennedy's Views on the Department

50. Long before he was nominated by President Trump to lead HHS, Secretary Kennedy had a history of advocating for the evisceration of the Department's statutorily mandated work promoting public health.

51. As early as 2013, he described the CDC's vaccine policies and decision-making as "like Nazi death camps."¹

52. Three years later, Secretary Kennedy founded Children's Health Defense (CHD), a non-profit organization dedicated to promoting false and misleading claims about the safety and efficacy of vaccines. In 2020, CHD financed a video, "Plandemic," which baselessly alleged the COVID-19 pandemic was planned as part of a global conspiracy involving HHS.²

53. Secretary Kennedy then wrote a book, <u>The Real Anthony Fauci</u>,³ accusing former National Institutes of Health (NIH) official Anthony Fauci of sabotaging HIV/AIDS research and treatments and conspiring with tech mogul Bill Gates and drugmakers to sell COVID-19 vaccines.

¹ Daniel Dale & Danya Gainor, *Fact check: RFK JR. Denied saying things he did say*, CNN (Feb. 1, 2025, 1:55 PM), <u>https://www.cnn.com/2025/02/01/politics/rfk-jr-fact-check-confirmation-heading/index.html</u>.

² Shannon Bond, <u>Inside RFK Jr.'s nonprofit's legal battles over vaccines and public health</u>, NPR (Dec. 4, 2024, 5:00 AM), <u>https://www.npr.org/2024/12/03/nx-s1-5198506/rfk-jr-anti-vaccine-chd-lawsuits</u>; Martin Enserink & Jon Cohen, *Fact-checking Judy Mikovits, the controversial virologist attacking Anthony Fauci in a viral conspiracy video*, SCIENCE (May 8, 2020), <u>https://www.science.org/content/article/fact-checking-judy-mikovits-controversial-virologist-attacking-anthony-fauci-viral</u>.

³ Robert F. Kennedy Jr., <u>The Real Anthony Fauci: Bill Gates</u>, <u>Big Pharma and the Global War on Democracy and</u> <u>Public Health</u> (2021).

54. The week before the 2024 election, Secretary Kennedy tweeted: "FDA's war on public health is about to end. This includes its aggressive suppression of psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine, vitamins, clean foods, sunshine, exercise, nutraceuticals and anything else that advances human health and can't be patented by Pharma. If you work for the FDA and are part of this corrupt system, I have two messages for you: 1. Preserve your records, and 2. Pack your bags."

55. After Trump won the 2024 election, Secretary Kennedy continued to share his intention to destroy HHS, this time naming the NIH, a division of HHS: "We need to act fast, and we want to have those people in place on Jan. 20 so that on Jan. 21, 600 people are going to walk into offices at NIH, and 600 people are going to leave."⁴

56. President Trump and other officials in the current federal administration support Secretary Kennedy's views about the Department and have expressed disdain for the work of the Department. In 2024, then-candidate Trump said of Robert Kennedy Jr., "I'm going to let him go wild on health. I'm going to let him go wild on the food. I'm going to let him go wild on medicines."⁵ Director of the Office of Management and Budget, Russell Vought shared Secretary Kennedy's disregard for the work of HHS and, in September 2024, at a panel discussion he said: "Look at CDC Most of them don't even do public health. They are researchers that publish material. Who knows if it's even relevant or not?"⁶

⁴ Rob Stein, *Trump may overhaul the NIH, with input from RFK, Republican lawmakers*, NPR (Nov. 12, 2024), <u>https://www.npr.org/2024/11/12/nx-s1-5183014/trump-election-2024-nih-rfk</u>.

⁵ Katherine Fung, *Everything RFK Jr. Has Said About What He'll Do If Named Trump Health Czar*, NEWSWEEK (Nov. 5, 2024, 8:02 AM), <u>https://www.newsweek.com/rfk-public-health-vaccines-flouride-drinking-water-1979990</u>.

⁶ Liz Essley Whyte & Natalie Andrews, RFK Jr. Plans 10,000 Job Cuts in Major Restructuring of Health Department, WALL ST. J. (Mar. 28, 2025, 1:15 PM), <u>https://www.wsj.com/politics/policy/rfk-jr-job-cuts-health-human-services-bdec28b0?msockid=3b1de0a03d0767c53feef45c3c446651</u>.

V. The March 27 Directive to Dismantle HHS

57. On January 20, 2025, the day President Trump was inaugurated, the administration began its systematic approach to dismantle HHS. The earliest steps were to impose severe restrictions on all public-facing agency activity, fire the independent inspector general, rescind job offers, and institute a hiring freeze. The next steps were to remove the existing key leaders within the agencies unsympathetic to Secretary Kennedy's favored views, and to fire tens of thousands of the rank and file. This coordinated dismantling has stopped crucial work that Plaintiff States relied upon. A proposed budget for 2026 shows that these steps were only the beginning of the cuts.

A. The Early Steps

58. On the new administration's first full day in power, January 21, 2025, Dorothy Fink, then Acting Secretary of HHS, ordered a sweeping communications freeze prohibiting public issuance of any document or communication until it has been reviewed and approved by a Presidential appointee.

59. On day two, January 22, all HHS travel was suspended immediately and indefinitely. The only exceptions were for return travel and for Indian Health Services (IHS) employees.

60. On January 25, President Trump fired HHS Inspector General Christi Grimm along with sixteen others from her office.

61. On February 11, the White House published Executive Order 14,210 "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," which ordered: "Agency Heads shall promptly undertake preparations to initiate largescale reductions in force (RIFs)" so as to "eliminat[e] waste, bloat, and insularity."

62. Robert F. Kennedy Jr. was confirmed as HHS Secretary on February 13, 2025. He was sworn in on the same day in the Oval Office.

63. Two days later, on February 15, 5,200 probationary workers across multiple HHS agencies received termination notices. In a letter attached to the termination email, signed by Jeffrey Anoka, acting head of Human Resources for HHS, recipients of the termination notice were told they were "not fit for continued employment because your ability, knowledge and skills do not fit the Agency's current needs, and your performance has not been adequate to justify further employment at the Agency." Additionally, many contractors were terminated at the same time.

64. Of the 5,200 notices, 1,250 of those were sent to employees of CDC—roughly ten percent of the workforce. Those employees came from a range of experience levels—from senior officials to the entire first-year class of the CDC's Epidemic Intelligence Services officers, known as "disease detectives."

65. On Friday March 8, all HHS employees received an offer to leave their job for as much as a \$25,000 buyout that was offered as part of the executive branch's "Fork in the Road" cuts to the federal civil service. The offers gave workers until March 14 to accept.

66. On March 25, the Senate confirmed Dr. Marty Makary to be the next Commissioner of FDA and Jay Battacharya to be Director of NIH. While Secretary Kennedy had been sworn in the same day he was confirmed by the Senate, Commissioner Makary and Director Battacharya would wait a week until April 1.

B. HHS Announced the March 27 Directive

67. On March 27, 2025, the HHS Press Office released "HHS Announces Transformation to Make America Healthy Again," which outlined a directive to lay off employees and reorganize the agency. The March 27 Directive is attached here to as Exhibit 1. The only legal

authority given was EO 14,210, which ordered the Secretary to prepare to initiate prompt, largescale RIFs. Plaintiff States challenge both components of the March 27 Directive here: the mass layoffs and the reorganizations.

68. The Announcement was accompanied by a "Fact Sheet: HHS' Transformation to Make America Healthy Again." The Fact Sheet is attached hereto as Exhibit 2.

69. In these documents, HHS announced a reduction in workforce of about 10,000 fulltime employees. Ex. 1 at 2. When combined with the early retirement and buyout offers, HHS will have lost a combined 20,000 employees—roughly a quarter of its workforce.

70. HHS's twenty-eight divisions would be restructured down to fifteen, including a new Administration for a Healthy America (AHA), and centralized human resources, information technology, procurement, external affairs and policy offices.

71. The new AHA would combine the Office of the Assistant Secretary for Health (OASH), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Toxic Substances and Disease Registry (ATSDR), and National Institute for Occupational Safety and Health (NIOSH).

72. The Administration for Strategic Preparedness and Response (ASPR), responsible for national disaster and public health emergency response, would transfer to CDC.

73. A new Assistant Secretary for Enforcement would oversee the Departmental Appeals Board, Office of Medicare Hearings and Appeals (OMHA), and Office for Civil Rights.

74. HHS would merge the Assistant Secretary for Planning and Evaluation (ASPE) with the Agency for Healthcare Research and Quality (AHRQ) to create the Office of Strategy.

75. The Administration for Community Living (ACL) would be reorganized, and critical programs that support older adults, people with disabilities, and their families and

caregivers, would be integrated into other HHS agencies, including the Administration for Children and Families (ACF), ASPE, and the Centers for Medicare & Medicaid Services (CMS).

76. HHS would close five of its ten regional offices.

77. The March 27 Directive claimed the terminations and reorganizations were policy driven and would "implement the Make America Healthy Again goal of ending the chronic disease epidemic."

78. The Fact Sheet expressly contemplated future layoffs: "No additional cuts are currently planned, but the Department will continue to look for further ways to streamline its operations and agencies."

79. That same day, Secretary Kennedy took to Twitter and said: "We are streamlining HHS to make our agency more efficient and more effective. We will eliminate an entire alphabet soup of departments, while preserving their core functions by merging them into a new organization called the Administration for a Healthy America or AHA. This overhaul will improve the health of the entire nation — to Make America Healthy Again."⁷

80. The Twitter post included a video of Secretary Kennedy saying: "The agency has been inefficient as a whole The rate of chronic disease and cancer increased dramatically as our department has grown."⁸

81. Work stopped immediately. On Friday, March 28, dozens of federal health employees within the Office of Infectious Disease and HIV/AIDS Policy (OIDP) were told they would be put on leave. Several of the Office's advisory committees, including the National Vaccine Advisory Committee and others that advise on HIV/AIDS response, had their meetings cancelled.

 ⁷ Secretary Kennedy (@SecKennedy), X (Mar. 27, 2025, 9:00 AM), <u>https://x.com/SecKennedy/status/1905243470366670926</u>.
 ⁸ Id.

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82. Congressional leaders and their staff learned about the reorganization and RIFs in real time as it was announced on March 27.

83. On March 28, Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER) at FDA, resigned. He had worked at FDA for thirteen years, served on the White House Coronavirus Task Force and is credited with leading Operation Warp Speed which delivered a COVID-19 vaccine in a matter of months. In his resignation letter, he wrote:

As you are aware, I was willing to work to address the Secretary's concerns regarding vaccine safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.⁹

84. Some FDA employees were told to go home with their laptops and prepare for the

possibility that they would not be back. If they received a termination email, they would lose access to the building.

C. On April 1, HHS Sent Termination Notices to 10,000 HHS Employees to Implement the March 27 Directive

85. Beginning in the early morning of April 1, 2025, HHS employees in all offices, administrations, agencies and sub-agencies began to receive termination notices. Some employees had not seen their early morning termination email before leaving for the office, and were surprised when they arrived at work to find their access cards had been deactivated.

86. The emailed notices instructed employees that they had been placed on administrative leave. The notices, which came from Tom Nagy within the HHS Human Resources office, told employees they would be formally terminated on June 2.

⁹ Letter from Peter Marks, Director of the Center for Biologics Evaluation and Research, to Sara Brenner, citing Commissioner of Food and Drugs (Mar. 28, 2025) (on file with Plaintiffs).

87. Many notices contained errors. For example, some listed incorrect information about workers' recent performance ratings. At FDA, the listed point of contact for the Equal Employment Opportunity office had departed a month earlier.

88. Employees were immediately cut off; they were locked out of their HHS-issued email, their HHS-issued laptop, their office, and the building. There was no notice, and there was no opportunity to contest, appeal, inquire, or offboard.

89. To date, the Department has stonewalled all efforts to learn which positions were terminated and who received a RIF notice. Senators, Members of the House of Representatives, and the news media all have sought to understand who was fired and learn which positions and programs were affected. Senator Cassidy, the leader of the U.S. Senate Committee on Health, Education, Labor, and Pensions, invited Secretary Kennedy to speak at an April 10 hearing to discuss the proposed reorganization of HHS. Secretary Kennedy did not appear.

90. Within two days of the mass firings, Secretary Kennedy told reporters that twenty percent of the employees who received RIF notices were fired in error: "Personnel that should not have been cut, were cut. We're reinstating them. And that was always the plan. Part of the—at DOGE, we talked about this from the beginning, is we're going to do 80% cuts, but 20% of those are going to have to be reinstated, because we'll make mistakes."¹⁰

91. In an April 9 interview, Secretary Kennedy again admitted that he knew "as many as 20%" of the cuts would be mistakes. He also agreed that HHS chose not to perform a "line-by-line" review of each employee's job responsibilities before issuing terminations, and made that choice because doing so would "take[] too long and you lose political momentum."¹¹

¹⁰ Alexander Tin, *RFK Jr., says 20% of health agency layoffs could be mistakes*, CBS NEWS (Apr. 3, 2025, 7:12 PM), <u>https://www.cbsnews.com/news/rfk-jr-hhs-job-cuts-doge-mistakes/</u>.

¹¹ Watch: RFK Jr.'s first network TV interview as HHS secretary, YOUTUBE (Apr. 9, 2025) (Originally aired on CBS News) <u>https://youtu.be/o2U0csKvqMY?si=sl_PrcAr9lxogj6C</u>.

92. HHS departments and programs are often interdependent, and one area not directly hit by terminations or the reorganization may still be unable to perform one of its functions as a result of terminations or a reorganization at another.

D. The March 27 Directive Was an Early Step in a Long-Term Plan to Eviscerate the Department

93. As detailed *infra*, the intended effect of the March 27 Directive was the wholesale elimination of many HHS programs that are critical to public health and safety. This is so even though Congress has appropriated funds for these programs and the result of the cuts will be that the Department does not spend appropriated funds.

94. Further evidence of this purpose came to light on April 16, when a leaked internal proposed budget document, entitled "Department of Health and Human Services (HHS) 2026 Discretionary Budget Passback" (the 2026 Passback), dated April 10, 2025, was published on multiple news outlets. This document showed that the administration is seeking to dismantle HHS and its agencies, first by firing their staff and then by fully eliminating the funding to the following HHS programs by cutting each program's budget to zero dollars:

- a. At CDC, the National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP, which included the Division for HIV/AIDS Prevention and the Division of STD Prevention); National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP, which included the Division of Reproductive Health and Office on Smoking and Health); Global Health Center (GHC), and the Prevention and Public Health Fund;
- b. Five programs from the National Center for Environmental Health (NCEH) and five from NIOSH; four programs under Ryan White HIV/AIDS and the Secretary's

Minority HIV/AIDS Fund; and sixteen programs formerly held within the National Health Service Corps and the Teaching Health Center Graduate Medical Education Program;

- c. At FDA, the budget for routine inspections of food facilities would be cut and the financial burden would thrust on to the states;
- d. At SAMSHA, fourteen primary care grants and programs; ten maternal and child health grants and programs; seventeen Mental Health Programs of Regional and National Significance (PRNS), five Substance Abuse Prevention PRNS, eighteen Substance Abuse Treatment PRNS and Certified Community Behavioral Health Centers;
- e. At ACF, the Low-income Home Energy Assistance Program (LIHEAP); Children and Family Services Programs including Head Start, Preschool Development Grants; Refugee and Entrant Assistance Programs including Transitional Medical Services and Refugee Support Services; and Nutrition and Disability Services Programs such as Voting Access for People with Disabilities and State Councils on Developmental Disabilities;
- f. At Health Resources and Services Administration (HRSA), Agency for Healthcare Research and Quality (AHRQ); Office of Medicare Hearings and Appeals (OMHA); and Administration for Strategic Preparedness and Response (ASPR); and
- g. At ACL, Preventative Health Services; Elder Falls Prevention; Lifespan Respite
 Care; Long-Term Care Ombudsman; Chronic Disease Self-Management
 Education; Elder Rights Support Activities; Elder Justice/Adult Protective

Services; Aging and Disability Resource Centers; and State Health Insurance Assistance Programs.

VI. The March 27 Directive Has Disabled HHS and Its Agencies From Performing Their Statutorily Required Functions

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95. The March 27 Directive's effects on HHS sub-agencies are profound and extensive. They are also complicated due to HHS's vast organizational structure. HHS is composed of dozens of sub-agencies generally referred to by acronyms which can appear similar at first glance, making its various functions difficult to comprehend to those unfamiliar with it. The effects of the March 27 Directive on HHS's programs are detailed in the paragraphs below.

A. Centers for Disease Control and Prevention (CDC)

Statutory Mandates

96. CDC's mission is to protect America from health, safety and security threats, both foreign and in the United States. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

97. The CDC was created under the authority of the Public Health Service Act of 1944. 42 U.S.C. Chapter 6A (PHSA). It was charged to protect deployed members of the military, to prevent exotic infections from being established in the United States, and to combat endemic infections within the United States.

98. The CDC is subject to and required to follow numerous congressional mandates. The mandates assigned to the CDC Director in 42 U.S.C. § 242c ("Appointment and authority of the Director of the Centers for Disease Control and Prevention"), include:

- a. Investigating, detecting, identifying, preventing and controlling diseases or conditions "to preserve and improve public health domestically and globally and address injuries and occupational and environmental hazards," *id.* § 242c(b)(1);
- b. Managing the overall direction of the CDC and the management and operation of its programs and activities across centers, institutes, and offices, including through priority setting reviews and the development of strategic plans, *id.* § 242c(b)(2)-(6); and
- c. Communicating, including through convening annual meetings, with public and private entities regarding relevant public health programs and activities, and, as applicable, the Strategic Plan, *id.* § 242c(b)(7).

99. The same statute requires CDC to develop, implement, and update a Strategic Plan that prevents, reduces, and eliminates the spread of communicable and noncommunicable diseases or conditions, and addresses injuries, and occupational and environmental hazards; supports the efforts of State, local, and Tribal health departments to prevent and reduce the prevalence of the diseases or conditions; contains, mitigates, and ends disease outbreaks; and enhances global and domestic public health capacities, capabilities, and preparedness, including public health data, surveillance, workforce, and laboratory capacity and safety, and other priorities established by the Director. 42 U.S.C. § 242c(c)(2)(A).

100. Aside from the Office of the Director, the CDC oversees the National Institute of Occupational Safety and Health, *see infra* Section VI.B, and eleven Centers, each of which manages additional divisions, programs, and offices.

101. Among other Centers, the CDC oversees the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) (Section VI.C); the National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP) (Section VI.D); the National Center for Environmental Health (NCEH) (Section V.E); the National Center on Birth Defects and Developmental Disabilities (NCBDDD) (Section VI.F); the National Center for Injury Prevention and Control (NCIPC) (Section VI.G); and the Global Health Center (GHC).

102. As a federal agency, the CDC is subject to the Freedom of Information Act (FOIA).5 U.S.C. § 552. It must, therefore, respond to requests for records, perform a reasonable search, and produce timely, diligent responses.

103. CDC's budget for core public health programs in Fiscal Year 2024¹² was approximately \$9.2 billion, reflecting Congress's view of the importance of its work to Americans' health. Many of CDC's obligations have been conducted in coordination with states and their political subdivisions, including disease prevention and control, public health research and data collection, preventive health services programs such as vaccination and cancer screening programs, and preparation for and response to public health emergencies. In FY 2023, for example, CDC reported that it had provided nearly \$15 billion in "grants and cooperative agreements . . . to health departments, universities, and other public and private agencies in the United States."¹³

104. Near the end of 2024, CDC employed approximately 12,000 people.

Implementation of the March 27 Directive against CDC, and its impact on Plaintiff States

105. On April 1, Defendants fired 2,400 employees from the CDC. These terminations came after HHS fired thousands of CDC's probationary employees in February. Defendants' firings reduced the GHC Division of Global HIV & Tuberculosis by roughly a quarter.

¹² In March 2025, Congress adopted a continuing resolution (CR) that adopted (for the most part) the same appropriations from FY 2024 for FY 2025. *See* Pub. L. No. 119-4, §§ 1101-1102 (2025). Thus, in this Complaint, the allegations refer to FY 2024 appropriations, and where relevant and necessary, indicate whether those appropriations were amended via the CR.

¹³ Centers for Disease Control and Prevention, Fiscal Year 2023 Grants Summarily Profile Report for U.S. States and District of Columbia, available at <u>https://perma.cc/CHU3-EKAG</u>.

106. Defendants fired all workers that handled FOIA requests.

107. Not only has the CDC been under a communications freeze and data purge, which the CDC has said were a response to the President's Day One Executive Orders, the communications team has been terminated including the leader of CDC communications, the studio team, and digital and social media communicators.

108. On March 25, the Director of the Public Health Infrastructure Center, the Director of NCBDDD, the Director of the Office of Science, the Director of the Office of Policy, Performance and Evaluation, and the Director of the Office of Health Equity announced their retirements from the Department. In addition, the Director of the Office of Communications, the Chief Operating Officer, and the Principal Deputy Director all departed CDC in February and March.

109. Additionally, since April 1, the March 27 Directive's layoffs have meant that many CDC infectious disease laboratories have either been shuttered or have had severely diminished capacity to test for infectious diseases. As a result, many states have sent their samples to Plaintiff New York State's Wadsworth Center, a state-run laboratory with elite capabilities. Wadsworth Center has many capabilities for testing for rare diseases and complex STIs that cannot be done anywhere else in the country except for the CDC before April 1.

110. For instance, only two labs in the U.S. can perform advanced testing for Chagas Disease: a CDC lab that is now closed, and the lab at Wadsworth. The same is true for Leptospirosis, a disease that can be fatal and/or cause kidney or liver failure without early detection and treatment. Even for more common diseases, like measles, rubella, gonorrhea, or hepatitis, Wadsworth has had to fill in for gaps created by closures of various CDC laboratories, including the Viral Hepatitis laboratory (discussed below).

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111. In a webpage listing the numerous infectious diseases for which it has "discontinued" or "temporarily paused" diagnostic testing, CDC expressly directs State Public Health Laboratories (SPHLs) and federal agencies to submit their specimens to Wadsworth Center for enteroviruses, such as enterovirus D68 and poliovirus, parechovirus, and picornavirus.¹⁴ Additionally, hemorrhagic fever testing has been "temporarily paused," and SPHLs and federal agencies are directed to submit their specimens to "Laboratory Response Network laboratories."¹⁵ The Wadsworth Center is the only laboratory within this network that can perform testing for these pathogens within twenty-four to forty-eight hours.

112. CDC will no longer test for Neisseria meningitis and Haemophilus influenzae, and directs that "[d]iagnostic testing should be referred to Vaccine Preventable Diseases Reference Centers."¹⁶ The Wadsworth Center is, again, one of these reference centers (and the most comprehensive). CDC will no longer test for key food-borne pathogens: Salmonella, Shigella, E. Coli, Listeria, and Campylobacter. CDC will no longer test for fungal pathogens.¹⁷ Some of these infections are now of major concern in nursing and assisted living homes due to drug-resistance that makes them untreatable. CDC will no longer test for Mycobacterium tuberculosis or conduct drug susceptibility testing.¹⁸ For all of these pathogens, the Wadsworth Center is considered as one of the top—and sometimes the only—reference center, with CDC no longer conducting the relevant testing.

113. Since CDC labs were closed, Wadsworth Center has seen new demand for its capabilities and its opinions. Wadsworth Center is responding to the urgent demand as it can;

¹⁴ Centers for Disease Control and Prevention, Infections Diseases Laboratories, Test Directory, available at <u>https://perma.cc/WK3X-RLD2</u>.

 $^{^{15}} Id.$

¹⁶ Id. ¹⁷ Id.

¹⁸ II.

however, it was not built to replace the CDC and it simply could never fill that hole. Wadsworth Center's pricing models, liability insurance, headcount, and human resources infrastructure were all built to serve the needs of Plaintiff State of New York. Only the CDC, with its federal financing, statutorily mandated fundings, and national footprint can keep Americans safe from the national threats of epidemics.

114. These attacks on the CDC leave it, and its Director, unable to meet the agency's statutory mandates under 42 U.S.C. § 242c(b):

115. *First*, the Director is required to "preserve and improve public health domestically and globally and address injuries and occupational and environmental hazards," *id.* § 242c(b)(1), but Defendants slashed employees and funds necessary to address injuries and occupational and environmental hazards, firing the most experienced and senior members of its team—members so senior and specialized it will be impossible to replace them in a timely manner that avoids holding up publication, application, and other deadlines or impacting the quality of CDC's work. The closure and cuts to infectious diseases laboratories within CDC are perhaps the most egregious example of how the March 27 Directive is destroying CDC's ability to meet its statutory mandates to investigate, detect, and identify diseases. *Id.* § 242c.

116. Second, the Director must implement and update the required Strategic Plan of CDC and its offices. *Id.* § 242c(b)(4), (c). The CDC published its 2022–2027 CDC Strategic Plan, which identified priorities and objectives "supporting the efforts of State, local, and Tribal health departments" to prevent and reduce the prevalence of diseases or conditions. Yet, the full plan does not appear on the CDC website and in any event, much of the March 27 Directive is incompatible with the Strategic Plan. Without employees sufficient to deliver on this Strategic Plan, Plaintiff

States and their citizens are less protected against disease and conditions and lose out on the benefits of that plan.

117. *Third*, the Director must "communicate" through meetings and otherwise, with Plaintiff States and other public and private entities, regarding health programs and activities. 42 U.S.C. § 242c(b)(7). Yet the CDC communications team lost both its leaders and its rank and file. CDC's ability to alert Plaintiff States to news related to emergency health threats such as the active bird flu and measles epidemics therefore has been limited. As long as the CDC communications team lacks staff and leadership, Plaintiff States and their citizens are at risk of not receiving the most current, reliable information that CDC is responsible to provide.

118. *Fourth*, Plaintiff States and its citizens have a right to demand and receive public documents from CDC under FOIA. 5 U.S.C. § 552. With no FOIA staff and no working FOIA office, CDC will be unable to timely and properly accept, review, and respond to FOIA requests as it must. The public and Plaintiff States will be harmed by the loss of access to CDC's records.

B. National Institute for Occupational Safety and Health (CDC, NIOSH) Statutory Mandates

119. The National Institute for Occupational Safety and Health (NIOSH or the Institute) sits within CDC and was created by Congress to address and prevent work-related injury and illness, and is the only federal agency statutorily authorized to conduct workplace health and safety research. 29 U.S.C. § 651 *et seq*. This is the same statute that created the Occupational Safety and Health Administration (OSHA), which sits in the Department of Labor. *Id*. While OSHA sets and enforces safety standards, NIOSH is required to: conduct or fund "research, experiments, and demonstrations relating to occupational safety and health"; "produce . . . criteria identifying toxic substances" including setting "exposure levels that are safe for various periods of employment"; and "publish . . . at least annually a list of all known toxic substances by generic family or other

useful grouping, and the concentrations at which such toxicity is known to occur"; disseminate information about occupational safety to employers and employees; conduct education programs about occupational safety; and contract with State personnel to provide compliance assistance for employers. 29 U.S.C. §§ 669(a)(1)-(3), 669(a)(6), 669(d), 670, 671(c)(2). Additionally, Congress has required that there be "permanently established" within NIOSH an Office of Mine Safety and Health, which is "responsible for research, development, and testing of new technologies and equipment to enhance mine safety and health." 29 U.S.C. § 671(h). The work of NIOSH can be divided into Extramural Programs, Intramural Programs, and Safety Surveillance Programs. In Fiscal Year 2024, Congress appropriated \$362,800,000 for NIOSH's work.

Extramural Programs

120. Extramural research programs operate at non-federal facilities and interface with private and public partners. For instance, before the March 27 Directive, NIOSH funded eighteen Education and Research Centers (ERCs), which NIOSH described as playing a key role in fulfilling its statutory directive to conduct either directly or with grants, "education programs to provide an adequate supply of qualified personnel to carry out the purposes" of the Occupational Safety and Health Act. 29 U.S.C. § 670(a). ERCs are academic institutions that provide graduate, post-graduate degree and academic certificate training in core and allied disciplines of occupational safety and health, including industrial hygiene, occupational health nursing, occupational medicine, and occupational safety. NIOSH also funded twelve Centers for Agricultural Safety and Health, designed to address emerging occupational safety and health problems in the agriculture, fishing, and forestry sector—sectors where workers experience fatal injury rates at over five times the rate of all other workers.

121. NIOSH also funded ten academic Centers of Excellence for Total Worker Health across the United States, which conducted multidisciplinary research to advance worker safety, health and well-being by building the scientific evidence base necessary to develop new solutions to complex occupational safety and health problems and offering practical solutions to keep workers safe and health, and helping employers build and retain a productive workforce.

122. Additionally, NIOSH funded twenty-three states to conduct state-based occupational safety and health surveillance—the State Occupational Safety and Health Surveillance Program. These programs often represent necessary, critical, and fundamental research and prevention activities tailored to the specific industries, occupational injury and health hazards of their state.

123. At the University of Washington in Seattle, for instance, NIOSH grants fund both the Northwest Center for Occupational Health and Safety, an ERC, and the Pacific Northwest Agriculture Safety and Health Center, an Agriculture Safety Center. Without NIOSH funding, these Centers will be forced to shutter.

Intramural Programs

124. Intramural programs cover specific research functions run by NIOSH employees, and are often mandated or authorized to exist within NIOSH by the Occupational Safety Act or another statute. One example is the National Occupational Research Agenda (NORA), a partnership program to stimulate innovative research and improved workplace practices. These partnerships include broad participation from universities, large and small businesses, professional societies, government agencies, and worker organizations to identify and research sector-specific research priorities.

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125. NIOSH operates laboratories and facilities across the country. Each has unique abilities, specialties, and equipment to study risks for professionals in dangerous work environments including but not limited to miners, health care workers, farmers, and firefighters. Two of its key facilities are located in Pittsburgh, PA, and Spokane, WA.

126. The Pittsburgh facility, which is home to the National Personal Protective Technology Laboratory (NPPTL), is the only laboratory authorized to review and approve respirators, including those used in health care and mining. 42 C.F.R. § 84.10(c) ("[T]he examination, inspection, and testing of all respirators will be conducted or caused to be conducted by the National Personal Protective Technology Laboratory."). Under the same rule, private partners have a legal right to communicate with the Pittsburgh lab to discuss applications for their products. *Id.* § 84.10(d) ("Applicants, manufacturers, or their representatives may visit or communicate with the NPPTL in order to discuss the requirements for approval of any respirator or the proposed designs thereof."). The Pittsburgh facility is also home to the Pittsburgh Mining Research Division, which has test facilities for pinpointing hazardous machine noise, mine roof supports, evaluating dust hazards and controls, and evaluating human performance in completing mining tasks

127. The Spokane NIOSH facility, Spokane Research Laboratory, is NIOSH's largest facility west of the Mississippi River, and, before the March 27 Directive, it was home to Spokane Mining Research Division (which studied issues arising from work in mining metal and nonmetal resources) and the Western States Division (which studied health and safety issues for maritime workers and firefighters). The Spokane Mining Research program developed safety maneuvers for miners and ran trainings on those safety maneuvers. It was the only facility of its kind doing this type of work.

The World Trade Center Health Program and Other Safety Surveillance Programs

128. NIOSH also oversaw three required surveillance programs related to miner- and firefighter-safety, and the World Trade Center Health Program.

First, under the Coal Mine Health and Safety Act of 1969, later amended by the 129. federal Mine Safety and Health Act of 1977, coal miners have the right to have respiratory diseases detected and, if a disease is detected, a right to transfer to positions that are less damaging to their lungs. 30 U.S.C. § 843. The Act requires that "[t]he operator of a coal mine shall cooperate with the Secretary of Health and Human Services in making available to each miner working in a coal mine the opportunity to have a chest roentgenogram" Id. § 843(a). These roentgenograms, or X-rays, are given on a specified schedule and "shall be read and classified" through procedures set by HHS, which must in turn provide miners with results and inform them of their rights under the chapter. Id. § 843(a). Those rights include, for miners showing signs of pneumoconiosis (lung disease caused by breathing in certain kinds of dust particles), the option of transferring from his position to another position in any area of the mine, for such period or periods as may be necessary to prevent further development of such disease. Id. § 843(b)(1). Until recently, NIOSH fulfilled, in part, these statutory directives through its Coal Workers' Health Surveillance Program (CWHSP), which provided health information to miners through health screenings and surveillance, including collection of test results, evaluation, classification, and recommendation of transfers to low-dust jobs.

130. *Second*, NIOSH administered the Health Hazard Evaluation (HHE) program, which was created by Section 20(a)(6) of the Occupational Safety and Health Act of 1970, and Sections 301 and 501 of the Federal Mine Safety and Health Act of 1977. 29 U.S.C. § 669(a)(6); 30 U.S.C. § 951(a)(11). As part of its implementing regulations, NIOSH must conduct investigations upon

request of possible safety and health hazards and conduct inspections resulting from employee or committee reports of unsafe of unhealthful working conditions. 29 C.F.R. § 1960.35(a). NIOSH is also required to provide a hazard evaluation program for all federal agencies. *Id.* § 1960.35(b).

131. *Third*, in 1998, Congress recognized the need to address the national problem of work-related firefighter deaths and serious injuries, and accordingly appropriated funds NIOSH to implement a firefighter safety initiative. As part of this initiative, NIOSH created the Fire Fighter Fatality Investigation and Prevention Program (FFFIPP), which conducted independent investigations of select career and volunteer firefighter medical and traumatic injury line-of-duty deaths. Since 1998, FFFIPP has investigated more than 700 firefighter line-of-duty deaths, and about forty percent of all firefighter deaths. The reports produced by FFFIPP contain summaries of the fire events, factors that contributed to the firefighter's death, and recommendations to prevent similar deaths. As part of the FFFIPP program, NIOSH also evaluated self-contained breathing apparatus (SCBAs) worn during incidents investigated by the FFFIPP to determine if the SCBA unit met the applicable regulations while worn during the incident, and whether it may have contributed to a firefighter fatal event. In doing so, NIOSH collects SCBA units from local fire departments and tests them at their laboratories.

132. *Fourth*, in 2018, Congress similarly recognized the need to develop and maintain a voluntary registry of firefighters in order to collect history and occupational information that can be used to determine the incidence of cancer among firefighters. It passed the Firefighter Cancer Registry Act of 2018, which was signed by then-President Trump on July 9, 2018, 2 U.S.C. § 280e-5, directing the CDC to develop and maintain a voluntary registry to collect data from firefighters to better understand the link between firefighting and cancer. The resulting National

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Firefighter Registry for Cancer, housed within NIOSH, was the largest effort ever undertaken to understand and reduce risk of cancer among U.S. firefighters.

133. *Finally*, NIOSH oversaw the World Trade Center Health Program (WTCHP). WTCHP was created by Congress in response to the health needs of responders and survivors of the 9/11 terrorist attacks. 42 U.S.C. 300mm (the Zadroga Act). WTCHP provides critical medical treatment, research, and monitoring to over 137,000 responders and survivors of the attacks on the World Trade Center, the Pentagon, and the Shanksville (PA) crash site. These survivors live, and can receive care under WTCHP, in every state.

134. Under the Zadroga Act, in order for responders or survivors to receive treatment, a medical doctor must certify that members coming forward with a new condition meet the requirements of the law. WTCHP does not employ staff physicians or individuals with medical degrees, and, instead, relies on NIOSH doctors to certify eligible members with new conditions. WTCHP does not have a staff epidemiologist and has always relied on NIOSH epidemiologists to review pending petitions for whether to add new conditions to the list of covered conditions. WTCHP also uses NIOSH staff to determine research grant awards, nearly \$20 million a year, which are required of the program to fund research on 9/11 conditions and care.

135. WTCHP also relies heavily on NIOSH's Office of Acquisition Services to oversee WTCHP contracts with its national network of providers. The office ensures that these contracts and providers meet the needs of enrollees and provides oversight and quality assurance for the network.

Implementation of the March 27 Directive against NIOSH, and its impact on Plaintiff States

136. Approximately 873 NIOSH employees (a sizable majority of the Institute's staff), including its director, Dr. John Howard, received termination notices on April 1. Dr. Howard was

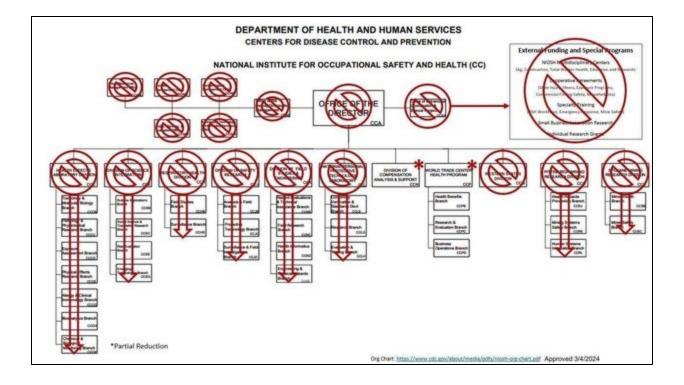
in the middle of his fourth six-year term as Director of NIOSH and had served under both Republican and Democratic administrations.

137. HHS announced that NIOSH (what was left of it) would be absorbed into AHA. Under the leaked 2026 Passback, AHA would only fund the Firefighter Cancer Registry, the National Mesothelioma Registry & Tissue Bank, WTCHP, and the Energy Employees Occupational Illness Compensation Program Act mandatory programs, while funding for all other NIOSH programs would be discontinued.

138. Since the mass terminations, NIOSH has immediately stopped services and closed locations. The Spokane Research Laboratory, whose labs performed statutorily mandated research into safe practices for miners and maritime workers, went into immediate shutdown transition on April 1. There, managers and engineers received RIF notices on April 1, and remaining workers received a notice of intent for a RIF that could occur sometime before June 30. Defendants provided no guidance to the Spokane Research Laboratory on how to wind down its operations and equipment in such a short time frame. Some of its equipment is kept on third-party property under a lease that extends beyond June 30, and other equipment is too large, heavy, and stationary to be moved or demolished.

139. On May 2, 2025, nearly all of the remaining NIOSH employees were laid off, who were all told their duties "have been identified as either unnecessary or virtually identical to duties being performed elsewhere in the agency." These employees were placed on administrative leave and told they would be officially separated on July 2, 2025. NIOSH employees confirmed to CBS News via an annotated organizational chart that NIOSH had effectively been completely dismantled, leaving only scattered few employees in two smaller sub-departments:

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140. The National Personal Protective Technology Laboratory in Pittsburgh, PA, which is required to vet and approve personal protective equipment, including N95 respirators, lost all or nearly all its employees. No other federal facility may issue these approvals. As of the date of filing, its website reads: "Due to the reduction in force across NIOSH, no new respirator approval applications can be accepted."¹⁹

¹⁹ Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), Personal Protective Equipment, available at https://perma.cc/ZYM2-TYTE; Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), Respirator Approval Program, available at https://perma.cc/G6K4-WEQF.

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CDC			
	Respirator Approval Program		
	▲ NOTICE Due to the reduction in force across NIOSH, no new respirator approval applications can be accepted.		
		Respirator Approval: How to Apply Information for manufacturers on how to apply for respirator approval.	

141. The Coal Workers' Health Surveillance Program—a Congressionally-mandated program—has also stopped work and stopped providing medical screenings or accepting new

requests for review of medical information to determine coal miners' rights for transfer to low-

dust jobs, as a direct result of the March 27 Directive. ²⁰

CDC	NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) Coal Workers' Health Surveillance Program		
	EXPLORE TOPICS V Q SEARCH		
	FEBRUARY 24, 2025		
Coal Workers' Health Surveillance Program			
	▲ NOTICE Due to the reduction in force across NIOSH, the NIOSH Coal Workers' Health Surveillance Program (CWHSP) is not providing any new medical screenings to coal miners or accepting any new requests for review of medical information to determine coal miners' rights for transfer to low-dust jobs.		
	AT A GLANCE The NIOSH Coal Workers' Health Surveillance Program (CWHSP) studies respiratory disease in miners. The program provides health information to miners through health screenings and surveillance.		

142. The Health Hazard Evaluations—another Congressionally-mandated program has announced that it will not accept any new health hazard evaluation requests due to the implementation of the March 27 Directive.²¹

The National Institute for Occupational Safety and Health (NIOSH)	Search Q
Notice Due to the reduction in force across NIOSH, no new health hazard evaluation requests can be accepted.	
Promoting productive work through safety and health	kplaces
Health Hazard Evaluations (HHEs)	

²⁰ Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), Coal Workers' Health Surveillance Program, available at <u>https://perma.cc/SU5C-W2NF</u>.

²¹ Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), Health Hazard Evaluations, available at <u>https://perma.cc/9HAP-MNVV</u>.

143. FFFIPP—another Congressionally-mandated program—has been stopped and will

not accept new requests, due to the implementation of the March 27 Directive.²²

CDC	NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) Firefighting		
	EXPLORE TOPICS V	Q search	
		OCTOBER 10, 2024	
	About the FFFIPP		
	▶ NOTICE Due to the reduction in force across NIOSH, no new NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) requests can be accepted.		
	PURPOSE The NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) conducts independent investigations of firefighter line-of-duty deaths and serious injuries. We develop prevention actions to help prevent similar events.		

144. Finally, the congressionally mandated National Firefighter Registry recently announced that firefighters could no longer enroll due to the NIOSH RIF:²³



²² Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), About the FFFIP, available at <u>https://perma.cc/Q9SR-6XPU</u>.

²³Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (NIOSH), National Firefighter Registry (NFR) for Cancer, available at <u>https://perma.cc/K9UP-BVDD</u>.

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145. The cessation of work at NIOSH facilities has deprived Plaintiff States of resources guaranteed to them under statute. As just one example, federal regulations require NIOSH certify respiratory equipment, 42 C.F.R. § 84.10(c), and an estimated five million American workers are required to use respirators for their jobs. Plaintiff States—as employers and operators of health care facilities and other settings where respiratory equipment is necessary—are harmed by the sudden cessation of certification of respiratory equipment, which will make it more difficult to source and purchase necessary respiratory equipment for State workers and State facilities. Further, with no one at the NIOSH facility, private partners lack any effective ability to communicate with the Pittsburgh lab to discuss requirements for approval or the proposed designs of their respiratory equipment. Id. § 84.10(d). And, without the facility in Pittsburgh, no respiratory equipment may be approved for manufacture or use and no partners can communicate with product reviewers.

146. The loss of highly skilled NIOSH workers also directly impacts the States and local communities where these workers were located. For instance, in Washington, NIOSH employees have frequently collaborated with Washington State Labor and Industries to analyze and describe workers' compensation claims among Washington mining operators. Recently, NIOSH Spokane employees collaborated with two industry partners to design, build and deploy a hybrid dust control system that proved to reduce airborne silica dust by ninety-three percent at a mine site near Spokane. Without these collaborations, States will need to curtail their own activities or divert funding from other necessary programs to fill the gap.

147. States have immediately lost their ability to participate in NIOSH-led partnerships. Without NORA, as just one example of a cancelled program, Plaintiff States will lack the reports, guidance, and trainings offered to improve workplace safety. The closure of NIOSH, and by

extension its safety councils, will lead to more dangerous work environments in all of NIOSH's covered industries.

148. Plaintiff States regularly rely on NIOSH's data and research findings to inform and support their own laws and regulations on worker safety. For instance, Washington's workplace safety rules frequently reference and rely on NIOSH research and publications in setting their own standards, and explicitly require NIOSH-certified equipment to be used in certain situations. *See, e.g.*, WAC 296-305-04001 (requiring firefighters' self-contained breathing apparatus to be NIOSH certified); WAC 296-842-11005 (relying on NIOSH certification for respirator selection for workplaces; noting "[i]f a respirator is not certified by NIOSH, you have no guarantee that it meets minimum design and performance standards for workplace use"); WAC 296-842-19005 (relying on NIOSH Pocket Guide to Chemical Hazards to determine whether immediately dangerous to life or health conditions exist); *see also* RCW 49.17.460 (relying on NIOSH alerts in setting policy for exposure to hazardous drugs, noting "[i]t is the intent of the legislature to require health care facilities to follow rules requiring compliance with all aspects of [NIOSH]'s alert regardless of the setting in order to protect health care personnel from hazardous exposure to such drugs.").

149. NIOSH's dismantling also directly, and significantly, endangers miners. For instance, by firing almost all the employees in the Respiratory Health Division, Defendants have made it impossible for NIOSH to implement the CWHSP, as the agency no longer has the necessary personnel or expertise to fulfill its statutory obligations to coal miners. The announcement that no new submissions will be accepted for CWHSP, a congressionally mandated program, is telling. Without NIOSH fulfilling these critical functions, the need for monitoring, prevention, and treatment of affected miners—all of which previously required the immense amount of resources and specialization of NIOSH—will now be borne fully by states. Critical

efforts to monitor and stem the incidence of black lung among our nation's miners will either be borne completely and imperfectly by a patchwork of state health institutions, or lost entirely.

150. The elimination of NIOSH's congressionally mandated and funded role in researching and monitoring mining safety is also endangering miner health efforts in other agencies that depend on NIOSH. For instance, the Department of Labor's Mine Health Safety Administration (MSHA), in partnership with NIOSH, was set to begin in April 2025 implementation of a rule regulating the time and amount, and required respiratory equipment, for miners working with toxic silica dust. "Lowering Miners' Exposure to Respirable Crystalline Silica and Improving Respiratory Protection," 89 Fed. Reg. 28,218 (Apr. 18, 2024) (the Silica Rule). Now, due to what MSHA calls "the unforeseen NIOSH restructuring, and other technical reasons," namely the closure of the NPPTL and its effect on "the supply of approved and certified respirators and personal dust monitors," MSHA announced it was postponing the compliance deadline for the Silica Rule until August 18, 2025. Put simply, if NPPTL remains effectively shuttered, the Silica Rule cannot be implemented, further endangering the lives and well-being of thousands of our nations' miners.

151. The wholesale elimination of NIOSH ERCs directly impacts the numerous centers at state agencies, such as the University of Washington, that will be forced to close without NIOSH funding. The impacts of the loss of these centers goes well beyond the inevitable layoffs of faculty and staff, or the elimination of incoming student classes and the resulting lost revenue for academic institutions. The closure of all ERCs diminishes (if not eliminates) the states' supply of occupational medical doctors, industrial hygienists, and other occupational safety and health professionals. Without these specialists, workplace hazards will go undetected, preventable injuries will increase, and evidence-based care for injured workers will decline.

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152. The eliminations of the remaining NIOSH intramural and extramural programs, such as the HHE program, Total Worker Health Centers, and state-based occupational health surveillance programs, will place added strain on Plaintiff-States' already-strained health and labor agencies, who do not have the resources, data, legal mandates, or reach of NIOSH to effectively replace the massive loss of institutional knowledge and application. In Washington, for instance, NIOSH's HHE Program has provided at least ten technical assistance evaluations to businesses and industry in the State of Washington over the last twenty years, covering issues like (1) Tuberculosis transmission from elephants to zoo employees; (2) chlorine gas release at a metal recycling facility; (3) exposure to potential hazards during harvesting and processing cannabis at an outdoor organic farm; and (4) concerns over occupational exposure to new drycleaning solvents among drycleaning workers. In each instance NIOSH conducted a thorough investigation and provided public recommendations and findings that provided industry guidance on strengthened safety protocols. After the March 27 Directive's gutting of NIOSH, no other federal agency would have the capability to provide the same service.

153. WTCHP had already lost probationary workers in February, and WTCHP lost sixteen more employees on April 1. These terminations came after HHS repeatedly said no members of WTCHP would be terminated. The program relies upon medical doctors at NIOSH to certify new cancers and terminations. The April 1 terminations, however, put all of NIOSH's medical doctors on administrative leave, severely impacting WTCHP. Since April 1, patients have experienced delays in receiving care and coverage for their medical needs.

154. Even the few hollowed-out NIOSH programs spared by the March 27 Directive's near-total cuts will be rendered functionally ineffective and place increased financial burden on the Plaintiff States. For instance, the National Firefighter Cancer Registry, despite being one of the

few NIOSH programs supposedly preserved, just announced they would not be taking any new submissions from firefighters. And WTCHP, which serves first-responders and survivors in every state, now has no staff to certify new diagnoses or new patients for coverage, as it must under the Zadroga Act. The result is that more people who are eligible for such programs will not receive coverage or reimbursement for their medical needs and will therefore need to rely on coverage from Plaintiff-State health plans to pay for their costs.

C. National Center for Chronic Disease Prevention and Health Promotion (CDC, NCCDPHP)

Statutory Mandates

155. The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) sits within CDC and supports healthy behaviors and preventive medical care to help people prevent and manage chronic diseases. Its work focuses on many of the leading causes of preventable deaths in the United States, including tobacco use, poor nutrition, lack of physical activity, and overuse of alcohol. More than seventy-five percent of its annual budget is used to support State, local, territorial, and Tribal partners.

156. The NCCDPHP oversaw both the Division of Reproductive Health and the Office on Smoking and Health until they were eliminated by the March 27 Directive.

157. The Division of Reproductive Health (DRH) worked to reduce the risk and improve the health of women and infants by studying maternal mortality, improving quality of care for mothers and infants, and collecting quality data on women and infants.

158. DRH studied many aspects of the health and well-being of pregnant people and babies, as set out by statute. 42 U.S.C. § 247b-12 ("Safe motherhood"). The Pregnancy Risk Assessment Monitoring System (PRAMS) is a program formerly housed within DRH collecting data nation-wide regarding maternal and infant health outcomes. PRAMS was a site-specific,

population-based surveillance system designed to identify groups of women and infants at high risk for health problems, to monitor changes in health status, and to measure progress towards goals in improving the health of mothers and infants.

159. Public and private health organizations partnered with DRH to collect PRAMS data and receive grant funding. That assistance reached beyond the grant itself. PRAMS partners were entitled to receive from the CDC, through their substantial programmatic involvement, post-award monitoring, technical assistance, performance reviews, and general assistance to carry out the award. Additionally, grants provide for a project officer or other staff to support the PRAMS project with "day-to-day" management. The data collected in the survey must be kept confidential pursuant to a Standard Data Management Plan.

160. PRAMS data collection activities are mandated by Congress. Specifically, Congress requires that the CDC "carry out programs . . . to collect, analyze, and make available data on prenatal smoking and alcohol and other substance abuse and misuse, including . . . additional information or data, as appropriate, on family health history, medication exposures during pregnancy, demographic information, such as race, ethnicity, geographic location, and family history, and other relevant information." 42 U.S.C. § 247b-13(a). State officials and health care providers rely on the massive survey data collected through PRAMS, which had been running for nearly forty years, to improve health outcomes. At least one state has used the PRAMS data to guide legislative efforts aimed at improving maternal health.

161. DRH also ran the Pregnancy Mortality Surveillance System, which ran national surveillance of pregnancy-related deaths in the United States. The Enhancing Reviews and Surveillance to Eliminate Maternal Mortality program supported public and private agencies and organizations that coordinated and managed Maternal Mortality Review Committees (MMRCs).

MMRCs are multidisciplinary committees formed at the state or local level that performed comprehensive reviews of deaths among women during and within a year of the end of a pregnancy. Currently, there are MMRCs in nearly every state and multiple U.S. territories. Data from MMRCs is critical to providing a deeper understanding of the circumstances surrounding each death to guide recommendations at the patient, provider, facility, system, and community level for preventing future deaths. This, too, is set out by law. 42 U.S.C. § 247b-12(d).

162. DRH also ran a Field Support Branch which provided guidance on the needs of pregnant and postpartum people and infants in emergencies. That Branch included a Maternal and Child Health Epidemiology Team, as well as a Global Reproductive Health Evidence for Action Team. The Field Support Branch's work was mandated by Congress, which has repeatedly reauthorized a law first passed in 2006 that required HHS to take pregnant women and other vulnerable populations into account when planning emergency responses. *See* Pandemic and All-Hazards Preparedness Act, Pub. L. 109-417.

163. DRH also studied assisted reproductive technology. A dedicated team collected data from assisted reproductive technology clinics on their pregnancy success rates and maintained a nation-wide database of clinics that offered in vitro fertilization (IVF). The team also produced an online tool that individuals interested in becoming pregnant could use to estimate their success of IVF and was in the middle of researching how to make treatments cheaper through state-mandated insurance. Much of this work was ordered by Congress. *See* Pub. L. 102-493.

164. In addition to the DRH, NCCDPHP oversaw the Office on Smoking and Health (OSH). OSH was the lead federal agency for comprehensive tobacco prevention and control and played a critical role in preventing youth tobacco use, which includes smoking, vaping, and other nicotine products, and helping adults to quit smoking. Cigarette smoking is the leading cause of

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preventable disease, disability, and death in the United States. OSH worked to prevent and reduce cigarette smoking by collecting, studying, and sharing information on cigarette smoking and its effects on health, as mandated by Congress. 15 U.S.C. § 1341 ("Smoking, research, education and information").

165. Among other projects, OSH managed a tobacco use data portal which provided access to the latest tobacco prevention and control data, graphs, and maps, as well as the State Tobacco Activities Tracking and Evaluation (STATE) System, which presented data on traditional Medicaid coverage of tobacco cessation treatments in fifty U.S. States and the District of Columbia. This dataset was used by Plaintiff States to assess tobacco cessation policies and served as a national clearinghouse of information for the public.

166. OSH also managed annual submissions of cigarette and smokeless tobacco ingredient reports from manufacturers, packagers, and importers as mandated under the Federal Cigarette Labeling and Advertising Act (15 U.S.C. § 1335a) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. § 4403(a)(1)(A)), and monitored tobacco use trends and health impacts in part to inform FDA regulations and enforcement of the Tobacco Control Act of 2009 (Pub. L. 111-31). In 2019, OSH linked contaminated vaping devices to fatal lung damage.

167. Further, OSH played an important role in surveillance and surveys, including the state-based Behavioral Risk Factor Surveillance System, National Health and Nutrition Examination Survey, and National Youth Tobacco Survey (NYTS). OSH's national surveillance system provided reliable, consistent, and cost-effective data collection that many Plaintiff States used to evaluate their work and monitor progress in tobacco use prevention. NYTS collected data on tobacco use by high school and middle school students, including which products they were

using, how often they use them, and how youth access them. OSH additionally published statelevel data on tobacco prevention use in the STATE System.

168. OSH committed to educating the public about the harms of tobacco use, including media campaigns such as Tips from Former Smokers (Tips Campaign). The Tips Campaign ads, which were placed on television, radio, and billboards, encouraged smokers to quit by featuring real people with serious health conditions caused by smoking and secondhand smoke exposure. The 2012–2018 Tips Campaign had a significant positive impact on Americans' health. CDC estimated that over 16.4 million smokers attempted to quit and approximately one million successfully quit because of the Tips Campaign. Smokers who saw Tips Campaign videos reported greater intentions to quit smoking, and former smokers with higher exposure to the ads were associated with lower odds of relapse. The Tips Campaign was credited with helping prevent approximately 129,000 early deaths during 2012–2018. Moreover, the Tips Campaign saved precious government resources: CDC estimates the Tips Campaign saved \$7.3 billion in smoking-related healthcare costs. Every \$3,800 spent prevented the early death of an American.

169. OSH scientists published high-quality reports on tobacco use trends that states utilized to prioritize interventions, monitor progress, and reduce disparities. OSH's Best Practices for Comprehensive Tobacco Control Program Guide advises states on how to develop, implement, and fund an evidence-based tobacco control program. OSH likewise dedicated its publications and resources to the "Publication Catalog and Ordering System" where state agencies and other users could access campaign materials and Surgeon General's reports. In addition, OSH provided resources for middle and high school educators to help young people avoid or quit vaping.

170. OSH maintained 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. OSH funded state quitlines to deliver resources such as counseling and medications—it funded more than seventy-five percent of quitline costs in five states and two U.S. territories and at least twenty-five percent for eighteen states. The Tips Campaign resulted in a sustained and dramatic increase of calls to quitlines, including over two million additional calls during 2012–2023.

171. OSH also provided millions in funding to the National and State Tobacco Control Program. OSH is the only federal agency that funds tobacco control efforts in fifty states, the District of Columbia, eight U.S. territories, and twenty-eight tribes and tribal organizations. The National and State Tobacco Control Program served as a backbone to protect the public from the harms of tobacco use. Participating states used OSH funds to prevent kids from using tobacco, reduce secondhand smoke exposure, help people quit smoking, and address disparities in tobacco use. Moreover, these investments served the public fisc. For every one dollar spent on strong tobacco control programs, states achieved a fifty-dollar return on investment, mostly due to the state averting paying increased health care costs to treat smoking-related illness.

172. In Fiscal Year 2024, Congress appropriated \$1,192,647,000 to the programs of the NCCDPHP.

Implementation of the March 27 Directive against NCCDPHP, and its impact on Plaintiff States

173. DRH, alone, lost most of its 100 employees. Defendants eliminated two of the three branches in the Division: Applied Sciences (which included the fifteen-person team responsible for PRAMS) and Women's Health and Fertility (forty employees).

174. The CDC has communicated to Plaintiff States that it is unable to provide the resources promised under the PRAMS agreements.

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175. The CDC has made no statements explaining how the statutorily mandated collection, review, and publication of the DRH data, prenatal care, contraception access, and efforts to reduce maternal and infant mortality would continue without interruption or a dip in quality after firing everyone in the division. Nor has DRH made any statement explaining how it will maintain data systems and keep those systems secure while there is no one working in DRH. These data systems were required under the terms of the PRAMS agreements, and the data includes extremely sensitive personal health information protected under numerous federal and state laws and regulations. Instead, the CDC has communicated to some Plaintiff States that it is no longer able to provide the contracted resources.

176. Plaintiff States have lost their PRAMS partnership support and all the critical reproductive health data that came with it. This includes data on maternal and infant health outcomes, maternal mortality, data on the needs of pregnant and postpartum people and infants in emergencies, pregnancy success rates in IVF—even data on how to lower the cost of IVF via state-mandated insurance. Plaintiff States rely on receiving that data. Plaintiff Connecticut, as one example, uses PRAMS data to collaborate with community and state organizations and provide insight into the experiences of the Medicaid population during pregnancy. This supported the development of the HUSKY Maternity Bundle, an initiative aimed at improving outcomes for people on Medicaid that launched this year.

177. In addition, the PRAMS agreements with Plaintiff States and local health departments committed substantial grant funding and post-award programmatic involvement such as trainings and technical assistance by CDC program officials and project scientists that will be lost. With all DRH staff terminated, including those who managed the grants and ran the trainings, Plaintiff States and their instrumentalities will lose out on the services and data that was promised

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to them. Some Plaintiff States have already been told that their project officer and/or technical monitor was on administrative leave, associated with the HHS RIFs. Plaintiff States have lost and will continue to lose out on programmatic action and knowledge of key maternal and infant health indicators related to maternal mortality and other important health risk factors and outcomes.

178. Due to the March 27 Directive, DRH also cannot support the MMRCs, which operate at the state or local level to review deaths that occur during or within one year of the end of pregnancy. Plaintiff States, and their MMRCs, received funding and programmatic assistance from CDC that directly supported the coordination, staffing, and management of MMRCs.

179. Defendants fired everyone in the DRH Field Support Branch, including individuals working directly on public health in the Plaintiff States and the entire team responsible for guidance on the needs of pregnant and postpartum people and infants in emergencies, such as COVID-19, Zika, and Ebola—all of which pose particular risks for pregnant women. An entire team working on assisted reproductive technology was also cut.

180. OSH, as well, was destroyed. All or nearly all of the roughly 120 full-time employees were dismissed along with many contract workers who lost their jobs in February. The former Director & Senior Medical Officer of OSH from 2010–2017, described what happened to OSH as "the greatest gift to the tobacco industry in the last half century."

181. OSH will be unable to fulfill its statutory mandates to collect and publish relevant data, manage annual submissions of cigarette ingredient reports from manufacturers and importers, and monitor tobacco use trends and health impacts to inform FDA regulations and enforcement policies.

182. CDC's website "Tobacco Ingredient and Nicotine Reporting," which provided relevant background and guidance for manufacturers, packagers, and importers of tobacco

products to report the ingredients and the quantity of nicotine in the products, now has a disclaimer that ingredient submissions are paused and no new Certificates of Compliance will be issued "[d]ue to the impact of the HHS Reduction in Force and reorganization." As mandated by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1335(a), and the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4403(a)(A), each manufacturer, packager, or importer of cigarettes or smokeless tobacco products must annually submit to OSH a list of ingredients added in the products. And yet, on the CDC's own website, it announced that because of the March 27 directive, it was pausing submissions:²⁴



183. Plaintiff States rely on these reports in a number of ways, including as a basis for their tobacco control or enforcement laws. In some Plaintiff States, one factor considered when deciding whether a brand may appear on its directory of products permitted for sale is participation in the Tobacco Ingredient and Nicotine Report.

184. Similarly, OSH education ads are unavailable to Plaintiff States. Before the March27 Directive, states could order free and low-cost tobacco education campaign materials to support

²⁴ Centers for Disease Control and Prevention, Smoking and Tobacco Use – Tobacco Ingredient and Nicotine Reporting, available at <u>https://perma.cc/KCF2-VTKH</u>.

its own communication efforts and avoid the high cost of producing new ads. Today, the Media Campaign Resource Center is unable to take orders.²⁵



185. Plaintiff States have similarly lost the benefit of having OSH reliably perform its statutory duties to "conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect", "establish and maintain a liaison with . . . other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health," and "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, 15 U.S.C. § 1341(a)(1), (3)-(4). These mandates compelled OSH to manage, among other products, the Tips From Former Smokers ad campaign and phone support system to connect smokers interested in quitting to their state quitline. OSH's scientific reports and studies have

²⁵ Centers for Disease Control and Prevention – Medica Campaign Resource Center (MCRC), available at <u>https://perma.cc/3WMQ-WAHV</u>.

supported smokefree indoor air protections and facilitated people to successfully quit smoking and those are similarly in jeopardy.

186. Relatedly, Plaintiff States' quitlines provide a variety of resources and interventions to help people quit tobacco that relied on federal funds from the FDA's Center for Tobacco Products. For example, the New York State Quitline offers free starter kits of nicotine replacement therapy supported by OSH funding. Without a working OSH, Plaintiff States stand to lose approximately \$16 million in funding for their state quitlines.

187. HHS cuts and layoffs to these critical resources, that have helped more than 1 million smokers to quit, would reduce access to these free or low-cost quitlines. Without state quitlines, fewer people will be encouraged to quit, fewer people will know where to get help, and fewer people will quit.

D. National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (CDC, NCHHSTP)

Statutory Mandates

188. The National Center for HIV, Viral Hepatitis, STD and Tuberculosis Prevention (NCHHSTP) sits within CDC and works "to reduce incidence of infection, morbidity and mortality, and health disparities in the U.S. and abroad."²⁶ Prior to April 1, NCHHSTP fulfilled this mission by monitoring public health, researching disease prevention, funding local programs that prevent disease, and developing and promoting strategies to reduce harm and other tools for providers and affected or at-risk communities. It was created to further the objectives set forth in the PHSA. In Fiscal Year 2024, Congress appropriated \$1,391,056,000 for the CDC's prevention research and other efforts relating to HIV/AIDS, viral Hepatitis, STIs, and Tuberculosis.

²⁶ Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention, NCHHSTP Strategic Priorities, available at <u>https://perma.cc/F3TS-9P3H</u>.

189. Among other divisions and offices, NCHHSTP oversaw the Division of HIV Prevention (DHP), whose mission is to promote health and quality of life by preventing HIV infection and reducing HIV-related illness and death in the United States, the Division of Sexually Transmitted Disease Prevention (DSTDP), whose mission is to maximize the impact of STI prevention through science, programs, and policy, and the Division of Viral Hepatitis (DVH), whose mission is to end the viral hepatitis epidemics through leadership in science and public health practices.

190. These Divisions ran Disease Intervention Training Centers to strengthen the capacity of local and state health departments to conduct intervention services for communicable diseases including HIV/AIDS. CDC is required, by statute, to "establish fellowship and training programs . . . to train individuals to develop skills in epidemiology, surveillance, testing, counseling, education, information, and laboratory analysis relating to [AIDS]." 42 U.S.C. § 300cc-31(a); *see also id.* § 300ff-111 (authorizing grants to train health personnel with regards HIV/AIDS interventions); *id.* § 300ee-4 (requiring technical assistance relating to AIDS).

Implementation of the March 27 Directive against NCHHSTP, and its impact on Plaintiff States

191. Several branches under the DHP lost their entire staff pursuant to the March 27 Directive: behavioral and clinical surveillance HIV research, HIV prevention capacity development, prevention communications, quantitative sciences, and all work that is global in nature.

192. DSTDP shut down a laboratory that analyzed and tracked complex sexually transmitted infections (STI Lab) around the country. The STI Lab lost seventy-seven scientists, with a collective 1,400 years of field experience. This was a state-of-the-art Bio Safe Level 4 lab that studied many infectious diseases, including HIV/AIDS and drug-resistant gonorrhea.

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193. The CDC also shut down the Division of Viral Hepatitis's (DVH) Laboratory Branch at CDC headquarters by laying off all twenty-seven of the lab's scientists on April 1, when scientists were given just one day to shut down the lab, secure approximately one million blood samples being preserved in the facility's multi-million dollar freezers, and pause investigations into current hepatitis outbreaks in at least seven states. Congress had appropriated \$53 million specifically to efforts to combat viral hepatitis. The DVH Lab, which was integral to research that was awarded a Nobel Prize in Medicine for helping to make the initial discovery of Hepatitis C in the 1980s, is the foremost viral Hepatitis laboratory in the United States and the world, and the research it conducts in real time to track active Hepatitis outbreaks using the virus's genetic code is not conducted by any other institution.

194. Because Defendants suddenly closed the DSTDP's STI Lab and the DVH Lab at CDC headquarters with no notice or explanation of how the work could possibly continue, Plaintiff States have had to find new partners to handle their most difficult testing needs that had previously been handled by the CDC.

195. The March 27 Directive has also meant that CDC has no one to run or manage agreements related to their Disease Intervention Training Centers. In a notice sent to states on April 10, 2025, CDC wrote:

Dear Funded Partner, Last week CDC experienced a large reduction in force (RIF), in accordance with President Donald Trump's Executive Order 14210 and the Department of Health and Human Services' (HHS) broader reorganization strategy to improve its efficiency and effectiveness. This cooperative agreement CDC-RFA-PS20-2003: STD/HIV Disease Intervention Training Centers (DITC) will not be extended. Unfortunately, the Division of STD Prevention (DSTDP) is no longer able to provide programmatic technical assistance or project monitoring as required by law. 196. Plaintiff States had relied on these training centers to support services and interventions that prevent the spread of HIV/AIDS. Plaintiff New York had been notified verbally that its funding would be renewed and was awaiting a formal notice of award when it received the April 10 notice that funding would be terminated because of the March 27 Directive. As a result, Plaintiff New York will lose \$300,000 in grant funding.

E. National Center for Environmental Health (CDC, NCEH)

Statutory Mandates

197. NCEH sits within CDC and exists to protect people's health from environmental hazards that can be present in the air we breathe, the water we drink, and the world that sustains us by investigating relationships between environmental factors and health, developing guidance, and building partnerships with U.S. and international agencies. Within NCEH sits the Division of Environmental Health Science and Practice (DEHSP) which, prior to April 1, 2025, provided critical environmental health support and funding for environmental health departments and other partners with similar missions.

198. DEHSP was the primary Division responsible for asthma control and lead poisoning prevention. It consisted of the Asthma and Air Quality Branch, the Climate and Health Activity, the Emerging Environmental Hazards and Health Effects Branch, the Environmental Public Health Tracking Branch, the Lead Poisoning Prevention and Surveillance Branch, and the Water, Food, and Environmental Health Services Branch.

199. DEHSP administratively oversaw and often collaborated with the otherwise independent Agency for Toxic Substances and Disease Registry (ATSDR). Congress ordered creation of ATSDR in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA Act), 42 U.S.C. § 9601 *et seq.*, and ordered ATSDR report directly to the Surgeon General, though it may cooperate with several other leaders of federal agencies, "and

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appropriate State and local health officials" to implement the health authorities of the CERCLA Act. *Id.* § 9604(i)(1). Under the first of those obligations, ATSDR must "in cooperation with the States, establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances." *Id.* § 9604(i)(1)(A).

200. DEHSP also played a key role in the National Environmental Public Health Tracking Program, which uses a network of people and information systems to deliver noninfectious disease, environmental, and socio-economic data from various sources. Congress appropriated funds to CDC to establish this program in 2002, and the program funds have continued to go to thirty-three states to consolidate data from local, State, and national levels to monitor and assess health risks for public health officials.

201. In Fiscal Year 2024, Congress appropriated \$191,850,000 for the work of NCEH.

Implementation of the March 27 Directive against NCEH and its impact on Plaintiff States

202. The entire DEHSP was eliminated. It is unclear how many staff were lost at ATSDR.

203. According to the leaked 2026 Passback, NCEH programs for the ALS registry, Climate and Health, Environmental & Health Outcome Tracking Network, Childhood Lead Poisoning, and Lead Exposure Registry are all slated to be eliminated.

204. The March 27 Directive calls for ATSDR to be absorbed by the new AHA.

205. At the time of the March 27 Directive, DEHSP was in the middle of responding to a lead crisis in Milwaukee, WI. Because of the terminations, DEHSP had to stop creating a plan for mass testing of schoolchildren for lead, stop holding weekly discussions with city health officials on the investigation, stop providing coaching and document reviews, and stop helping stakeholders with technical questions. The Director of ATSDR wrote to city officials: "I sincerely regret to inform you that due to the complete loss of our Lead Program, we will be unable to support you with this."

206. Other state and local health departments across the country will also be negatively affected. For example, the CDC, and in particular ATSDR and DEHSP, played an important role in pooling and disseminating knowledge and best practices, providing technical expertise and assistance, and helping adapt lessons from across the country to specific problems, like the discovery of lead paint in Milwaukee school buildings. ATSDR and DEHSP cannot, because of the layoffs and rushed reorganization, continue to perform their duties to respond to lead exposures.

207. Plaintiff States also rely on data published by NCEH, including the Environmental Public Health Tracking Program, which cannot be operated as no one is left at DEHSP to help maintain, update, collect, or publish the program. Plaintiff States are left without federal information that Congress paid for to inform their own responses to environmental health emergencies, including lead exposures.

F. National Center on Birth Defects and Developmental Disabilities (CDC, NCBDDD)

Statutory Mandates

208. Congress established the NCBDDD within CDC under the Children's Health Act of 2000. Prior to April 1, 2025, the NCBDDD and its programs served to prevent birth defects like spina bifida and congenital heart defects, prevent over 30,000 people with hemophilia from suffering bleeding crises while protecting the blood supply for all Americans, and address the special needs of people with disabilities. NCBDD is required to: (1) "collect, analyze, and make available data on birth defects, developmental disabilities, and disabilities and health"; (2) "operate regional centers for the conduct of applied epidemiological research on the prevention of such

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defects and disabilities"; (3) conduct public education on same; (4) "conduct research on and to promote the prevention of such defects and disabilities, and secondary health conditions among individuals with disabilities"; and (5) establish a program to prevent and reduce suffering from spina bifida. 42 U.S.C. § 247b-4(a)(2).

209. The NCBDDD oversaw multiple divisions, including the Division of Blood Disorders and Public Health Genomics, which works to promote health, prevent disease, and reduce health inequities for people at increased genetic risk across the lifespan, so they can have the opportunity to be as healthy as possible. NCBDDD is also required by statute to fund and support programs to improve and expand newborn screening for heritable diseases. 42 U.S.C. §§ 300b-8, 300b-9. Among the programs that NCBDD funded to comply with this mandate was the Early Hearing Detection and Intervention Programs (EHDI), which expanded public health capacity with regards to children who are deaf or hard of hearing.

210. The CDC is required to "continue efforts, including by awarding grants, to develop or establish mechanisms to improve the treatment of sickle cell disease, and to improve the prevention and treatment of complications of sickle cell disease, in populations with a high proportion of individuals with sickle cell disease." 42 U.S.C. § 300b-5(b)(1)(A). The CDC is also required to set up a National Coordinating Center for sickle cell disease. *Id.* § 300b-5(b)(3)(A).

211. NCBDD also oversaw the Division of Human Development and Disability. This Division promotes health equity by studying public health information, reducing disparities, promoting healthy living, and supporting inclusive health programs. These programs are required by statute. 42 U.S.C. § 247b-4(a)(2)(c).

212. NCBDD ran extramural programs and funding in many Plaintiff States.

213. In Fiscal Year 2024, Congress appropriated \$206,060,000 for the work of NCBDDD.

Implementation of the March 27 Directive against NCBDDD, and its Impact on Plaintiff States

214. More than forty percent of the 225 scientists and public health workers at the NCBDDD were subject to the RIF and put on administrative leave, eliminating the staff responsible for carrying out many of NCBDDD's statutorily mandated functions, notwithstanding Congress' appropriations for the Center's crucial work.

215. The cuts completely eliminated the Division of Blood Disorders and Public Health Genomics, which performed research on conditions such as hemophilia, sickle cell disease, and many other conditions impacting blood. The American Society of Hematology and ninety related organizations called for Secretary Kennedy to reverse the cuts at the Division of Blood Disorders, cuts which are "effectively dismantling this critical division."

216. The cuts also completely eliminated the Disability and Health Promotion Branch, which sat within the Division for Human Development and Disability. Also in the Division for Human Development and Disability, all but one member of the EHDI team was laid off. In an email sent to all recipients of EHDI funding, the Division of Human Development and Disability wrote that, "the typical functions of project officers, health/data scientists and evaluation scientists are not occurring," even though the "primary requirement" of EHDI grant recipients (including some of Plaintiff States) "is data submission." The email also explained that there was only one person "currently supporting all IT-related requests for" NCBDDD, and indicated that, "[a]s a result of the RIF," the review of future grant applications was "on hold."

217. NCBDDD's Disability and Health Data Science teams work with the National Syndromic Surveillance Program Disability Data, which monitors emergency department visits to

detect public health outbreaks and other health issues affecting people with disabilities. All the people responsible for that program were terminated.

218. Without people in the Division of Blood Disorders and Public Health Genomics and the Division of Human Development and Disabilities, Plaintiff States will lose critical federal expertise and support both in ongoing activities and funding which now have no one to administer them on the federal level.

G. National Center for Injury Prevention and Control (CDC, NCIPC) Statutory Mandates

219. The mission of the National Center for Injury Prevention and Control (NCIPC or the Injury Center), which sits within CDC, is to prevent injury, overdose, suicide, and violence across the lifespan through science and action. It works proactively with partners to track trends, conduct research, raise awareness, and implement prevention programs.

220. The work of NCIPC was established in 1993 and was created by the Injury Control Act of 1990, which amended the PHSA to revise and extend the program for the prevention and control of injuries. Injury Control Act of 1990, Pub. L. 101-558, 104 Stat. 2772 (1990). NCIPC is governed by 42 U.S.C. § 280b.

221. Within NCIPC sits the Office of the Director and three divisions, including the Division of Injury Prevention. The Division of Injury Prevention's mission is to prevent injuries by connecting data, science, and action to ensure healthy communities. This work is required by statute. 42 U.S.C. § 280b (requiring CDC to "conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries"); *id.* § 280b-0 ("the Director of the Centers for Disease Control and Prevention, shall—

assist States and political subdivisions of States in activities for the prevention and control of injuries").

222. In Fiscal Year 2024, Congress appropriated \$761,379,000 for the work of NCIPC.

Implementation of the March 27 Directive against NCIPC and its impact on Plaintiff States

223. Entire teams at NCIPC that focused on motor vehicle crashes, child maltreatment, rape prevention and education, drowning, traumatic brain injury, falls in the elderly, and other issues were cut. More than 200 positions at NCIPC were eliminated as a result of the March 27 Directive. An entire branch responsible for analyzing data for NCIPC and maintaining the Web-Based Injury and Statistics Query and Reporting System was eliminated. Much of this work was required by statute; the result is that funding appropriated by Congress will not be spent.

224. Teams that were not destroyed by terminations, like the Division of Overdose Prevention, still lost necessary technical support and cannot carry out their work.

225. Plaintiff States had relied on NCIPC and its datasets on injury and violence to improve their on-the-ground efforts. The data was used to efficiently deploy measures meant to prevent overdose, motor vehicle accidents, drownings, and other lethal accidents.

226. CDC partnered with the Consumer Product Safety Commission on the National Electronic Injury Surveillance System, which collects data on injuries from approximately 100 hospitals across the U.S. As a result of the March 27 Directive, data collection efforts through that System will be significantly limited, including that data on injuries from motor vehicle crashes, falls, alcohol, adverse drug effects, work-related injuries will no longer be collected.

H. Food and Drug Administration (FDA)

Statutory Mandates

FDA is responsible for protecting the public health by assuring the safety, efficacy, 227. and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also provides accurate, sciencebased health information to the public.

228. FDA was first created by the Pure Food and Drug Act of 1906, which itself was passed as a response to Upton Sinclair's The Jungle. Pub. L. 59-384. That act was then replaced by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seg (FDCA). FDA also derives statutory authority from a number of other laws, including the PHSA.

By law the FDA shall, among other things, "promote the public health by promptly 229. and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Further, the Commissioner of the FDA shall be responsible for, among other things, "coordinating and overseeing the operation of all administrative entities within the Administration," id. § 393(d)(2)(B), "research relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out this chapter," id. § 393 (d)(2)(C), and "conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration," id. § 393(d)(2)(D).

230. The FDA is comprised of nine Center-level organizations and thirteen Headquarter Offices, including the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER); the Human Foods Program (HFP); the Center for Veterinary Medicine (CVM); and the Center for Tobacco Products (CTP).

231. CBER regulates biological products which were first regulated by Congress in the Biologics Control Act of 1902. Pub. L. 57-244. CBER also regulates biological products under the authority of the PHSA, *e.g.*, 42 U.S.C. § 262 ("Regulation of biological products") and the FDCA as enabling statutes for oversight of biological products.

232. The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C § 262(i)(1).

233. CDER, which regulates drugs, operates under several statutes including the FDCA, which established FDA's authority to regulate drugs and require pre-market approval for safety.

234. The term "drug" is defined in statute as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C § 321(g)(1).

235. HFP oversees all FDA activities related to food safety and nutrition and is organized under the Deputy Commissioner of Human Foods. The term "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f).

236. CVM derives its authority from the FDCA, which regulates animal drugs, animal food and feeds, and animal medical devices. 21 U.S.C. § 301 *et seq*. The FDCA was amended by several acts, such as the Animal Drug Availability Act, Pub. L. 104-250 (ADAA), Animal Medicinal Drug Use Clarification Act, Pub. L. 103-396 (AMDUCA), Animal Drug User Fee Act, Pub. L. 108-130 (ADUFA), Animal Generic Drug User Fee Act, Pub. L. 110-316 (AGDUFA), Food Safety Modernization Act, Pub. L. 111-353 (FSMA), Generic Animal Drug and Patent Term Restoration Act, Pub. L. 100-670 (GADPTRA), and Minor Use and Minor Species Animal Health

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Act, Pub. L. 108-252 (MUMS). Among other duties, CVM reviews pre-market animal food ingredient submissions, including approving safe food additives for animal food use, *see id.* § 360b; designates new animal drugs for minor use or minor species, *see id.* § 360ccc-2; and monitors and investigates side effects and product quality problems that are reported for animal food, drugs, and devices once sold on the market, *see id.* § 351.595

237. The term "new animal drug" is defined in statute as, among other things, "any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed . . ." 21 U.S.C. § 321(v). The term "animal feed" is defined as "an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal." *Id.* § 321(w).

238. In 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31 (Tobacco Control Act)) amended the Federal Food, Drug, and Cosmetics Act (21 U.S.C. § 301 *et seq.*, (FDCA)) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products and to protect the public from the harmful effects of tobacco product use. The Tobacco Control Act directed FDA to establish a Center for Tobacco Products (CTP) to implement the law. 21 U.S.C. § 387a(e). Among other duties, CTP conducts compliance checks on vendors and retailers to ensure that tobacco products are not sold to those under the age of twenty-one, 21 U.S.C. § 387f, reviews premarket applications for new tobacco products before they can be marketed in the United States, 21 U.S.C. § 387j ("Application for review of certain tobacco products"), enforces advertising and promotion restrictions, 21 U.S.C. § 387f-1, and educates the public about the risks of tobacco use including the dangers of e-cigarettes and other tobacco products, 21 U.S.C. § 393(d)(2)(D).

239. CTP is led by a director, and oversees five offices: the Office of Management, Office of Regulations, Office of Science, Office of Health Communication and Education, and the Office of Compliance and Enforcement.

240. In Fiscal Year 2024, FDA's budget was approximately \$6.6 billion, of which \$3.5 billion was appropriated by Congress. The remainder of the FDA's budget was paid for by user fees, many of which were generated by the Prescription Drug User Fee Act. More than eighty percent of FDA's budget was spent on its work ensuring the safety and reliability of human drugs, foods, tobacco, devices/radiological health, biologics, and animal drugs and feed. As of October 2024, FDA was responsible for regulating the food, medical, and tobacco products industries which cumulatively account for \$3.9 trillion in economic activity.

241. FDA is headquartered in Silver Spring, Maryland, and has hundreds of field offices and fifteen laboratories located across all fifty states, the United States Virgin Islands, and Puerto Rico. FDA had more than 18,000 employees in 2024.

Implementation of the March 27 Directive against FDA and its impact on Plaintiff States

242. On April 1, Defendants fired 3,500 employees (nearly twenty percent of the agency's full-time employees) from FDA including many high-ranking, experienced agency leaders from CBER, CDER, CVM, HFS, and CTP.

243. Those terminated agency leaders included: the Director of the Office of Regulatory Operations, CBER; the Associate Director of Policy, CBER; the Associate Director of Product Management, CBER; the Deputy Director of CBER; the Director of the Office of New Drugs, CDER; the Director of the Office of Strategic Programs, CDER; the Director of CTP; the Director of the Office of Science, CTP; the Chief Veterinary Officer, CVM; and the Chief Medical Officer.

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244. These leaders joined many other FDA leaders who departed after Election Day 2024 but before April 1, 2025, including: the Director of CBER; the Deputy Director of CBER; the Director of the Office of Clinical Evaluation, CBER; the Chief of the Laboratory of Molecular and Developmental Immunology, CBER; the Director of CDER; the Deputy Director of CDER; the Deputy Director for Clinical Science, CDER; the Chief Counsel of the FDA; the Chief Medical Officer of the FDA; the Deputy Commissioner of the Human Foods Program; the Director of the Office of Product Evaluation and Quality, Center for Devices and Radiological Health; the Deputy Director of the Center for Science, Center for Devices & Radiological Health; the Director of the Digital Health Center of Excellence, Center for Devices & Radiological Health; the Deputy Directors of the Oncology Center of Excellence; the Deputy Director of the Oncology Center of Excellence; and the Principal Deputy Commissioner.

245. The unnecessary, sudden firing of so many of FDA's most experienced and knowledgeable staff will cripple the Administration's ability to perform its statutory mandate of "promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). As has already become apparent, FDA regulators missed the April 2 deadline for a key decision regarding approval of Novavax, a COVID-19 vaccine, which already received emergency-use approval. The agency was set to rule on Novavax's application on April 1. Yet the deadline for the agency to act passed and the agency failed to take action.

246. Similarly, the terminations have already incapacitated FDA's ability to conduct research on food products. Because FDA staff in an Illinois food safety lab were eliminated, FDA suspended a planned exercise, that was to be coordinated with a network of veterinary testing labs around the country, to ensure FDA could properly detect the bird flu virus in milk. The exercise

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was postponed because, as the FDA said in email: "Unfortunately, significant Reductions In Force (RIF), including a key quality assurance officer, at FDA's Human Food Program Moffett Center has caused immediate and significant impact on the Veterinary Laboratory Investigation and Response Network We regret to inform you that the Interlaboratory Comparison Exercise for detecting Highly Pathogenic Avian Influenza in milk (HPAI ICE-1), set to ship later this month, is suspended." The FDA said the effort "would have been critical to ensure confidence in the laboratory methods for food safety and animal health." The program was entirely suspended for at least the rest of Fiscal Year 2025.

247. The April 1 termination notices also devastated CTP. CTP's Director was placed on administrative leave. The Office of Regulations, an office of about 30, was cut down to one person. The Office of Management was cut entirely. The leadership of the Office of Science was removed. The Office of Compliance and Enforcement, whose employees sought fines against stores that repeatedly sold tobacco to customers under twenty-one, was wiped out. On average, the Office of Compliance and Enforcement brought more than 100 complaints a week seeking civil monetary penalties against retailers, but after the April 1 mass firings that operation came to a sudden halt and silenced CTP's central tool for preventing illegal tobacco sales.

248. CTP cannot continue to operate, as it must under the Tobacco Control Act, after the cuts. Its enforcement abilities have been stopped in its tracks. The cuts prompted a sprint by some remaining enforcement officials to seek extensions for the active complaints against retailers slated to go before the HHS board charged with reviewing them. Inside the FDA, the cuts raised fears about CTP's ability to continue enforcing the tobacco sales laws. The lack of federal regulated industry compliance by the FDA's surveillance, inspections, and investigations creates an opportunity for a windfall for importers of dangerous and illegal products such as disposable

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flavored vapes or e-cigarettes. Without enforcement the ongoing proliferation of disposable flavored vapes from China, that has already alarmed U.S. lawmakers, in the U.S. may skyrocket, particularly impacting children who find the sweet flavors and flashy designs appealing.

249. Further, CTP has been unable to meet its mandates under the Tobacco Control Act and review premarket applications for new tobacco products before they can be marketed in the U.S., enforce regulations, and educate the public about the risks of tobacco use, including the dangers of e-cigarettes and other tobacco products. Before April 1, CTP had reviewed premarket tobacco applications for about 27 million e-cigarette products and approved only the thirty-four ecigarette products that met the applicable public health standard required by law, including that the potential for the approved products to benefit adults who smoke outweighed the risk to youth. Now bereft of employees, CTP has stopped diligently reviewing new applications. Many Plaintiff States' laws depend on FDA product review and approval to determine which products may be legally sold in their state based on an exemption for FDA-approved e-cigarette products.

250. CTP has already asked some terminated employees to return; specifically the staffers responsible for investigating and penalizing retailers who illegally sell tobacco to minors. There has been no public statement about how many employees returned and for how long they will be employed.

I. Administration for Children and Families (ACF)

Statutory Mandates

251. ACF administers programs and provides advice to the Secretary on issues relevant to children, youth, and families such as child support enforcement, community services, developmental disabilities, family assistance, Native American assistance, and refugee resettlement.

252. ACF was created in 1991, 42 U.S.C. § 12311, though its oldest program is the Children's Bureau which was established in 1912. The establishment of ACF, which involved a reorganization of preexisting HHS offices under the authority of Section 6 of the Reorganization Plan No. 1 of 1953, 42 U.S.C. § 3501, placed greater emphasis and focus on the needs of America's children and families.

253. Congress set forth that ACF would be established within HHS and be headed by a Commissioner on Children, Youth, and Families. 42 U.S.C. § 12311. The Commissioner is charged with statutory duties including, *inter alia*: the collection and dissemination of information relating to the problems of young people and families; administering the grants authorized in title 42, chapter 127, subchapter I; assisting in the establishment and implementation of various types of programs; providing technical assistance and consultation to the States; gathering statistics that other federal agencies are not collecting; developing policies and priorities for the programs and activities under title 42, chapter 127; and convening conferences with State and local agencies on programs for children, youth, and families. *Id.* § 12312(a).

254. ACF managed many statutorily mandated programs including Head Start, which was created by the Head Start Act, 42 U.S.C. § 9801, and amended by the Improving Head Start for School Readiness Act of 2007, Pub. L. 110-134; Temporary Assistance for Needy Families, which was created by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. 104-193; Child Care and Development Fund block grants, which operate under the Child Care & Development Block Grant Act of 2014, Pub. L. 113-186; Low-Income Home Energy Assistance Program (LIHEAP), which was established by Title XXVI of the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35.

255. Prior to April 1, 2025, ACF was comprised of twenty-three offices, including the Immediate Office of the Assistant Secretary and the Office of Regional Operations, which facilitated the work of the ten regional offices around the country. Those offices included the Office of Early Childhood Development (which oversaw the Offices of Child Care and Head Start) and the Office of Community Services (which oversaw LIHEAP, among other programs).

256. As of January 21, 2025, ACF employed 2,400 federal employees, and an additional 500 contractors, with some staff working at the central office in Washington, D.C., and the majority working out of the regional offices in Atlanta, Boston, Chicago, Dallas, Denver, Kansas City, MO, New York City, Philadelphia, San Francisco and Seattle. As of May 2024, ACF administered more than 60 programs with a budget appropriated by Congress of more than \$70 billion.²⁷

Implementation of the March 27 Directive at ACF and its impact on Plaintiff States

257. Approximately 500 staff members at ACF received a RIF notice on April 1, 2025. These were in addition to the roughly 200 probationary employees who were already on administrative leave, and another 200 who had left under the Fork in the Road option. At bottom, ACF has gone from a head count of 2,400 at the beginning of 2025 to 1,500—a loss of about thirty-eight percent.

258. All regional staff in ACF's Boston (Region 1), New York City (Region 2), Chicago (Region 5), San Francisco (Region 9), and Seattle (Region 10) offices were terminated. These regional offices offered critical support to ACF's Head Start, Child Care, Family Assistance programs, and the Children's Bureau. The program specialists at these offices were intimately familiar with the complex structures and operations of the countless providers, grantees, and state

²⁷ <u>https://perma.cc/PJ5T-GAYU</u>.

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and local agencies that ACF served. In fact, the majority of Office of the Head Start employees within ACF work out of the regional offices. Further, the closure of many regional offices means that grantees will have to travel farther on average to reach their regional office. The National Head Start Association has said the cuts happened without a "clear plan for how the administration intends on supporting Head Start." The programs that receive Head Start and Child Care funds are deeply reliant on federal money: during the brief hold on federal grants in February, many Head Start grantees were unable to make payroll the day of the freeze and several Head Start centers temporarily closed.

259. Given the current delays in processing payment to Head Start programs, many programs are at imminent risk of being forced to pause or cease operations. Plaintiff States rely upon functional, fully operational Head Start programs and will be harmed in numerous ways if Head Start programs in their States are forced to pause operations or close. Hundreds of thousands of children (and their families) would be left without childcare, early education, and health supports, which would inevitably impact and strain the Plaintiff States' social support programs. Some Plaintiff States administer, and receive direct funding in support of, Head Start programs. For example, Washington State has several public colleges and institutions of higher learning that operate Head Start programs pursuant to grant funding from the Office of Head Start.

260. Head Start programs also give preference to foster children, who have few other options for free childcare. Many foster parents would have to reconsider whether they could continue to foster children in the child welfare system if they had to forego the high quality, free childcare provided by Head Start. With fewer Head Start programs, Plaintiff States would face increased difficulties in recruiting foster parents and caring for their most vulnerable youth.

261. Additionally, Plaintiff States inspect and license childcare centers operating in their jurisdictions. Head Start programs are subject to heightened inspection and licensing standards, and as a result, they have historically required far fewer resources to inspect and license by the Plaintiff States. If Head Start programs close, the inspection and licensure burden on Plaintiff States will increase as the balance shifts towards newer centers that are not subject to other inspection regimes.

262. Terminated ACF staff were responsible for not only processing and administering billions in Head Start funding to programs in the Plaintiff States, but for providing training and technical assistance, monitoring, and other program support. This would include site visits for safety and program integrity. Now, without dedicated program specialists to email or call, Head Start providers have been instructed to send all inquiries to a generic email box.

263. The Head Start program funds the employment of a State Director of Head Start Collaboration within each State. 42 U.S.C. § 9837b(a). These State Directors work closely with Office of Head Start employees in the regional offices and Head Start grantees within their States to coordinate and facilitate the administration of Head Start services. Since the regional staffs of Regions 1, 2, 5, 9, and 10 were terminated, the State Directors within those regions—who are employed by the agencies within Plaintiff States administering children and family services—have been inundated with requests for help from Head Start grantees whose funding was delayed, or otherwise could not reach their usual contacts within the regional offices for routine assistance.

264. As for LIHEAP, the entire staff was terminated. LIHEAP grants are distributed to Plaintiff States to assist low-income households that pay a high portion of their income to meet their energy needs, and protects low-income households by reducing the risk of unsafe heating and cooling situations and practices. Because Defendants had fired everyone at the office, no one was left behind capable of operating the formula to distribute funds remaining on the Fiscal Year 2025 contracts. Defendants had to hire someone back from administrative leave long enough to issue LIHEAP funds to the Plaintiff States, later than usual, on April 30.

265. Congress allocated \$4.1 billion to LIHEAP in Fiscal Year 2024 to offset high utility bills for roughly 6.2 million people. The terminated staff provided technical support, and monitoring and reporting assistance. The loss of these contacts, who were instrumental in helping Plaintiff States manage LIHEAP funds, will cause delays and disruptions to Plaintiff State's future LIHEAP funded projects.

266. Under the 2026 Passback, programs under LIHEAP (including all discretionary funding, and Infrastructure Investment and Jobs Act funding), Children and Families Services Programs (including Head Start, Preschool Development Grants, Community Services Block Grants, Community Economic Development, Rural Community Development, Medical-Legal Partnerships Plus, Affordable Housing and Supportive Services Demo, and Primary Prevention Youth Homelessness Demo), and Nutrition and Disability Services Programs (including State Councils on Developmental Disabilities, Developmental Disabilities Protection and Advocacy, Developmental Disabilities Projects of National Significance, Paralysis Resource Center, Limb Loss Resource Center, and Voting Access for People with Disabilities) are all slated to be eliminated.

J. Administration for Community Living (ACL)

Statutory Mandates

267. Congress enacted a number of laws between 2012 and 2015 creating the ACL and consolidating programs of the Administration on Aging, the Office on Disability, and the Administration on Development Disabilities to protect and support older adults and all persons with disabilities. Other components have since been transferred to ACL from different federal

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agencies. ACL currently is divided into nine units: the Office of the Administrator; the Administration on Aging; the Administration on Disabilities; the National Institute on Disability, Independent Living, and Rehabilitation Research; the Center for Innovation and Partnership; the Center for Management and Budget; the Center for Regional Operations; the Office of External Affairs; and the Center for Policy and Evaluation.

268. ACL's programs are authorized under the Older Americans Act, 42 U.S.C. § 3001 *et seq.*; Section 504 of the Rehabilitation Act, 29 U.S.C. § 794; the Developmental Disabilities Assistance and Bill of Rights Act of 2000, 42 U.S.C. § 15001 *et seq.*; the Workforce Innovation and Opportunity Act, 29 U.S.C. § 3101 *et seq.*; and other statutes.

269. The Older Americans Act establishes an Administration on Aging, headed by an Assistant Secretary for Aging. 42 U.S.C. § 3011(a). The Administration on Aging is one of the nine units of ACL. The Assistant Secretary is appointed by the President and confirmed by the Senate. *Id.* § 3011(b). Among other responsibilities, the Assistant Secretary "shall serve as the effective and visible advocate for older individuals within [the Department] and with other departments, agencies, and instrumentalities of the Federal Government by maintaining active review and commenting responsibilities over all Federal policies affecting older individuals." *Id.* § 3012(a). And the Assistant Secretary and the regional offices of the Administration are charged with providing technical assistance to State agencies and persons who provide nutrition services under the Older Americans Act. *Id.* § 3016. In addition, the Assistant Secretary is charged with submitting an annual report to Congress on the activities carried out under the Act, including the Administration's various data collection activities. *Id.* § 3018.

270. ACL protects the federal civil rights of older adults and persons with disabilities. For example, ACL also implemented Section 504 of the Rehabilitation Act, 29 U.S.C. § 794, key legislation that prohibits discrimination on the basis of disability, in programs receiving federal financial assistance from HHS, as well as throughout the agency.

271. The Workforce Innovation and Opportunity Act transferred the National Institute on Disability, Independent Living and Rehabilitation Research and the assistive living and independent living programs from the Department of Education to ACL. 29 U.S.C. § 762. It also created the Independent Living Administration, which is part of the Administration on Disabilities within ACL. *Id.* § 796-1.

272. ACL operates on "the fundamental principle that older adults and people of all ages with disabilities should be able to live where they choose, with the people they choose, and with the ability to participate fully in their communities." ACL advances that goal by funding services and supports—primarily to states and networks of community-based organizations—and by investing in research, education, and innovation.

273. Congress appropriated approximately \$2.5 billion to ACL in Fiscal Year 2024. ACL spent the bulk of that funding on programs to provide assistance on health and wellness for the elderly and disabled, protecting rights and preventing abuse, supporting consumer control, strengthening the networks of community-based organizations, and funding research.

274. ACL is headquartered in Washington, D.C. and had ten Regional Support Centers in Boston, New York, Philadelphia, Atlanta, Chicago, Dallas, Kansas City, Denver, San Francisco and Seattle, which act as liaisons at the regional and local levels and with 574 federally recognized tribes. ACL had approximately 243 employees as of September 2024.

Implementation of the March 27 Directive at ACL and its impact on Plaintiff States

275. ACL suffered a forty percent reduction in staff. On information and belief, every member of the agency's fiscal staff was placed on administrative leave. In addition, at least one regional liaison was initially terminated and then temporarily reinstated.

276. At the same time, its "critical programs," according to the March 27 Directive, would be reorganized into ACF, ASPE, and CMS. HHS still has not clarified which are the "critical programs," how that will work, or how HHS will enact these terminations and reorganizations without breaks in service and tracking all.

277. Plaintiff States fear harm to their efforts to serve their older residents and residents with disabilities. Without the technical expertise and grant support that ACL staff have provided in the past, they anticipate that it will become more difficult to apply for grants and receive funds in a timely manner. For example, by October 1, 2025, all states must comply with new regulations, promulgated in 2024, which are the first substantial revisions to the Older Americans Act program regulations in more than thirty-five years and include significant changes to the obligations on state agencies. *See* 89 Fed. Reg. 11,566 (Feb. 14, 2024). Without staff, ACL will not be able to provide typical and needed ongoing guidance to states to clarify new regulatory requirements and ensure timely federal review and approval of state plans.

K. Substance Abuse and Mental Health Services Administration (SAMHSA) Statutory Mandates

278. SAMHSA leads public health efforts to advance behavioral health for people in the United States. Its mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring access and better outcomes for all.

279. SAMHSA was created in 1992 when Congress amended the PHSA to reorganize the agencies addressing substance misuse and behavioral health. The Act abolished the Alcohol, Drug Abuse, and Mental Health Administration and consolidated substance-abuse related functions within SAMHSA. Pub L. 102-321, 106 Stat. 323 (1992), 42 U.S.C. § 290aa. Congress ordered SAMHSA be administered by an Assistant Secretary and assigned that administrator dozens of statutory obligations under Section 290aa(d).

280. Under 42 U.S.C. § 290aa(d)(4), SAMHSA must "conduct and coordinate demonstration projects, evaluations, and service system assessments." To that end, SAMHSA manages the National Survey on Drug Use and Health (NSDUH), an annual survey conducted via face-to-face interviews in people's homes and online that collects, and after review provides, nationally representative data on the use of tobacco, alcohol, and drugs; substance use disorders; mental health issues; and receipt of substance use and mental health treatment among the civilian, noninstitutionalized population aged twelve or older in the U.S. According to SAMHSA, the NSDUH is "paramount in meeting a critical objective of SAMHSA's mission . . . and selected areas as required by [42 U.S.C. 290aa(d)(4)]."²⁸

281. As required by 42 U.S.C. 290aa(l), the Assistant Secretary of SAMHSA must develop and carry out a strategic plan. The Strategic Plan, 2023–2026, is available on SAMHSA's website, and contains renewed commitments to SAMHSA's objectives of Preventing Substance Use and Overdose; Enhancing Access to Suicide Prevention and Mental Health Services; Promoting Resilience and Emotional Health for Children, Youth, and Families; Integrating Behavioral and Physical Health Care; and Strengthening the Behavioral Health Workforce. In furtherance of those priorities, the Strategic Plan committed to many initiatives, including

²⁸ <u>https://perma.cc/2JFC-7URB</u>.

treatment and recovery programs (*e.g.*, State/Tribal Opioid Response programs and Building Communities of Recovery grants), public awareness efforts ("Talk. They Hear You." an underage drinking campaign), technical assistance and training to communities and organizations (*e.g.*, The Strategic Prevention Technical Assistance Center, and Prevention Technology Transfer Center Network), and infrastructure grants and partnerships between SAMHSA and state agencies to develop culturally appropriate service delivery systems.

282. The statute that created SAMHSA also created three centers for SAMHSA to manage: Center for Substance Abuse Treatment, 42 U.S.C. § 290bb, Center for Substance Abuse Prevention, *id.* §§ 290bb-21—290bb-25g, and the Center for Mental Health Services, *id.* § 290bb-31–290cc-13. The Directors of these Centers also have dozens of statutory obligations. *See* 42 U.S.C. §§ 290bb, 290bb-21, 290bb-31.

283. SAMHSA also manages the Center for Behavioral Health Statistics and Quality which is required under the 21st Century Cures Act. 42 U.S.C. § 290aa-4.

284. SAMHSA also oversaw several smaller offices, including the 988 & Behavioral Health Crisis Coordinating Office. Congress ordered the Assistant Secretary of SAMHSA to operate a National Suicide Prevention Lifeline program. 42 U.S.C. § 290bb-36c(a) ("The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program."). The law requires the Secretary to maintain the program's many activities, *id.* § 290bb-36c(b), consult with State departments of health in developing requirements of crisis centers across the country, *id.* § 290bb-36c(c)(3), and share secure and de-identified epidemiological data with the CDC, *id.* § 290bb-36c(d), and demographic data with state and local agencies, *id.* § 290bb-36c(e). Congress also requires that SAMHSA establish an Office of Minority Health that reports directly to the Director. 42 U.S.C. § 300u-6a.

285. SAMHSA received funding under several federal statutes including the Bipartisan Safer Communities Act (BSCA), Pub. L. 117-159 (2022) (assigning \$800 million for mental health services block grants, the National Child Traumatic Stress Network, Project AWARE, Mental Health Awareness Training, and the National Suicide Prevention Lifeline through Fiscal Year 2025), the Comprehensive Addiction and Recovery Act (CARA), Pub. L. 114-198 (2016), and the Sober Truth on Preventing (STOP) Underage Drinking Act, Pub. L. 109-422 (2006).

286. SAMHSA also worked out of each of HHS's ten regional offices. The SAMSHA regional offices provide leadership, consultation, and partner with state, tribal, territorial, and local community stakeholders.

287. SAMHSA's FY2024 budget was more than \$7.4 billion. As of September 2024, SAMSHA employed 916 federal workers.

Implementation of the March 27 Directive against SAMHSA and its impact on Plaintiff States

288. SAMHSA lost half of its employees, including the Director of SAMHSA's Center for Mental Health Services, to the April 1 terminations. SAMHSA also lost its central offices for the Center for Mental Health Services, the Center for Substance Abuse Prevention, and many of their contract management staff. All ten of SAMHSA's regional offices were closed, along with its external engagement team, the Office of Minority Health (notwithstanding Congress's express requirement that SAMSHA establish and staff this office) and the Office of Behavioral Health Equity, among others. SAMHSA had already lost ten percent of its staff in February.

289. Defendants terminated the entire team responsible for the critical NSDUH. No plan has been announced to continue this legally mandated survey.

290. A quarter of the team assigned to work on 988 Lifeline digital communications, which work on improving awareness of the program (a required activity under 42 U.S.C. § 290bb-

36c(b)(4)), was terminated. According to one 988 Lifeline digital communications worker, the layoffs will impact awareness about the 988 Lifeline.

291. The 2026 Passback would eliminate forty-one SAMHSA programs, including Mental Health programs, Substance Abuse Prevention programs, Substance Abuse Treatment programs, and the Certified Community Behavioral Health Centers.

292. Plaintiff States have lost access to reliable and up-to-date data collected and published by a team of SAMHSA experts because they were all fired as part of the March 27 Directive. The NSDUH provided key, long-term trending data on drug use, tobacco use, alcohol use and mental health disorder prevalence and patterns in Plaintiff States. It allowed for comparison across states and jurisdictions used for coordination and planning. Cessation of NSDUH, which SAMHSA must produce by Congressional mandate, has eliminated the source of key indicators used by Plaintiff States to track trends and progress on overdose prevention, tobacco prevention, alcohol prevention, and mental and behavioral health.

293. Plaintiff States have also lost their point of contact and grant managers for dozens of grants that had been run through SAMHSA and their now-closed regional offices. Those funds were ordered spent by Congress under enacted laws and outlined in SAMHSA's Strategic Plan 2023—2026. Plaintiff States have no means of submitting inquiries or confirming the approval or distribution of grants that affect tens of millions of dollars and thousands of employees after the March 27 Directive terminated all staff in the regional offices, no grant managers remain at SAMHSA's headquarters, and HHS attempts to eliminate forty-one SAMHSA programs in the 2026 Passback.

294. Plaintiff States have lost the benefit of substance-abuse related services, including State/Tribal Opioid Response programs and staff who supported and provided communications

relating to the 988 Suicide and Crisis Lifeline; educational outreach such as the "Talk. They Hear You." campaign against underage drinking; and technical assistance and training to communities and organizations that comes from The Strategic Prevention Technical Assistance Center and Prevention Technology Transfer Center Network. These types of services are required under the Assistant Secretary's statutory obligations as well as other congressional mandates.

L. Administrative Offices

Statutory Mandates

295. ASPE, established in 1966, serves as the principal advisor to the Secretary and is responsible for policy development in health, disability, human services, data, and science. ASPE performs research and evaluation studies, develops policy analyses, and estimates the costs and benefits of policy alternatives under consideration by the HHS or Congress. It was comprised of five offices, including the Office of Human Services Policy (HSP) which performs research and analyses on issues relating to health policy for the Secretary, and its health policy research includes reports to Congress, research and issues briefs, and its authored or sponsored published work in journals. HSP serves as a liaison with other agencies on broad economic matters and is the Department's lead on poverty measurement.

296. HSP's Division of Data and Technology is responsible for the annual updates to federal poverty guidelines, which are used by federal, State, local, and Tribal agencies to assess eligibility for certain means tested programs. A 1981 appropriations act requires the Secretary to create and update annually the federal poverty guidelines. Omnibus Budget Reconciliation Act of 1981, Pub. L. 97-35, 95 Stat. 357, 42 U.S.C. § 9902(2). The Division of Data and Technology also prepared a required, annual report to Congress on indicators and predictors of "welfare dependence." Welfare Indicators Act of 1994, Pub. L. 103-432, 42 U.S.C. § 1314a(d)(1). That Act requires the report to include three programs: Temporary Assistance for Needy Families (TANF)

(which replaced the Aid to Families with Dependent Children program), the Supplemental Security Income program (SSI), and the Supplemental Nutrition Assistance Program (SNAP) (formerly the Food Stamp Program). ASPE has submitted twenty-three of these highly technical reports to Congress.

297. The Office of the Assistant Secretary of Health (OASH) was first created in 1967 following the Reorganization Plan No. 3 of 1966. The plan allowed the Secretary of Health, Education, and Welfare to restructure the PHS and was later renamed as OASH following the Department of Education Organization Act in 1972. OASH serves as the central hub for leadership and coordination within HHS and its operating divisions and is dedicated to developing policy recommendations on public health issues. Directed by the Assistant Secretary for Health, OASH oversees many smaller offices including Office of Infectious Disease and HIV/AIDS Policy (OIDP).

298. OIDP manages the National Vaccine Program (NVP), which Congress established by statute, 42 U.S.C. § 300aa-1, and which has the following mandatory duties: vaccine research; vaccine development; safety and efficacy testing of vaccines; licensing of vaccine manufacturers and vaccines; production and procurement of vaccines; distribution and use of vaccines; necessity and effectiveness of vaccines; and monitoring adverse events related to vaccines and immunization activities. 42 U.S.C. § 300aa-2. One of the initiatives under NVP is Ending the HIV Epidemic in the U.S. (EHE), which monitored the spread of new HIV infections in the U.S. and aimed to end the HIV epidemic by 2030. EHE, which was launched under the first Trump administration, provides resources, expertise, and technology to fifty-seven geographic focus areas, many of which are within Plaintiff States. Congress approved \$573 million in funding to CDC, HRSA, IHS, and NIH for Fiscal Year 2024 to support continued scale-up and implementation of EHE.

Implementation of the March 27 Directive against the Administrative Offices and its impact on Plaintiff States

299. More than two-thirds of the ASPE has been laid off under the March 27 Directive. All told, ASPE went from 140 staff members to forty. The terminations included every member of the team that, until April 1, annually updated the federal poverty guidelines and reported to Congress on indicators of welfare dependence, including its long-time leader. The fired workers had years of expertise in doing the complex work of gathering and analyzing data to arrive at the federal poverty guidelines.

300. Plaintiff States will be harmed by the layoffs to ASPE's unit that calculates federal poverty guidelines, as they rely on those guidelines being both up-to-date and accurate in the administration of federal and State benefits. Because the federal poverty guidelines are used for so many programs—from Head Start, to Medicaid, to SNAP, to the National School Lunch and Breakfast Programs, to Legal Services Corporation-funded programs—the impact of inaccurate and out-of-date guidelines would have immense effects on Plaintiffs States in the administration of State programs. For instance, Plaintiff States use the benefits to calculate individual and family eligibility for means-tested benefits programs, such as TANF and Medicaid. With inaccurate or out-of-date federal poverty guidelines, Plaintiff States risk denying benefits to eligible individuals and families or issuing benefits to ineligible individuals and families. Of course, programs such as Medicaid implicate State dollars as well as federal funding.

301. The entire staff of OIDP was terminated. At the end of 2024, OIDP employed roughly sixty people who oversaw the NVP which, in turn, included the EHE program. Also, 150 employees in the Office of HIV Prevention at the CDC and its key leaders have been reassigned to other programs, leaving one of OIDP's key partners in the EHE initiative powerless.

302. The March 27 Directive will have a similarly disastrous effect on OIDP and its effort to end the HIV/AIDS epidemic. In fact, the cuts to OIDP will not only end the consistent progress made by EHE—an initiative President Trump started in 2019—but the gains that have been made over the past six years will be lost.

M. Regional Offices

Statutory Mandates

303. As of January 2025, there were ten regional offices of HHS in Atlanta, Boston, Chicago, Dallas, Denver, Kansas City, Mo., New York, Philadelphia, San Francisco and Seattle. These regional offices are hosted by the Office of Intergovernmental and External Affairs (IEA) within the Department. The functions of the IEA include: advising HHS officials on State, local, and Tribal issues; facilitating communication between HHS and State, local, and Tribal governments; and coordinating the regional offices.

304. Each regional office has a Regional Director. The Regional Directors are subject to presidential appointment and represent the Department in maintaining close contact with State, local, and Tribal governmental officials and offices, as well as non-government organizations.

305. Moreover, several subagencies within HHS designate members of their staffs to work out of the regional offices. Each of ACF, ACL, ATSDR, CMS, FDA, HRSA, IHS, and SAMHSA maintains Regional Operating Division Offices. Certain subagencies rely more heavily on the regional offices than others; for example, the majority of Head Start employees work out of the regional offices rather than in ACF headquarters. Office of Head Start employees in the regional offices support the administration of grants, oversight, and technical assistance to Head Start grant recipients.

Implementation of the March 27 Directive against Regional Offices and its impact on Plaintiff States

306. Pursuant to the March 27 Directive, the Department closed half of the regional offices in early April, terminating all regional office staff therein. The regional offices eliminated were Boston (Region 1), New York (Region 2), Chicago (Region 5), San Francisco (Region 9), and Seattle (Region 10).

307. The impacts of the Regional Office closures were immediate, preventing the Department from carrying out a range of statutorily mandated functions. For example, as part of ACL's activities providing food assistance to senior citizens, Congress charged the regional offices of the Administration on Aging with "disseminating, and providing technical assistance . . . to State agencies, area agencies on aging, and persons that provide nutrition services." 42 U.S.C. § 3016. Without any regional staff in Regions 1, 2, 5, 9, and 10, this statutory mandate cannot be satisfied.

308. Plaintiff States rely on regional office employees for critical program support. Plaintiff States fear the abrupt closure of half of the regional offices will cause disruption in the disbursement of obligated funds and delays to—or even the suspension of—services provided to Plaintiff States and the general public by regional office staff, including monitoring, site visits, and technical assistance in a variety of programs funded by Congress and administered by HHS.

CAUSES OF ACTION

Count I Violation of the Separation of Powers Doctrine – Usurping Legislative Authority (Against All Defendants)

309. The States reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

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310. Article I, Section 1 of the United States Constitution enumerates that: "[a]ll legislative Powers herein granted shall be vested in . . . Congress." U.S. Const. Art. I, Sec. 1.

311. "The Framers viewed the legislative power as a special threat to individual liberty, so they divided that power to ensure that 'differences of opinion' and the 'jarrings of parties' would 'promote deliberation and circumspection' and 'check excesses in the majority." *Seila Law LLC*, 591 U.S. at 223 (quoting The Federalist No. 70, at 475 (A. Hamilton) and No. 51, at 350).

312. Thus "important subjects . . . must be entirely regulated by the legislature itself," even if Congress may leave the Executive 'to act under such general provisions to fill up the details." *West Virginia v. EPA*, 597 U.S. 697, 737 (2022) (Gorsuch, J., concurring) (quoting *Wayman v. Southard*, 10 Wheat. 1, 42-43, 6 L.Ed. 253 (1825)).

313. The separation of powers doctrine thus represents a central tenet of our Constitution. *See, e.g., Trump v. United States*, 603 U.S. 593, 637–38 (2024); *Seila Law LLC v. CFPB*, 591 U.S. 197, 227 (2020).

314. Consistent with these principles, the Executive's powers are limited to those specifically conferred by the Constitution and federal statutes, and do not include any undefined residual or inherent power.

315. Rather, the Executive is required to "take Care that the Laws be faithfully executed." U.S. Const. Art. II, § 3; *Utility Air Reg. Grp. v. Env't Prot. Agency*, 573 U.S. 302, 327 (2014) ("Under our system of government, Congress makes laws and the President . . . 'faithfully execute[s]' them.").

316. Here, where Congress has created the Department of Health and Human Services, the Executive and its agencies cannot incapacitate it absent Congressional action that directs them

to do so. The March 27 Directive challenged herein thus violates constitutional and statutory mandates, contravenes Congressional intent, and is unlawful.

317. This court is authorized to enjoin any action by the Executive and his agencies that "is unauthorized by statute, exceeds the scope of constitutional authority, or is pursuant to unconstitutional enactment." *Youngstown Sheet & Tube Co. v. Sawyer*, 103 F. Supp. 569, 576 (D.D.C. 1952), *aff'd*, 343 U.S. 579. Thus, Plaintiff States are further entitled to a preliminary and permanent injunction preventing Defendants from implementing the March 27 Directive.

318. Pursuant to 28 U.S.C. § 2201, the States are also entitled to a declaration that the HHS's implementation of the March 27 Directive violates the constitutional separation of powers doctrine, and impermissibly arrogates to the executive power that is reserved to Congress.

Count II Violation of the Appropriations Clause (Against All Defendants)

319. Plaintiffs incorporate by reference the allegations contained in the preceding paragraphs.

320. The Appropriations Clause of the Constitution provides in part that "[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." U.S. Const. Art. I, § 9, cl. 7. The clause "means simply that no money can be paid out of the Treasury unless it has been appropriated by an act of Congress." *Off. of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 424 (1990) (quoting *Cincinnati Soap Co. v. United States*, 301 U.S. 308, 321 (1937)).

321. The Appropriations Clause likewise requires that the executive spend appropriated funds for their designated purpose. *See City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1235 (9th Cir. 2018) ("Absent congressional authorization, the Administration may not redistribute or withhold properly appropriated funds in order to effectuate its own policy goals."); *In re Aiken*

Cnty., 725 F.3d 255, 261 n.1 (D.C. Cir. 2013) ("[A] President sometimes has policy reasons . . . for wanting to spend less than the full amount appropriated by Congress for a particular project or program. But in those circumstances, even the President does not have unilateral authority to refuse to spend the funds.") (Kavanaugh, J.).

322. Here, Congress has expressly directed that funds be expended for the operations of the agency that it has created. Defendants' unilateral executive action to decline to expend appropriated funds therefore infringes on Congress's appropriations power and is unconstitutional. Among the funds that Defendants have declined to expend are those that Congress appropriated: to CDC to research occupational safety for miners and maritime workers and to screen for health problems in high risk occupations; to CDC to collect data about the health and well-being of pregnant people and infants; to CDC and FDA for supporting State-led tobacco control efforts; to CDC to research viral Hepatitis, HIV/AIDS, and STIs; to FDA to conduct mandated enforcement, research, and compliance efforts relating to tobacco; and to SAMHSA to support communications around 988 Lifeline.

323. This court is authorized to enjoin any action by the Executive and its agencies that "is unauthorized by statute, exceeds the scope of constitutional authority, or is pursuant to unconstitutional enactment." *Youngstown Sheet & Tube Co. v. Sawyer*, 103 F. Supp. 569 (D.D.C. 1952), *aff'd*, 343 U.S. 579 (1952). Thus, Plaintiff States are further entitled to a preliminary and permanent injunction preventing Defendants from implementing the March 27 Directive.

324. Pursuant to 28 U.S.C. § 2201, the States are also entitled to a declaration that the March 27 Directive violated the Appropriations Clause.

Count III *Ultra Vires* – Conduct Outside the Scope of Statutory Authority Conferred on the Executive (Against All Defendants)

91

325. The States reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

326. Neither the President nor an agency can take any action that exceeds the scope of their constitutional and/or statutory authority.

327. Federal courts possess the power in equity to grant injunctive relief "with respect to violations of federal law by federal officials." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326–27 (2015). Indeed, the Supreme Court has repeatedly allowed equitable relief against federal officials who act "beyond th[e] limitations" imposed by federal statute. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

328. Defendants' conduct in dismantling HHS and many of its constituent agencies is contrary to law and outside of Defendants' authority. Defendants laid off so many employees, that they functionally closed departments that who worked on statutorily mandated programs across agencies, whether in labs detecting viral Hepatitis, or in departments supporting tobacco control efforts, or in studying lead poisoning.

329. Pursuant to 28 U.S.C. § 2201, Plaintiff States are entitled to a declaration that the March 27 Directive is contrary to law and outside of Defendants' authority.

330. Plaintiff States are further entitled to a preliminary and permanent injunction preventing Agency Defendants from implementing the March 27 Directive.

Count IV Violation of the Administrative Procedure Act – Contrary to Law (Against All Defendants)

92

331. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

332. Agency Defendants are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

333. Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . contrary to constitutional right, power, privilege, or immunity," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(B)–(C).

334. Congress enacted the APA "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 391 (2024) (quoting *U.S. v. Morton Salt*, 338 U.S. 632, 644 (1950)). In *Loper Bright*, the Supreme Court clarified that historical principles of "respect" did not equate to deference, and that "Section 706 makes clear that agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference." *Id.* at 392 (emphasis in original). Rather, it "remains the responsibility of the court to decide whether the law means what the agency says." *Id.* (quoting *Perez v. Mortg. Bankers Ass 'n*, 575 U.S. 92, 109 (2015) (Scalia, J., concurring in judgment)).

335. An agency may not take any action that exceeds the scope of its constitutional or statutory authority.

336. No constitutional or statutory authority authorizes HHS to refrain from fulfilling its statutory duties, or to violate federal law.

337. No constitutional or statutory authority permits HHS to refuse to spend money Congress has appropriated for HHS and its various functions.

338. An agency likewise may not violate its own regulations. When a federal agency promulgates "[r]egulations with the force and effect of law," those regulations "supplement the bare bones" of federal statutes. *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260, 265 (1954). "It is an abecedarian principle of administrative law that agencies must comply with their own regulations." *Manguriu v. Lynch*, 794 F.3d 119, 122 (1st Cir. 2015) (citation omitted). An agency's action may be set aside pursuant to the APA if the action violates the agency's own procedures, particularly if that error prejudices the interest of a person before the agency. *See Wilson v. Comm'r of Soc. Sec.*, 378 F.3d 541, 545 (6th Cir. 2004); *see also Town of Weymouth, Mass. v. Mass. Dep't of Env't Prot.*, 961 F.3d 34, 47 (1st Cir. 2020), *on reh'g*, 973 F.3d 143 (1st Cir. 2020) ("[A]n agency action may be set aside as arbitrary and capricious if the agency fails to 'comply with its own regulations.'" (quoting *Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014)).

339. Defendants lack authority to reorganize departments and administrations in direct contravention of statutory authority that created the departments and administrations in the first place. The Agency Defendants lack authority to use layoffs to override the limitations on their own power to dismantle statutorily mandated agency functions. These agency actions are unauthorized, unprecedented, and not entitled to deference by this Court.

340. The March 27 Directive was a final agency action, because it marked "the consummation" of agency decision making and determined "rights or obligations . . . from which legal consequences" flowed. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citations omitted).

341. In implementing the March 27 Directive, the Agency Defendants have acted contrary to the statutes and regulations governing the administration of Department functions and appropriating money for it to administer.

342. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiff States are entitled to a declaration that the Agency Defendants lack legal authority to implement the March 27 Directive, contrary to congressional directive and intent, and have, in so doing, acted contrary to law, outside of statutory authority, and in violation of the APA.

343. Plaintiff States are also entitled to vacatur of the March 27 Directive, and a preliminary and permanent injunction preventing the Agency Defendants from implementing the March 27 Directive.

Count V Violation of the Administrative Procedure Act – Arbitrary & Capricious (Against All Defendants)

344. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

345. Defendants include "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

346. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

347. An agency action is arbitrary or capricious where it is not "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). An agency must provide "a satisfactory explanation for its action[,] including a rational connection between

the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

348. That "reasoned explanation requirement of administrative law . . . is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public." *Dep't of Commerce v. New York*, 588 U.S. 752, 785 (2019). Agencies may not rely on explanations that are "contrived" or "incongruent with what the record reveals about the agency's priorities and decision making process." *Id.*

349. An action is also arbitrary and capricious if the agency failed to consider . . . important aspects of the problem before it. *Dep't of Homeland Sec. v. Regents of the Univ. of Calif.*, 591 U.S. 1, 25 (2020) (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43).

350. In addition, when an agency "rescinds a prior policy," the agency must, at minimum, "consider the 'alternatives' that are within the ambit of the existing policy," "assess whether there were reliance interests," and "weigh any such interests against competing policy concerns." *Dep't of Homeland Sec. v. Regents*, 591 U.S. 1, 30, 33 (2020).

351. The March 27 Directive is arbitrary and capricious because the Defendants provided no reasoned basis or explanation for its decision to dismantle agencies performing essential public health and human services work.

352. The March 27 Directive is arbitrary and capricious because the Agency Defendants failed to consider the consequences of their actions.

353. The March 27 Directive is arbitrary and capricious because the Department's stated reasons for the layoffs and reorganization—to promote "efficiency" and "accountability"—are pretext for Secretary Kennedy's stated goal of attacking science and public health.

354. The March 27 Directive is arbitrary and capricious because the Agency Defendants' actions impede their ability to perform the Department's functions, both those that are required by statute and those that are not.

355. The March 27 Directive is arbitrary and capricious because it fails to take into account important reliance interests.

356. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiff States are entitled to a declaration that the Agency Defendants' actions implementing the March 27 Directive violate the APA because they are arbitrary and capricious.

357. Plaintiff States are also entitled to vacatur of the Agency Defendants' implementation of the March 27 Directive pursuant to 5 U.S.C. § 706, and a preliminary and permanent injunction preventing Agency Defendants from implementing the March 27 Directive.

358. Under the APA, a court must "hold unlawful and set aside agency action, findings, and conclusions found to be . . . contrary to constitutional right, power, privilege, or immunity," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(B)–(C).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff States pray that this Court:

- Issue a judicial declaration that the March 27 Directive (as defined above to include the RIF and reorganization), is unlawful because it violates the United States Constitution and the Administrative Procedure Act;
- ii. Pursuant to 5 U.S.C. § 705, stay the March 27 Directive;
- iii. Pursuant to 5 U.S.C. § 706, vacate the March 27 Directive;

- iv. Preliminarily and permanently enjoin Defendants from implementing the March 27 Directive;
- v. Award the Plaintiff States their reasonable fees, costs, and expenses, including attorneys' fees, pursuant to 28 U.S.C. § 2412; and

vi. Grant other such relief as this Court may deem proper.

Dated: May 5, 2025

Respectfully submitted,

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EXHIBIT 1

27/03/2025.ace 1:25-cv-00196-MRD-PASiHs ADaguariantian to Filed Develop Aga Rages of 5 PageID #: 103

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202-690-6343 Submit a Request for Comment <https://hhscewp.my.site.com/aspapublic/s for-comment>

HHS Announces Transformation to Make America Healthy Again

Washington, D.C. — March 27, 2025 — Today, the U.S. Department of Health and Human Services (HHS) announced a dramatic restructuring in accordance with President Trump's Executive Order, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative."

The restructuring will address this and serve multiple goals without impacting critical services. First, it will 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. When combined with HHS' other efforts, including early retirement and Fork in the Road, the restructuring results in a total downsizing from 82,000 to 62,000 full-time employees.

Secondly, it will streamline the functions of the Department. Currently, the 28 divisions of the HHS contain many redundant units. The restructuring plan will consolidate them into 15 new divisions, including a new Administration for a Healthy America, or AHA, and will centralize

core functions such as Human Resources, Information Technology, Procurement, External Affairs, and Policy. Regional offices will be reduced from 10 to 5.

Third, the overhaul will implement the new HHS priority of ending America's epidemic of chronic illness by focusing on safe, wholesome food, clean water, and the elimination of environmental toxins. These priorities will be reflected in the reorganization of HHS.

Finally, the restructuring will improve Americans' experience with HHS by making the agency more responsive and efficient, while ensuring that Medicare, Medicaid, and other essential health services remain intact.

"We aren't just reducing bureaucratic sprawl. We are realigning the organization with its core mission and our new priorities in reversing the chronic disease epidemic," HHS Secretary Robert F. Kennedy, Jr. said. "This Department will do more – a lot more – at a lower cost to the taxpayer."

The specific contents of the restructuring plan that have been announced so far are as follows:

- Creation of the Administration for a Healthy America (AHA), which will combine multiple agencies the Office of the Assistant Secretary for Health (OASH), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Toxic Substances and Disease Registry (ATSDR), and National Institute for Occupational Safety and Health (NIOSH) into a new, unified entity. This centralization will improve coordination of health resources for low-income Americans and will focus on areas including, Primary Care, Maternal and Child Health, Mental Health, Environmental Health, HIV/AIDS, and Workforce development. Transferring SAMHSA to AHA will increase operational efficiency and assure programs are carried out because it will break down artificial divisions between similar programs.
- Strengthening the Centers for Disease Control and Prevention (CDC): the Administration for Strategic Preparedness and Response (ASPR), responsible for national disaster and public health emergency response, will transfer to the CDC, reinforcing its core mission to protect Americans from health threats.
- New Assistant Secretary for Enforcement: HHS will create a new Assistant Secretary for Enforcement to oversee the Departmental Appeals Board (DAB), Office of Medicare Hearings and Appeals (OMHA), and Office for Civil Rights (OCR) to combat waste, fraud, and abuse in federal health programs.
- Research and Evaluation for Health Policy: HHS will merge the Assistant Secretary for Planning and Evaluation (ASPE) with the Agency for Healthcare Research and Quality (AHRQ) to create the Office of Strategy to enhance research that informs the Secretary's policies and improves the effectiveness of federal health programs.

• Reorganization of the Administration for Community Living (ACL): Critical programs that support older adults and people with disabilities will be integrated into other HHS agencies, including the Administration for Children and Families (ACF), ASPE, and the Centers for Medicare and Medicaid Services (CMS). This reorganization will not impact Medicare and Medicaid services.

"Over time, bureaucracies like HHS become wasteful and inefficient even when most of their staff are dedicated and competent civil servants," Secretary Kennedy said. "This overhaul will be a win-win for taxpayers and for those that HHS serves. That's the entire American public, because our goal is to Make America Healthy Again."

For more detailed information, please visit our fact sheet </about/news/hhs-restructuring-doge-factsheet.html>.

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Note: All HHS press releases, fact sheets and other news materials are available at https://www.hhs.gov/about/news/index.html </about/news/index.html>. Like HHS on Facebook, follow HHS on X @HHSgov <https://x.com/hhsgov>, @SecKennedy <https://x.com/seckennedy>, and sign up for HHS Email Updates <https://cloud.connect.hhs.gov/subscriptioncenter>. Last revised: March 27, 2025

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MARCH 18, 2025 | PRESS RELEASE

Content created by ASPA Press Office Content last reviewed March 27, 2025

EXHIBIT 2

Document 1-2 108

Fact Sheet: HHS' Transformation to Make America **Healthy Again**

hhs.gov/about/news/hhs-restructuring-doge-fact-sheet.html

March 27, 2025



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The restructuring of HHS is proceeding in accordance with President Trump's Executive Order, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative." Over the past four years, during the Biden administration, HHS's budget increased by 38% and its staffing increased by 17%.

- 1. The plan combines personnel cuts, centralization of functions, and consolidation of HHS divisions, including:
 - The current 82,000 full-time employees will be reduced to 62,000
 - 28 divisions will be consolidated to 15
 - 10 regional offices will become 5
 - Human Resources, Information Technology, Procurement, External Affairs, and Policy will be centralized.

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- 2. Regarding FDA, CDC, NIH, and CMS:
 - FDA will decrease its workforce by approximately 3,500 full-time employees, with a focus on streamlining operations and centralizing administrative functions. This reduction will not affect drug, medical device, or food reviewers, nor will it impact inspectors.
 - The CDC will decrease its workforce by approximately 2,400 employees, with a focus on returning to its core mission of preparing for and responding to epidemics and outbreaks. This includes moving ASPR under CDC to enhance coordination of response efforts. NOTE: The "CDC" decrease would only be 1,400 if you included the individuals coming over from ASPR (approx. 1,000 individuals).
 - The NIH will decrease its workforce by approximately 1,200 employees by centralizing procurement, human resources, and communications across its 27 institutes and centers.
 - CMS will decrease its workforce by approximately 300 employees, with a focus on reducing minor duplication across the agency. This reorganization will not impact Medicare and Medicaid services.
- 3. The consolidation and cuts are designed not only to save money, but to make the organization more efficient and more responsive to Americans' needs, and to implement the Make America Healthy Again goal of ending the chronic disease epidemic.
- 4. No additional cuts are currently planned, but the Department will continue to look for further ways to streamline its operations and agencies.
- 5. A new Administration for a Healthy America (AHA) will consolidate the OASH, HRSA, SAMHSA, ATSDR, and NIOSH, so as to more efficiently coordinate chronic care and disease prevention programs and harmonize health resources to low-income Americans. Divisions of AHA include Primary Care, Maternal and Child Health, Mental Health, Environmental Health, HIV/AIDS, and Workforce, with support of the U.S. Surgeon General and Policy team.
- 6. HHS will have a new Assistant Secretary for Enforcement to provide oversight of the Departmental Appeals Board (DAB), Office of Medicare Hearings and Appeal (OMHA), and the Office for Civil Rights (OCR) to combat waste, fraud, and abuse.
- 7. HHS will combine the Assistant Secretary for Planning and Evaluation (ASPE) and Agency for Healthcare Research and Quality (AHRQ) into the Office of Strategy to conduct research that informs the Secretary's policies and evaluates the effectiveness of the Department's programs for a healthier America.
- 8. The critical programs within the Administration for Community Living (ACL) that support older adults and people of all ages with disabilities will be split across the Administration for Children and Families (ACF), Assistant Secretary for Planning and Evaluation (ASPE), and Centers for Medicare and Medicaid Services (CMS).

Content created by Assistant Secretary for Public Affairs (ASPA) Content last reviewed March 27, 2025

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For more information on HHS's web notification policies, see Website Disclaimers.

EXHIBIT 3

Glossary of Acronyms

Acronym	Term						
ACF	Administration for Children and Families						
ACL	Administration for Community Living						
АНА	Administration for a Healthy America (a new operating agency within HHS)						
AHRQ	Agency for Health Care Research and Quality (an operating division within HHS)						
ASPE	Office of the Assistant Secretary for Planning and Evaluation (an administrative office)						
ASPR	Administration for Strategic Preparedness and Response						
ATSDR	Agency for Toxic Substances and Disease Registry						
CBER	Center for Biologics Evaluation and Research (sits within FDA)						
CDC	Centers for Disease Control and Prevention						
CDER	Center for Drug Evaluation and Research (sits within FDA)						
CMS	Centers for Medicare & Medicaid Services						
СТР	Center for Tobacco Products (sits within FDA)						
CVM	Center for Veterinary Medicine (sits within FDA)						

Acronym	Term					
CWHSP	Coal Workers' Health Surveillance Program (a program administered by NIOSH)					
DEHSP	Division of Environmental Health Science and Practice (sits within NCEH)					
DHP	Division of HIV Prevention (sits within CDC)					
DRH	Division of Reproductive Health (sits within NCCDPHP)					
DSTDP	Division of Sexually Transmitted Disease Prevention (sits within NCHHSTP)					
DVH	Division of Viral Hepatitis (sits within NCHHSTP)					
EHDI	Early Hearing Detection and Intervention Programs (a program administered by NCBDDD)					
ЕНЕ	Ending the HIV/AIDS Epidemic (a program administered by OIDP)					
ERC	Education and Resource Centers (a program administered by NIOSH)					
FDA	Food and Drug Administration					
FFFIPP	Fire Fighter Fatality Investigation and Prevention Program (a program administered by NIOSH)					
GHC	Global Health Center (sits within CDC)					
HEW	Department of Health, Education, and Welfare (a former cabinet-level agency created by Congress in 1953)					
HHE	Health Hazard Evaluation (a program administered by NIOSH)					

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Acronym	Term						
ння	Department of Health and Human Services						
HRSA	Health Resources and Services Administration						
HSP	Office of Human Services Policy (an administrative office)						
IHS	Indian Health Service						
LIHEAP	Low-Income Home Energy Assistance Program (a program administered by ACF)						
MMRC	Maternal Mortality Review Committee (multidisciplinary committees formed at the state or local level to review pregnancy-related deaths, a program administered by DRH)						
MSHA	Mine Health Safety Administration (sits within Department of Labor)						
NCBDDD	National Center on Birth Defects and Developmental Disabilities (sits within CDC)						
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion (sits within CDC)						
NCEH	National Center for Environmental Health (sits within CDC)						
NCHHSTP	National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (sits within CDC)						
NCIPC	National Center for Injury Prevention and Control (sits within CDC)						
NIH	National Institutes of Health (an operating division within HHS)						

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Acronym	Term					
NIOSH	National Institute for Occupational Safety and Health (sits within CDC)					
NORA	National Occupational Research Agenda (a program administered by NIOSH)					
NPPTL	National Personal Protective Technology Laboratory (a program administered by NIOSH)					
NSDUH	National Survey on Drug Use and Health (a program administered by SAMHSA)					
NTCP	National and State Tobacco Control Program (a program administered by OSH)					
NVP	National Vaccine Program (a program administered by OIDP)					
NYTS	National Youth Tobacco Survey (a program administered within OSH)					
OASH	Office of the Assistant Secretary for Health (an administrative office)					
OIDP	Office of Infectious Disease and HIV/AIDS Policy (an administrative office)					
ОМНА	Office of Medicare Hearings and Appeals (an administrative office)					
оѕн	Office of Smoking and Health (sits within NCCDPHP)					
PHS	Public Health Service (led by the Surgeon General)					
PRAMS	Pregnancy Risk Assessment Monitoring System (a program administered by DRH)					
PRNS	Mental Health Programs of Regional and National Significance					

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Acronym	Term
SAMHSA	Substance Abuse and Mental Health Services Administration (an operating division within HHS)
SCBA	Self-Contained Breathing Apparatus
SPHL	State Public Health Laboratory
TANF	Temporary Assistance for Needy Families (a program administered by ACF)
WTCHP	World Trade Center Health Program (a program administered NIOSH)

JS 44 (Rev. 03 2 ase 1:25-cv-00196-MRD-PASCIV DCV 00 2 ER SHEED 05/05/25 Page 1 of 2 PageID #:

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118 INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box. Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment

to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)

- **III.** Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: <u>Nature of Suit Code Descriptions</u>.
- V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction. Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.