UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DOCTORS FOR AMERICA, PO Box 21161 2300 18th Street NW Lobby Washington, DC 20009,	
Plaintiff,	
V.	
OFFICE OF PERSONNEL MANAGEMENT, 1900 E Street NW Washington, DC 20415,	Civil Action No. 25-322
CENTERS FOR DISEASE CONTROL AND PREVENTION, 1600 Clifton Road Atlanta, GA 30329,	
FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993,	
and	
DEPARTMENT OF HEALTH & HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201,	
Defendants.	

COMPLAINT

1. On January 31, 2025, Defendants Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), agencies within defendant Department of Health and Human Services (HHS), removed from publicly

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accessible websites a broad range of health-related data and other information used every day by health professionals to diagnose and treat patients and by researchers to advance public health, including through clinical trials meant to establish the safety and efficacy of medical products.

2. Prior to the sudden, unannounced removal, these Defendants had maintained these or similar webpages and datasets on their websites for years. The removal of the webpages and datasets creates a dangerous gap in the scientific data available to monitor and respond to disease outbreaks, deprives physicians of resources that guide clinical practice, and takes away key resources for communicating and engaging with patients. The removal of this information deprives researchers of access to information that is necessary for treating patients, for developing clinical studies that produce results that accurately reflect the effects treatments will have in clinical practice, and for developing practices and policies that protect the health of vulnerable populations and the country as a whole.

3. This action is brought to challenge (1) the action of Defendant Office of Personnel Management (OPM) directing agencies to remove or modify webpages and datasets; and (2) the removal by CDC, FDA, and HHS of webpages and datasets. Defendants failed to provide required notice of their action to remove these vitally important webpages and datasets, and their actions are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. *See* 5 U.S.C. § 706(2). Defendants failed to provide any rationale for removing any specific webpage or dataset, and any such justification would fly in the face of the longstanding recognition that the webpages and datasets are essential to the government's goal of promoting public health.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, namely, the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. §§ 3501 *et seq.*, and the Administrative Procedure Act (APA), 5 U.S.C. §§ 702, 706.

5. Venue is proper in this judicial district under 28 U.S.C. § 1391(e)(1) because defendants are agencies of the United States.

PARTIES

6. Plaintiff Doctors for America (DFA) is a nonpartisan, not-for-profit, 501(c)(3) organization of over 27,000 physicians and medical trainees including medical residents and students in all 50 states, representing all medical specialties. DFA mobilizes doctors, other health professionals, and medical trainees to be leaders who put patients over politics to improve the health of patients, communities, and the nation. DFA's work focuses on access to affordable care, community health and prevention, and health justice and equity. DFA focuses on what is best for patients and does not accept any funding from pharmaceutical or medical device companies. Members that comprise DFA include clinicians who provide direct care to patients, those who provide education to other clinicians and trainees, and those who conduct clinical and public health research. 7. Defendant OPM is a federal agency within the meaning of the PRA, 44 U.S.C. § 3502(1), and the APA, 5 U.S.C. § 551(1), that is headquartered in Washington, D.C.

8. Defendant CDC is a federal agency within the meaning of the PRA, 44 U.S.C. § 3502(1), and the APA, 5 U.S.C. § 551(1), that is headquartered in Atlanta, GA. CDC's mission is "to protect America from health, safety and security threats, both foreign and in the U.S."¹

9. Defendant FDA is a federal agency within the meaning of the PRA, 44 U.S.C. § 3502(1), and the APA, 5 U.S.C. § 551(1), that is headquartered in Silver Spring, MD. FDA's mission is to "protect]] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices" and to "advance[e] the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."²

10. Defendant HHS is a federal agency within the meaning of the PRA, 44 U.S.C. § 3502(1), and the APA, 5 U.S.C. § 551(1), that is headquartered in Washington, D.C. HHS's mission "is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering

¹ https://www.cdc.gov/about/cdc/index.html.

² https://www.fda.gov/about-fda/what-we-do.

sound, sustained advances in the sciences underlying medicine, public health, and social services."³

STATUTORY FRAMEWORK

11. Congress enacted the PRA to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government" and "provide for the dissemination of public information on a timely basis, on equitable terms, and in a manner that promotes the utility of the information to the public and makes effective use of information technology." 44 U.S.C. §§ 3501(2), (7).

12. To accomplish those goals, the PRA mandates that every agency must "ensure that the public has timely and equitable access to the agency's public information" and must "regularly solicit and consider public input on the agency's information dissemination activities." 44 U.S.C. §§ 3506(d)(1), (2). The PRA further mandates that agencies must "provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products." *Id.* § 3506(d)(3).

13. Agencies, including HHS, have promulgated guidance making clear that the term "information dissemination product" includes "any electronic document ... or web page" that an agency disseminates to the public.⁴

³ https://www.hhs.gov/about/index.html.

 $^{^4\,\}rm https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information.$

FACTS

Executive Order 14168 and OPM's memorandum

14. On January 20, 2025, President Donald Trump issued Executive Order 14168, titled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."⁵ The Order directed agencies to combat what the President described as "gender ideology," including by requiring agencies to "use the term 'sex' and not 'gender' in all applicable Federal policies and documents."

15. On January 29, 2025, Charles Ezell, the Acting Director of OPM, issued a memorandum titled "Initial Guidance Regarding President Trump's Executive Order *Defending Women*."⁶ The memorandum required that "[n]o later than 5:00 p.m. EST on Friday, January 31, 2025," agency heads must, among other things, "terminate any [agency programs] that promote or inculcate gender ideology" and "[t]ake down all outward facing media (websites, social media accounts, etc.) that inculcate or promote gender ideology."

16. When it issued its memorandum, OPM asserted that it possessed authority to require agencies to act based on 5 U.S.C. §§ 1103(a)(1), (5). Those provisions vest in the Director of OPM authority for "securing accuracy, uniformity, and justice in the functions of [OPM]," *id.* § 1103(a)(1), and "executing, administering, and enforcing—(A) the civil service rules and regulations of the President and the

⁵ https://www.whitehouse.gov/presidential-actions/2025/01/defending-womenfrom-gender-ideology-extremism-and-restoring-biological-truth-to-the-federalgovernment/.

⁶ https://www.opm.gov/media/yvlh1r3i/opm-memo-initial-guidance-regarding-trump-executive-order-defending-women-1-29-2025-final.pdf.

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Office and the laws governing the civil service; and (B) the other activities of the Office including retirement and classification activities; except with respect to functions for which the Merit Systems Protection Board or the Special Counsel is primarily responsible," *id.* § 1103(a)(5).

Removal of data and webpages

17. In response to OPM's memorandum, agencies have removed numerous webpages and databases related to medical treatment and public health.

18. CDC has removed numerous webpages and datasets that served as resources to clinicians, researchers, and the general public. Among those recently removed from CDC's website are:

a. Webpages for "The Youth Risk Behavioral Surveillance System." CDC has explained that this resource "identifies emerging issues, and plans and evaluates programs to support youth health" and "gives the best picture of what is going on at national, state, and local levels." CDC has also stated that information is "used by health departments, educators, lawmakers, doctors, and community organizations to inform school and community programs, communications campaigns, and other efforts." Information from these webpages is important for understanding the mental health challenges that youth face, including bullying and other safety issues at school, as well as the health-related behaviors and exposures such as electronic vaping and cigarettes and their potential effect on mortality and disability in youth. CDC maintained the webpages since at least 1999. The front page as of January 23, 2025, is archived at https://web.archive.org/web/20250123183607/ https:/www.cdc.gov/yrbs/.

b. Webpages on "Data and Statistics" for "Adolescent and School Health." The webpages provided information and datasets collected by CDC's Division on Adolescent and School Health (DASH) on youth school health policies and practices. The front page as of December 20, 2024, which had listed multiple national datasets including the Youth Risk Behavior Surveillance System, School Health Profiles, and Adolescent Behaviors and Experiences Survey, is archived at https://web.archive.org/web/20241220225258/https://www.cdc.gov/healthyyouth/data-statistics/index.html.

Webpages for "The Social Vulnerability Index." The webpages c. provided information and datasets that "help public health officials and local planners better prepare for and respond to emergency events with the goal of decreasing human suffering, economic loss, and health inequities." The information has helped identify communities with barriers to maternal healthcare, enabling targeted, cost-effective solutions like expanding access to prenatal services and improving health outcomes for mothers and families. CDC maintained the webpages since at least 2020. The front page as of January 21,2025,is archived https://web.archive.org/web/ at 20250121005832/https:/atsdr.cdc.gov/place-health/php/svi/index.html.

d. Webpages for "The Environmental Justice Index." The webpages provided information that "delivers a single rank for each community to identify and map areas most at risk for the health impacts of environmental burden." This information has been used to identify communities at elevated risk from natural disasters so that first responders can be better prepared to save lives in emergencies. The front page as of January 21, 2025, is archived at https://web.archive.org/web/20250121013828/https://www.atsdr.cdc.gov/ place-health/php/eji/index.html.

e. A report on "PrEP for the Prevention of HIV Infection in the U.S.: 2021 Guideline Summary." The webpage provided "health care providers the latest information on prescribing pre-exposure prophylaxis (PrEP) for HIV prevention to their patients and increasing PrEP use by people who could benefit from it." The webpage as of January 19, 2025, is archived at https://web.archive.org/web/20250119145832/https://www.cdc.gov/hivnexus/m edia/pdfs/2024/04/cdc-hiv-together-brochure-prepguidelineupdate2021provider.pdf.

f. Webpages for "HIV Monitoring." The webpages provided information and datasets that CDC gathered from public health labs, healthcare systems, and population surveys in order to better understand the distribution of HIV among different populations and communities. The front page as of January 23, 2025, is archived at https://web.archive.org/web/20250123181509/https://www.cdc.gov/hiv-data/.

Among the HIV Monitoring pages that CDC removed are those about the National HIV Behavioral Surveillance program, which is a cross-sectional survey collecting data on risk behaviors, testing behaviors, and prevention to help guide research and local public health efforts to reduce HIV transmission. The front page for the National HIV Behavioral Surveillance program as of January 23, 2025, is archived at https://web.archive.org/web/20250123024336/ https://www.cdc.gov/hiv-data/nhss/index.html.

g. A webpage on "Getting Tested for HIV." The page explained why individuals should get tested for HIV, how they can get tested, and what test results mean. The page was a key source of information for patients and an important communication tool for physicians. The webpage as of January 24, 2025, is archived at https://web.archive.org/web/20250124144310/https:// www.cdc.gov/hiv/testing/index.html.

h. Webpages on "National ART Surveillance System (NASS)." The webpages provided information and datasets from CDC's National ART (Assisted Reproductive Technologies) Surveillance System, which since 1996 has collected data on ART procedures from fertility clinics across the country as mandated by the Fertility Clinic Success Rate and Certification Act of 1992. The pages were a key source of information for patients and an important communication tool for physicians, providing them with datasets that have been used to shape guidelines around ART and information regarding longterm health outcomes. The front page as of January 17, 2025, is archived at https://web.archive.org/web/20250117223212/https://artreporting.

cdc.gov/Default.aspx.

i. A webpage for "CDC Contraceptive Guidance for Health Care Providers." The webpage served "to remove unnecessary medical barriers to accessing and using contraception and to support providing person-centered contraceptive counseling and services in a noncoercive manner." The webpage as of December 21, 2024, is archived at https://web.archive.org/web/20241221054405/https://www.cdc.gov/contracepti on/hcp/contraceptive-guidance/index.html.

19. FDA has removed several pages that provided important guidance for researchers who develop clinical trials. Among those recently removed from FDA's website are:

A webpage on "Study of Sex Differences in the Clinical Evaluation a. of Medical Products." The page provided "recommendations for increasing enrollment of females in clinical trials, analyzing and interpreting sex-specific data, and including sex-specific information in regulatory submissions of medical products" in order "to help ensure the generalizability of results and facilitate exploration of potential differences in effects by sex." The webpage as of January 14, is archived 2025, \mathbf{at} https://web.archive.org/web/20250114151146/https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/study-sex-differences-clinicalevaluation-medical-products.

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b. A webpage on "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies." The page provided information on regulatory requirements for novel drugs and devices intended to improve enrollment of underrepresented populations across age, sex, and race and ethnicity in clinical studies in order to ensure the accuracy and reliability of results across demographic groups. The webpage as of 2025,January 25, \mathbf{is} archived at https://web.archive.org/web/20250125170756/https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/diversity-action-plans-improveenrollment-participants-underrepresented-populations-clinical-studies.

20. CDC, FDA, and HHS did not provide any notice that these webpages and datasets would be removed and no longer publicly accessible.

21. After CDC removed information from its website, it posted statements on remaining portions of its website that "CDC's website is being modified to comply with President Trump's Executive Orders." Defendants have provided no other justification for removal of the webpages and datasets.

22. The decisions by CDC, FDA, and HHS to remove the webpages and datasets contradict their stated missions and are causing and will cause substantial harm to Plaintiff and its members, as well as other physicians, researchers, and patients who rely on the removed webpages and datasets.

23. DFA and the physicians and medical trainees that constitute its membership rely on webpages and datasets that have been removed in response to

OPM's memorandum, including several pages that related to current evidence and guidelines for providing clinical care, guidance documents on FDA's website that guide clinician-investigators in conducting clinical trials that provide accurate information about the efficacy and safety of treatments and products across all populations, and numerous publicly available datasets that inform targeted public health interventions.

24. For example, DFA members had relied daily on CDC webpages with guidelines on "PrEP for the Prevention of HIV Infection in the U.S." and "U.S. Medical Eligibility Criteria for Contraceptive Use." DFA members used those webpages, and other removed pages, to guide how they treat patients, particularly patients with other medical conditions that must be taken into account to safely recommend and prescribe treatment options.

25. DFA members also routinely utilized CDC's guidelines related to the testing and treatment of human immunodeficiency virus (HIV), including materials created specifically to help clinicians integrate routine screening of HIV and testing among adolescents into clinical practice. Without access to these clinical guidance pages, DFA's members have had to seek out other resources to guide the diagnosis and treatment of their patients.

26. Moreover, many members of DFA are engaged in clinical and public health research. DFA and its members have used publicly available datasets from the CDC and HHS websites to conduct groundbreaking research on infectious

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disease, factors associated with pediatric health, and structural determinants of health to inform local, state, and federal policy efforts.

27. For example, clinical research utilizing the Social Vulnerability Index (SVI) during the COVID-19 pandemic provided states with critical information on which locations and which populations were at higher risk from the impact of the pandemic and where further resources would likely be needed as part of response efforts.

28. Without access to the data CDC has removed, this type of critical research will be far more difficult, if not impossible.

29. For those physicians and trainees who design and run clinical trials on medical products, FDA webpages provide critical information around best practices in conducting their studies.

30. DFA members have relied on FDA webpages, including those on "Study of Sex Differences in the Clinical Evaluation of Medical Products" and "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies," to design and carry out clinical trials.

31. Without the guidance provided by those webpages, the studies that researchers, including DFA members, seek to develop are at greater risk of failing to elicit accurate information regarding the efficacy and safety of medical products across the full range of populations that would be prescribed or administered the treatment once authorized by FDA.

COUNT I (Against OPM)

32. The APA empowers this Court to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or taken "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

33. OPM has received no delegation of authority, whether by statute or otherwise, to require removal of webpages or datasets by other agencies.

34. The statute that OPM identified as the source of its authority, 5 U.S.C.§§ 1103(a)(1), (5), does not authorize or delegate lawful authority for OPM's actions.

35. Because no statute authorizes OPM to require other agencies to remove webpages or datasets, OPM's memorandum exceeds its statutory authority.

36. By issuing its memorandum without statutory authority, OPM acted in excess of statutory authority, and took agency action that was not in accordance with law.

COUNT II (Against CDC and HHS)

37. The APA empowers this Court to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or taken "without observance of procedure required by law," *id.* § 706(2)(D).

38. The webpages and datasets that CDC, an agency within HHS, removed are significant information dissemination products. *See* 44 U.S.C. § 3506(d)(3).

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39. Because it provided no advance public notice before removing the webpages and datasets, CDC failed to comply with the PRA requirement that an agency must "provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products." *Id*.

40. Because it removed webpages and datasets that convey information it still possesses, CDC failed to comply with the PRA requirement that an agency "ensure that the public has timely and equitable access to the agency's public information." *Id.*

41. By removing the webpages and datasets in violation of the PRA, CDC and HHS failed to observe procedures required by law, or took agency action that was arbitrary, capricious, an abuse of discretion, or not in accordance with the PRA, in contravention of the APA.

COUNT III (Against FDA and HHS)

42. The APA empowers this Court to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

43. By removing the webpages that contain important information about clinical trials that is vital to medical professionals, FDA, an agency within HHS, took agency action that was arbitrary, capricious, an abuse of discretion, or not in accordance with law, in contravention of the APA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

- (1) Declare that OPM's memorandum exceeds the authority granted to it by law;
- (2) Declare that CDC and HHS have violated the PRA and APA;
- (3) Declare that FDA and HHS have violated the APA;
- (4) Order CDC and HHS to restore webpages and datasets that were removed in violation of the PRA;
- (5) Order CDC and HHS to comply with their duties under the PRA, including the duty to provide adequate notice before removing or substantially modifying other webpages or datasets related to public health and medicine and the duty to ensure timely and equitable public access to the agencies' public information;
- (6) Order FDA and HHS to restore webpages and datasets that were removed in violation of the APA;
- (7) Enjoin CDC and HHS from removing or substantially modifying webpages and datasets that qualify as significant information dissemination products without providing adequate notice;
- (8) Enjoin CDC and HHS from removing or substantially modifying webpages and datasets that qualify as significant information dissemination products where doing so would deny the public timely and equitable access to the agencies' public information;
- (9) Award Plaintiff its costs, attorneys' fees, and other disbursements for this action; and
- (10) Grant any other relief this Court deems appropriate.

Dated: February 4, 2025

Respectfully submitted,

<u>/s/ Zachary R. Shelley</u> Zachary R. Shelley (DC Bar No. 90021549) Adina H. Rosenbaum (DC Bar No. 490428) Allison M. Zieve (DC Bar No. 424786) Public Citizen Litigation Group 1600 20th Street NW Washington, DC 20009 (202) 588-1000 zshelley@citizen.org

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