UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DOCTORS FOR AMERICA, PO Box 21161 2300 18th Street NW Lobby Washington, DC 20009,

CITY AND COUNTY OF SAN FRANCISCO,

1 Dr. Carlton B. Goodlett Place San Francisco, CA 94102,

Plaintiffs,

v.

OFFICE OF PERSONNEL MANAGEMENT, 1900 E Street NW Washington, DC 20415,

CENTERS FOR DISEASE CONTROL AND PREVENTION, 1600 Clifton Road Atlanta, GA 30329,

FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue Silver Spring, MD 20993,

DEPARTMENT OF HEALTH & HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201,

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, 5600 Fishers Lane, 7th Floor Rockville, MD 20857, Civil Action No. 25-322-JDB

FIRST AMENDED COMPLAINT

CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY,

5600 Fishers Lane Rockville, MD 20857,

CENTERS FOR MEDICARE & MEDICAID SERVICES, 7500 Security Boulevard Baltimore, MD 21244,

HEALTH RESOURCES AND SERVICES ADMINISTRATION. 5600 Fishers Lane Rockville, MD 20857,

NATIONAL CENTER FOR HEALTH STATISTICS. 3311 Toledo Road Hyattsville, MD 20782,

NATIONAL INSTITUTES OF HEALTH, 9000 Rockville Pike Bethesda, MD 20892,

and

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, 5600 Fishers Lane Rockville, MD 20857,

Defendants.

1. On or about January 31, 2025, Defendant Department of Health and Human Services (HHS) and its component agencies, including Defendants the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Center for Behavioral Health Statistics and Quality (CBHSQ), the Centers for Medicare & Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the National Center for Health Statistics (NCHS), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA), (collectively, Health Agency Defendants) removed from publicly accessible websites a broad range of health-related data and other information that was used every day by health professionals to diagnose and treat patients, by researchers to advance public health—including through clinical trials meant to establish the safety and efficacy of medical products—and by local governments and their public health agencies to protect and promote the health of their residents.

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 clinical providers of access to information that is necessary for providing care to patients, deprives researchers of information that is necessary for developing clinical studies that produce results that accurately reflect the effects treatments will have in clinical practice, and deprives public health practitioners and agencies of

information that is needed 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; (2) the removal of webpages and datasets by the Health Agency Defendants; and (3) the policy implemented through the removals. Defendants failed to provide required notice of their action to remove these vitally important webpages and datasets, and their actions and the policies they reflect are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. See 5 U.S.C. § 706(2).

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.*, the Evidence-Based Policymaking Act of 2018, *id.* § 3563 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. Plaintiff the City and County of San Francisco (San Francisco) is a municipal corporation organized and existing under and by virtue of the laws of the State of California. The San Francisco Department of Public Health (SFDPH) is a constituent department of San Francisco, with the mission of protecting and promoting the health of all San Franciscans.
- 8. 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.
- 9. 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). 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 sound, sustained advances in the sciences underlying medicine, public health, and social services." HHS is the parent of component agencies including CDC, FDA, AHRQ, CBHSQ, CMS, HRSA, NCHS, NIH, and SAMHSA.

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

- 10. 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). CDC's mission is "to protect America from health, safety and security threats, both foreign and in the U.S." CDC is the parent agency of Defendant NCHS.
- 11. 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). 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 "advanc[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."³
- 12. Defendant AHRQ 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). AHRQ's mission "is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions."⁴
- 13. Defendant CBHSQ 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). CBHSQ's mission "is to provide

² https://www.cdc.gov/about/cdc/index.html.

 $^{^{\}scriptscriptstyle 3}$ https://www.fda.gov/about-fda/what-we-do.

⁴ https://www.ahrq.gov/cpi/about/index.html.

current behavioral health data, research, and evaluation findings to practitioners, health promotion specialists, policymakers, and the Public."⁵

- 14. Defendant CMS 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). CMS is tasked with "work[ing] in partnership with the entire health care community to improve quality, equity and outcomes in the health care system."
- 15. Defendant HRSA 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). HRSA's mission is "[t]o improve health outcomes and achieve health equity through access to quality services, a skilled health workforce, and innovative, high-value programs."
- 16. Defendant NCHS 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). NCHS's mission is to "collect[], analyze[], and disseminate[] timely, relevant, and accurate health data and statistics."
- 17. Defendant NIH 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). NIH's "mission is to seek fundamental knowledge about the nature and behavior of living systems and the

⁵ https://www.samhsa.gov/data/about-us/our-mission.

 $^{^6}$ https://www.cms.gov/about-cms.

⁷ https://www.hrsa.gov/about.

 $^{{\}rm 8\ https://www.cdc.gov/nchs/about/mission.html.}$

application of that knowledge to enhance health, lengthen life, and reduce illness and disability."9

18. Defendant SAMHSA 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). "SAMHSA's 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 equitable access and better outcomes." SAMHSA is the parent agency of Defendant CBHSQ.

STATUTORY AND REGULATORY FRAMEWORK

The Paperwork Reduction Act

- 19. 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).
- 20. 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

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⁹ https://www.nih.gov/about-nih/what-we-do/nih-almanac/about-nih.

¹⁰ https://www.samhsa.gov/about/mission-vision.

mandates that agencies must "provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products." *Id.* § 3506(d)(3).

21. 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.¹¹

The Information Quality Act

- 22. Congress enacted the Information Quality Act (IQA) to build on the PRA. 44 U.S.C. § 3516 note. The IQA requires the Office of Management and Budget (OMB) to issue guidance to agencies "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of ... the Paperwork Reduction Act." *Id.* The statute requires the OMB guidance to, among other things, direct other agencies to issue their own "guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency." *Id.*
- 23. In 2002, OMB issued the guidance required by the IQA. See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002).

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 $^{^{11}\,\}mathrm{https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information.}$

- 24. Pursuant to the IQA and OMB guidance, HHS issued Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, which "apply to information disseminated by HHS agencies on or after October 1, 2002." HHS's Guidelines "apply to a wide range of government information dissemination activities across HHS and are generic enough to fit all types of media, including print, electronic, and other forms within HHS." *Id*.
- 25. The HHS Guidelines recognize that HHS's programs include "most of the nation's federal capacity for public health protection and preparedness." *Id.* And they recognize that "development and dissemination of timely and high quality data and information is ... critical" to "HHS partners in the health and human services communities" because "HHS agencies are responsible for dissemination of authoritative health, medical and safety information on a real time basis in order to protect the health of the public against urgent and emerging threats." *Id.* In this way, the HHS Guidelines set parameters to ensure that nothing will "limit or delay the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." *Id.* In particular, the Guidelines explain that HHS agencies' quality assurance methods must ensure information is objective ("presented in an accurate, clear, complete, and unbiased manner"), useful ("by staying informed of

 $^{^{\}rm 12}$ https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information.

information needs and developing new data"), and maintained with integrity (to protect information against "alteration, loss, or destruction"). *Id*.

- 26. The HHS Guidelines also provide specific guidance for HHS agencies that "develop and disseminate authoritative health and human services information intended for consumers and the professional community" and for "[p]ublic health surveillance and epidemiological information" where "the primary information is developed by State and local government agencies ... and reported to CDC for national aggregation and analysis." *Id.* And "when transparency of information is relevant for assessing the information's usefulness from the public's perspective," the HHS Guidelines make clear that "the agency must take care to ensure that transparency has been addressed in its review of the information." *Id.* HHS's Guidelines further affirm the agency's "commitment to making data and information supported with public funds available to the public." *Id.*
- 27. Both the HHS Guidelines and those established by its component agencies emphasize the steps that the agencies take to ensure information disseminated by the agencies meets requisite standards, and each recognizes that information undergoes rigorous review before release. See id.

Evidence-Based Policymaking Act of 2018

28. Title III of the Foundations of Evidence-Based Policymaking Act of 2018 (Evidence-Based Policymaking Act) requires that each "statistical agency" "shall (A) produce and disseminate relevant and timely statistical information; (B) conduct

credible and accurate statistical activities; [and] (C) conduct objective statistical activities." 44 U.S.C. § 3563(a)(1).

- 29. OMB has issued a final rule implementing the Evidence-Based Policymaking Act and placing on statistical agencies requirements related to the dissemination of "statistical products." 5 C.F.R. § 1321. The rule applies to "recognized statistical agencies," including NCHS and CBHSQ, which are components of CDC and SAMHSA, respectively. *See* Fundamental Responsibilities of Recognized Statistical Agencies and Units, 89 Fed. Reg. 82453, 82455 (Oct. 11, 2024) (listing "Recognized Statistical Agencies").
- 30. The OMB rule defines "statistical products" as "information dissemination products that are published or otherwise made available for public use that describe, estimate, forecast, or analyze the characteristics of groups, customarily without identifying the persons or organizations that comprise such groups or individual data observations with respect to those persons or organizations. Statistical products include general-purpose tabulations, analyses, projections, forecasts, or other statistical reports. Statistical products include products of any form, including both printed and electronic forms." 5 C.F.R. § 1321.2.
- 31. The OMB rule charges each statistical unit with "maximiz[ing] the timeliness of statistical products by minimizing the time interval between the release of statistical products and the reference date" and by "publicly announc[ing] and adher[ing] to a schedule for the release of statistical products." *Id.* §§ 1321.5(c)–(d). It further requires statistical agencies to "[p]roduce statistical products that are

impartial and free from undue influence and the appearance of undue influence by ... disseminating impartial statistical products in a clear and complete manner, without limitation or selection to promote a particular policy position or group interest." *Id.* § 1321.7(a)(1).

32. The rule requires the parent agencies of statistical agencies, like HHS (for NCHS and CBHSQ), CDC (for NCHS), and SAMHSA (for CBHSQ), to "[a]llow the publication of statistical products without requiring clearance of the content from offices or officials outside of the Recognized Statistical Agency" and to "[s]upport the impartiality of the Recognized Statistical Agency and Unit in its production and dissemination of statistical products by ensuring it is permitted to determine the methods for conducting statistical activities for statistical purposes and for disseminating statistical products." *Id.* § 1321.7(b).

FACTS

Executive Order 14168 and OPM's memorandum

33. 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." 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."

 $^{^{13}\} https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/.$

- 34. 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*." 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."
- 35. 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 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

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

¹⁴ https://www.opm.gov/media/yvlh1r3i/opm-memo-initial-guidance-regarding-trump-executive-order-defending-women-1-29-2025-final.pdf.

- 37. HHS removed from its website numerous webpages and datasets that served as resources to clinicians, researchers, government public health agencies, and the general public. The removed webpages include pages providing information from the Healthy People 2030 program about health-related challenges and disparities faced by LGBT people, and a webpage on gender-affirming care for young people.
- 38. HHS component CDC and its subcomponent NCHS removed numerous webpages and datasets that served as resources to clinicians, researchers, government public health agencies, and the general public. The removed information includes:
 - 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.

- 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.
- Webpages for "The Social Vulnerability Index." The webpages 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.
- 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.
- 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."

- 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. 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.
- 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.
- 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 with information regarding long-term health outcomes.

- 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."
- A webpage with vaccine guidelines for clinicians called the "Interim Clinical Considerations for Use of Vaccine for Mpox Prevention in the United States."
- 39. HHS component FDA 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 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."
 - 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.

- Webpages on Risk Evaluation and Mitigation Strategies (REMS) for approved drugs. The REMS provides physicians and other health professionals with education and instructions for prescribing and administering FDA-approved drugs with serious safety concerns to further ensure that the drugs' benefits outweigh any risks.
- 40. HHS component AHRQ removed numerous webpages and datasets that served as resources to clinicians, researchers, and government public health agencies. Among those recently removed from AHRQ's website are webpages on "Endometriosis: A Common and Commonly Missed and Delayed Diagnosis" and "Copy and Paste' Notes and Autopopulated Text in the Electronic Health Records."
- 41. HHS component HRSA removed numerous webpages that served as resources to clinicians, researchers, government public health agencies, and the general public, including a report on "Caring for Women with Opioid Use Disorder" and a website that provided a "one-stop shop for technical assistance (TA) and training resources for HRSA's Ryan White HIV/AIDS Program (RWHAP), the federal program that funds local and state agencies to deliver HIV care for people with HIV who do not have full health insurance."
- 42. HHS component CMS removed webpages that served as resources to clinicians, researchers, government public health agencies, and the general public, including a webpage that provided access to CMS datasets.

- 43. HHS component NIH removed numerous webpages that served as resources to clinicians, researchers, and government public health agencies, including webpages that provide physicians, patients, and researchers with information about abortion and webpages that provide physicians, patients, and researchers with information about health disparities in Spanish.
- 44. HHS component SAMHSA and its sub-component CBHSQ removed numerous webpages and datasets that served as resources to clinicians, researchers, and government public health agencies. Among those recently removed from SAMHSA and CBHSQ's website are webpages for the 2023 Adolescent LGB+Behavioral Health Report, which derives from CBHSQ's National Survey on Drug Use and Health (NSDUH).
- 45. The Health Agency Defendants did not provide any notice that these webpages and datasets would be removed and no longer publicly accessible.
- 46. 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.
- 47. In response to the temporary restraining order issued in this litigation on February 11, 2025, Defendants restored to their websites the webpages specifically identified by Plaintiff DFA. On many of those pages, Defendants added a statement saying: "Per a court order, HHS is required to restore this website as of 11:59PM ET, February 14, 2025. Any information on this page promoting gender ideology is

extremely inaccurate and disconnected from the immutable biological reality that there are two sexes, male and female. The Trump Administration rejects gender ideology and condemns the harms it causes to children, by promoting their chemical and surgical mutilation, and to women, by depriving them of their dignity, safety, well-being, and opportunities. This page does not reflect biological reality and therefore the Administration and this Department rejects it."

Injury to Plaintiffs

- 48. The decisions by the Health Agency Defendants to remove the webpages and datasets contradict their stated missions and are causing and will cause substantial harm to Plaintiff DFA and its members, and to Plaintiff San Francisco, especially SFDPH, as well as other physicians, researchers, and government public health agencies who have long relied on the removed webpages and datasets.
- 49. DFA and the physicians and medical trainees that constitute its membership relied 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.
- 50. SFDPH regularly relied on the removed websites and datasets, including at a clinic devoted to preventing, diagnosing, and treating sexually

transmitted infections (STIs) and HIV, and in its role preventing unintended pregnancy, and for declaring a local health emergency when necessary, tracking disease outbreaks, and overseeing sampling, analysis, and other efforts to respond to or abate local health emergencies and protect the public health.

- 51. For example, DFA members and SFDPH 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 and SFDPH 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.
- 52. DFA members and SFDPH 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.
- 53. Access to current information on the CDC website is essential to SFDPH in other areas as well. For example, delays in Morbidity and Mortality Weekly Reports (MMWRs), lack of real-time information from the CDC website on H5N1 (bird flu), measles, and other high-threat and evolving outbreaks impacts the San Francisco's preparedness and clinical response.

- 54. DFA members and SFDPH have also relied on information from other HHS agencies as well, including SAMHSA and CBHSQ's reports to understand trends in substance use disorders and receipt of treatment, to inform patients' treatment (DFA members) and to compare outcomes of SFDPH's own programs with nationally reported measures (SFDPH).
- 55. Moreover, many DFA members and SFDPH personnel are engaged in clinical and public health research, surveillance, and analyses. For example, DFA and its members have used publicly available datasets from Defendants' websites to conduct groundbreaking research on infectious disease, factors associated with pediatric health, and structural determinants of health to inform local, state, and federal policy efforts.
- 56. 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.
- 57. DFA members and SFDPH 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, carry out, or assess clinical trials.
- 58. 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.

- 59. DFA members have also relied on webpages that were removed from the HHS website and the websites of its component agencies—including those of CMS, HRSA, NIH, and SAMHSA—to, for example, inform how they care for patients. Without those webpages, providing informed care to patients and staying abreast of medical and public health developments will be more difficult.
- 60. DFA members and SFDPH personnel have also relied on research articles hosted on Defendants' websites, and they depend on that research being publicly available in its unaltered form.

COUNT I (Against OPM)

- 61. 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).
- 62. OPM has no authority, by statute or otherwise, to require removal of webpages or datasets posted online by other agencies.
- 63. The statute that OPM identified as the source of its authority, 5 U.S.C. §§ 1103(a)(1), (5), does not authorize or delegate authority for OPM's action.
- 64. Because no statute authorizes OPM to require other agencies to remove webpages or datasets, OPM's memorandum exceeds its statutory authority.

65. By issuing its memorandum without statutory authority and in contradiction to its obligations under federal law, OPM acted in excess of statutory authority and took agency action that was not in accordance with law.

COUNT II (Against Health Agency Defendants)

- 66. 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).
- 67. The webpages and datasets that the Health Agency Defendants removed or substantially modified are significant information dissemination products. See 44 U.S.C. § 3506(d)(3).
- 68. Because they provided no advance public notice before removing or substantially modifying the webpages and datasets, the Health Agency Defendants 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*.
- 69. Because they removed, in part or full, webpages and datasets that convey information that they possess, the Health Agency Defendants 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*.
- 70. Because they removed in part or full webpages and datasets that qualify as statistical products or allowed such webpages and datasets to be removed, HHS,

including components such as CDC, SAMHSA, NCHS, and CBHSQ, violated their duties under the Evidence-Based Policymaking Act of 2018 and the regulations thereunder.

- 71. Because they posted inaccurate disclaimers on webpages that were restored following the Court's temporary restraining order, HHS, including components such as CDC, SAMHSA, NCHS, and CBHSQ, violated their duties under the Evidence-Based Policymaking Act and the regulations thereunder.
- 72. By removing the webpages and datasets, the Health Agency Defendants failed to observe procedures required by law, and took agency action that was arbitrary, capricious, an abuse of discretion, or not in accordance with the PRA and the Evidence-Based Policymaking Act.

COUNT III (Against All Defendants)

- 73. 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).
- 74. Defendants' adoption of a policy requiring removal or modification of the webpages and datasets described herein lacked reasonable justification, runs counter to existing policies with respect to their duties under the PRA, the IQA, and the Evidence-Based Policymaking Act, and was arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

(1) Declare that OPM's memorandum exceeds the authority granted to it by law;

- (2) Declare that the Health Agency Defendants' removal of webpages and datasets violates the PRA, the Evidence-Based Policymaking Act and its regulations, and the APA;
- (3) Order the Health Agency Defendants, including their components, to restore webpages and datasets that they removed or modified, or that they directed to have removed or modified, in response to the OPM memo or without reasoned justification;
- (4) Enjoin OPM from taking any action to enforce its memorandum;
- (5) Enjoin the Health Agency Defendants, including their components, from removing or substantially modifying webpages and datasets that qualify as significant information dissemination products without providing adequate notice;
- (6) Enjoin the Health Agency Defendants, including their components, from removing or modifying webpages and datasets where doing so would deny the public timely and equitable access to the agencies' public information;
- (7) Enjoin the Health Agency Defendants, including their components, from changing the content of statistical products to promote a particular policy position;
- (8) Enjoin the Health Agency Defendants, including their components, from denying timely access to statistical products;
- (9) Award Plaintiffs their costs, attorneys' fees, and other disbursements for this action; and

(10) Grant any other relief this Court deems appropriate.

Dated: February 18, 2025 Respectfully submitted,

/s/ Zachary R. Shelley

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* Motion to appear pro hac vice forthcoming