Samara Spence* (DC Bar No. 1031191)
Jeffrey B. Dubner* (DC Bar No. 1013399)
Sean A. Lev* (DC Bar. No. 449936)
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
sspence@democracyforward.org
jdubner@democracyforward.org
slev@democracyforward.org
(202) 448-9090

Counsel for Plaintiffs

**pro hac vice application forthcoming*

James R. Williams (CA Bar No. 271253)
Greta S. Hansen (CA Bar No. 251471)
Douglas M. Press (CA Bar No. 168740)
Lorraine Van Kirk (CA Bar No. 287194)
Office of the County Counsel
County of Santa Clara
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
lorraine.van_kirk@cco.sccgov.org
(408) 299-5900

Counsel for the County of Santa Clara

Lisa S. Mankofsky* (DC Bar No. 411931)
Matthew Simon* (DC Bar No. 144727)
Center for Science in the Public Interest
1220 L Street, NW, Ste. 300
Washington, DC 20005
lmankofsky@cspinet.org
msimon@cspinet.org
(202) 777-8381

Counsel for Center for Science in the Public Interest

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

COUNTY OF SANTA CLARA, CALIFORNIA TRIBAL FAMILIES COALITION, NATIONAL ASSOCIATION OF PEDIATRIC NURSE PRACTITIONERS, AMERICAN LUNG ASSOCIATION, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, and NATURAL RESOURCES DEFENSE COUNCIL,

Plaintiffs,

vs.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and NORRIS COCHRAN, in his official capacity as Acting Secretary of Health and Human Services,

Defendants.

Case No. 5:21-cv-01655

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Administrative Procedure Act Case

TABLE OF CONTENTS

Page

Plaintiffs the County of Santa Clara, California Tribal Families Coalition, National Association of Pediatric Nurse Practitioners, American Lung Association, the Center for Science in the Public Interest, and Natural Resources Defense Council (collectively, "Plaintiffs"), by and through undersigned counsel, hereby allege as follows:

INTRODUCTION

1. Plaintiffs bring this action under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*, and the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 *et seq.*, to challenge a final rule recently issued by the U. S. Department of Health and Human Services ("HHS" or "Department") entitled "Securing Updated and Necessary Statutory Evaluations Timely," 86 Fed. Reg. 5694 (Jan. 19, 2021) ("Sunset Rule" or "Rule"). Under the guise of an RFA plan for periodically reviewing preexisting regulations that significantly impact small entities, the Sunset Rule amends nearly all HHS regulations to include self-executing expiration dates. The Rule's impact is vast and unprecedented. Absent separate Department action, approximately 17,200 regulations will "expire" in 2026, with additional regulations automatically terminating afterward.

2. HHS, together with its subagencies—such as the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA"), and the Centers for Medicare and Medicaid Services—administers a broad range of statutory programs that impact nearly every aspect of the American healthcare system, food and drug manufacturing, and social services systems. These programs operate pursuant to regulations that govern, for example, health insurance, hospitals and clinics, pharmaceuticals and vaccines, mental health treatment, Medicare and Medicaid, public health emergency prevention and preparedness, food safety, protections for children and the elderly, and much more. The affected healthcare sector alone accounts for nearly one-fifth of the U.S. economy.

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3. HHS has issued regulations implementing its substantive statutes since its inception in 1953. To date, HHS has approximately 18,000 regulations on the books, covering everything from ventilators to the privacy of personal and heath information.

4. The Sunset Rule, which was proposed and finalized entirely during the outgoing administration's lame-duck period, amends *nearly all* HHS regulations to add self-executing expiration dates. Under the Rule, the vast majority of the Department's existing regulations are set to expire automatically in 2026, with the remainder set to expire over the following five years. The only way under the Rule to prevent expiration is for HHS to conduct and finalize retrospective review of each regulation. This would require a resource-intensive and time-consuming effort on par with full notice-and-comment rulemaking, but at a pace 20 times faster than the Department has ever conducted retrospective review in the past—all without any guarantee that the Department *will* conduct such review. The Rule does not even specify which of the Department's 18,000 existing regulations are exempted under the limited exceptions. In other words, the outgoing administration planted a ticking timebomb set to go off in five years unless HHS, beginning right now, devotes an enormous amount of resources to an unprecedented and infeasible task.

5. The Rule creates incalculable costs and chaos. It schedules rescission of thousands of the regulations that structure Plaintiffs' highly technical operations and obligations, delineate their and their members' rights, and protect the populations they serve. It directly harms Plaintiffs and the general public, including the elderly, children, healthcare professionals, tribal governments and members, and anyone who needs medical care, is affected by pandemics or disasters, or simply eats food.

6. The Sunset Rule, moreover, creates immediate uncertainty and instability throughout the healthcare system at the very time that the public most needs clear guidelines due to a global pandemic. Plaintiffs have no guarantee that HHS will complete retrospective review on such a mass scale and must assume that any, or all, of the regulations that affect them will disappear. Regulated entities and individuals, such as

hospitals and nurse practitioners, will be unable to plan their operations to the financial and physical detriment of patients. All Plaintiffs will have to divert significant resources to monitor the progress of each regulation that affects them and to attempt to stem the effects of potential automatic expiration.

7. If the Rule takes effect, it will require substantial, and likely unachievable, efforts on the part of HHS to prevent regulations from expiring. The resulting cost to society is steep. To simply keep its existing regulatory framework, HHS and its subagencies will need to redirect significant resources away from such vital work as combatting the COVID-19 pandemic and protecting the country against future public health emergencies.

8. The Sunset Rule violates the APA, the RFA, and the statutory authorities underlying the Department's original regulations.

9. First, the Rule was issued without procedures or tribal consultation required by law. The Department promulgated the Rule after a rushed notice-and-comment period that hundreds of commenters decried as providing inadequate time for them to meaningfully participate. The limited public process was particularly problematic because affected parties were asked to discern, and comment on (over the holidays, no less), the impacts of a sweeping and vague proposal in the middle of a global pandemic, which was appropriately the primary focus of their efforts. HHS also refused to consult with Indian tribes, as required under HHS policy and the federal government's tribal trust responsibilities, despite the Rule's significant and direct effects on tribes and funding for tribal programs.

10. Second, the Sunset Rule is contrary to law and in excess of the Department's authority. It relies on the RFA, which by the Department's own estimate does not authorize review of 89% of the regulations amended. And it schedules elimination of nearly all HHS regulations without consideration of the factors required by that statute. It also expressly relies on the myriad HHS substantive statutes for authority,

but in fact eliminates regulations required by those statutes and fails to address factors mandated by those statutes and the APA.

11. Third, the Rule violates the APA's prohibition against arbitrary and capricious agency action. Among other things, the Department's justification for the Rule—to "incentivize" retrospective regulatory review—is irrational on its face. It assumes without support that HHS can induce itself to increase its pace of review 20-fold merely by imposing on the general public the severe consequence of losing needed regulations. Moreover, the Department did not plausibly show that it *can* meet the contemplated review schedule or meaningfully consider the harm and costs the "incentive" would cause.

12. Plaintiffs respectfully request that the Court declare that the Sunset Rule violates the APA because it was issued without procedures or consultation required by law, is contrary to law, and is arbitrary and capricious. The Rule should be vacated and set aside.

PARTIES

13. Plaintiff County of Santa Clara (the "County") is a charter county and political subdivision of the State of California, located in the Northern District of California. The County is home to almost two million people who rely on the County to provide essential healthcare services and to oversee regional public health. The County owns and operates the County of Santa Clara Hospitals and Clinics, a network of safety-net hospitals and medical clinics that provide specialized, preventative, primary, and routine healthcare services, primarily to underserved patients. Together, the County's public hospitals and clinics serve nearly 200,000 individual patients per year. The County also operates a Social Services Agency that provides a wide array of essential safety-net services; an Emergency Medical Services Agency that accredits emergency responders and oversees all 911 ambulance response countywide; a Behavioral Health Services Department that provides mental health and substance use prevention and treatment services to tens of thousands of patients each year; a health insurance plan called Valley

Health Plan; and a Public Health Department that is responsible for regional public health services throughout Santa Clara County, including managing the County's response to the COVID-19 pandemic.

14. Plaintiff California Tribal Families Coalition ("CTFC") is an Internal Revenue Code ("IRC") Section 501(c)(4) nonprofit membership association and an "Indian organization" under the Indian Child Welfare Act. Its members are 42 federally recognized sovereign tribes and 3 statewide tribal leader associations from across California, and it is led by a 12-member Board of Directors chosen from among the duly elected tribal leaders of CTFC's member tribes. CTFC's mission is to protect the health, safety, and welfare of tribal children and families, which are inherent tribal governmental functions and are at the core of tribal sovereignty and tribal governance. CTFC's member tribes are governments entitled under the Indian Self-Determination and Education Assistance Act, Pub. L. No. 93-638, 88 Stat. 2203, to request that operation of, and funding for, federal programs be transferred to tribal administration. CTFC's member tribes are affected by nearly all HHS programs. Among other things, they receive HHS funding for operation of tribal health services and/or receive services directly from Indian Health Services programs, substance abuse programs, and social programs, such as Temporary Assistance for Needy Families. HHS regulations govern the member tribes' funding for and operation of such programs. One of CTFC's core missions is to advocate for the incorporation of tribal concerns into regulations, including HHS regulations of great importance to its tribal members, such as regulations on healthcare, mental health, substance abuse, programs for the elderly, child welfare, and foster care.

15. Plaintiff National Association of Pediatric Nurse Practitioners ("NAPNAP") is an IRC Section 501(c)(6) nonprofit professional membership association, representing more than 8,000 healthcare practitioners, with 18 specialty practice issues groups and 53 chapters. It is the nation's only professional association for pediatric nurse practitioners and their fellow pediatric-focused advanced practice registered nurses, who are dedicated to improving the quality of health care for infants, children, adolescents, and young adults.

NAPNAP's members treat millions of patients a year in a wide variety of healthcare settings, including pediatric offices, hospitals, specialty clinics, public or school-based healthcare facilities, and others. They are regulated and affected by thousands of HHS regulations under such programs as Medicaid and the Children's Health Insurance Program. NAPNAP's mission is to empower pediatric-focused advanced practice registered nurses and key partners to optimize child and family health.

16. Plaintiff American Lung Association ("ALA") is an IRC Section 501(c)(3) nonprofit voluntary health organization incorporated in the State of Maine, with its principal place of business in Chicago, Illinois. One of ALA's core missions is to advocate for policies that improve the prevention and cure of lung disease and that improve the quality of life of people living with lung disease. These include policies that reduce the burden of asthma, expand access to affordable healthcare for patients with or at risk for lung diseases, reduce tobacco use through tobacco regulation and cessation efforts, and increase screening for those at high risk of lung cancer. ALA has spent substantial resources advocating for such programs before HHS. For example, in 2015, ALA testified at a hearing to urge HHS to expand Medicare coverage to include early detection computed tomography ("CT") scans for high-risk Medicare beneficiaries. ALA also works to improve public education on HHS programs that benefit at risk populations. For example, ALA generates and maintains a lung cancer screening toolkit that tracks coverage of and barriers to low-dose computed tomography ("LDCT") lung cancer screening under state Medicaid fee-for-service programs. Similarly, ALA depends on HHS regulations governing tobacco products, such as a 2016 regulation deeming e-cigarette subject to the Tobacco Control Act, which significantly affects ALA's Not On Tobacco program, Freedom from Smoking program, and Lung Helpline cessation assistance service.

17. Plaintiff the Center for Science in the Public Interest ("CSPI") is an IRC Section 501(c)(3) nonpartisan nonprofit organization headquartered in Washington, DC, with approximately 450,000 members. CSPI is independently owned and operated and is not dominant in its field of public health advocacy. CSPI is a science-based consumer

advocacy organization that seeks to promote: (1) a healthy population with a reduced burden of preventable disease, and (2) an equitable food system in which healthy, sustainable food is accessible to all. CSPI values independence, scientific rigor, and transparency. A core aspect of CSPI's mission is ensuring that food, dietary supplements, and drugs are safe and transparently labeled. The FDA, an HHS sub-agency, administers several statutes relevant to this work, including the Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as 21 U.S.C. § 301, *et seq*.); the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353; the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325; portions of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119; the Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885; and the Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 891.

18. Plaintiff Natural Resources Defense Council ("NRDC") is an IRC Section 501(c)(3) national not-for-profit environmental and public health organization, headquartered in New York City, with more than three million members and online activists. One of NRDC's core missions is to conduct advocacy and educate the public to protect public health and the environment. In service of this mission, NRDC advocates for health-protective regulations at FDA (including the regulation of food additives, 21 C.F.R. §§ 170.3-180.37; bottled water, *id.* §§ 129.1-129.80; and antibiotics in animal agriculture, *id*. §§ 556.1-556.770, 558.3-558.680) and HHS (including regulations that protect human test subjects, 45 C.F.R. part 46). NRDC also educates its members and the public about these and other HHS regulations.

19. Defendant United States Department of Health and Human Services ("HHS" or "Department") is a federal agency headquartered in Washington, DC, at 200 Independence Avenue, SW, Washington, DC 20201. HHS is an "agency" within the meaning of the APA. 5 U.S.C. § 551(1). HHS is a cabinet-level department that

encompasses several sub-agencies, including the CDC, FDA, Centers for Medicare and Medicaid Services, Indian Health Service, and National Institutes of Health.

20. Defendant Norris Cochran is sued in his official capacity as the Acting U.S. Secretary of Health and Human Services. His official address is 200 Independence Avenue, SW, Washington, DC 20201.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under federal law.[1] The Court also has subject matter jurisdiction pursuant to 5 U.S.C. § 611(a).

22. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e)(1) because Plaintiff County of Santa Clara resides in this district and there is no real property involved in this action.

23. The Sunset Rule is a final agency action for which there is no other adequate remedy in court. 5 U.S.C. § 704.

24. This Court has authority to grant the requested relief in this case pursuant to the APA, 5 U.S.C. § 706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

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[1] Under 28 U.S.C. § 1331, this APA challenge is properly brought in the district courts because the vast majority of the regulations amended by the Sunset Rule fall under statutory provisions that have no specific direct-review provision. *See Owner-Operators Indep. Drivers Ass'n v. Skinner*, 931 F.2d 582, 585 (9th Cir. 1991) (district courts have jurisdiction over APA claims "unless Congress specifically maps a judicial review path"). However, Plaintiffs are also filing a "protective" petition for review in the U.S. Court of Appeals for the Ninth Circuit because certain regulations amended by the Rule are subject to provisions conferring initial jurisdiction on the courts of appeals. *E.g.*, 21 U.S.C. § 360g (jurisdiction for challenges to the regulation of medical devices arises in the courts of appeals); *see also Nat'l Fed'n of the Blind v. U.S. Dep't of Transp.*, 827 F.3d 51, 58 (D.C. Cir. 2016) (parties should "file suit in both the court of appeals and the district court" when there is doubt as to the proper forum). Plaintiffs intend to ask the Ninth Circuit to hold the petition in abeyance pending the resolution of this case.

LEGAL AND STATUTORY BACKGROUND

I. The Administrative Procedure Act ("APA")

25. The APA allows a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" to seek judicial review of that action. 5 U.S.C. § 702. Under the APA, courts must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id* § 706(2)(C), or "without observance of procedure required by law," *id*. § 706(2)(D).

II. The Regulatory Flexibility Act ("RFA")

26. The RFA requires agencies to publish a "plan for the periodic review of the rules . . . which have or will have a significant economic impact upon a substantial number of small entities." 5 U.S.C. § 610(a). The RFA does not authorize reviews of rules that lack "a significant economic impact upon a substantial number of small entities." *See id.* §§ 602, 605, 610.

27. The purpose of RFA review is "to determine whether" covered regulations "should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of []small entities." *Id.* § 610(a).

28. In conducting review under the RFA, the agency "shall consider" five statutory factors. *Id*. § 610(b). Those are: (1) the "continued need for the rule"; (2) the "nature of complaints or comments" concerning the rule; (3) the "complexity of the rule"; (4) the "extent to which the rule overlaps, duplicates or conflicts" with other rules; and (5) the "length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors" affecting the rule have changed. *Id*.

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FACTUAL ALLEGATIONS

I. HHS Regulates Healthcare, Disease Control, and Food and Drug Safety.

29. HHS was established as a cabinet level department in 1953, when it was called the Department of Health, Education, and Welfare. Its name was changed to the Department of Health and Human Services in 1980. The mission of HHS is to provide services that benefit the health and well-being of Americans and by fostering advances in the science underlying medicine, public health, and social services.[2]

30. HHS contains dozens of sub-agencies and offices, including the CDC, FDA, Centers for Medicare and Medicaid Services, Indian Health Service, Administration on Community Living, Administration for Children and Families, and National Institutes of Health.

31. HHS operates programs that affect every aspect of the U.S. healthcare system. These include, for example, the Medicare and Medicaid programs, which insure 139 million Americans, including 36.6 million children; the Children's Health Insurance Program, which insures over 7 million children; and the Healthcare.gov Insurance Marketplace, which enrolled nearly 8.3 million people in insurance plans in 2020 alone.

32. HHS administers almost every major federal statute governing healthcare, including, for example, the Medicare and Medicaid provisions of the Social Security Act, Pub. L. No. 74-271, 49 Stat. 620, which include hospital health and safety requirements; the ACA, which governs health insurance; the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, which governs privacy and portability of health information; and the Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115, which establishes programs for securing health information; in addition to the countless supplements and amendments to these statutes.

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[2] *About HHS*, https://www.hhs.gov/about/index.html (last visited Mar. 5, 2021).

33. Other HHS-administered statutes regulate the safety and contents of food, medications, vaccines, and medical devices, and protect the public from tobacco products, such as the Nutrition Labeling and Education Act; the Dietary Supplement Health and Education Act; the Food Safety Modernization Act; the Food Allergen Labeling and Consumer Protection Act; the Federal Food, Drug and Cosmetic Act, Pub. L. 75-717, 52 Stat. 1040; and the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776.

34. HHS agencies operate programs that for prepare for, respond to, and help the nation recover from public health emergencies under the Pandemic and All Hazards Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831, and related statutes.

35. The Department maintains programs dedicated to services for tribes both in and outside the healthcare context, under such statutes as the Indian Health Care Improvement Act, Pub. L. 111-148, § 10221, 124 Stat. 119, 935-37. Pursuant to the Indian Self-Determination and Education Assistance Act, HHS formally transfers operation of, and funds for, these and other HHS programs to tribes under certain circumstances.

36. HHS also administers critical social-welfare programs, including the Temporary Assistance for Needy Families program, Head Start, the Unaccompanied Alien Children program, and programs addressing child support, child nutrition, adoption, foster care, and the elderly.

37. HHS oversees highly regulated industries through thousands of technical, interdependent, and complex regulations that implement several notoriously "Byzantine" statutes.[3] *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981). Such regulations govern the myriad real-life factors that affect individual and public health, such as medical device standards, pharmaceutical manufacturing, and food contaminants.

[3] The Department's substantive statutes have at times been "aptly described" as a "virtually impenetrable thicket of legalese and gobbledygook." *Lamore v. Ives*, 977 F.2d 713, 716 (1st Cir. 1992).

38. To date, HHS has promulgated approximately 18,000 active regulations to implement the entire range of statutes the Department administers.[4] 86 Fed. Reg. at 5,740.

II. HHS Proposes Massive Deregulation of the Healthcare Industry in the Midst of a Pandemic, While Providing a Truncated Notice-and-Comment Period and Refusing to Consult with Indian Tribes.

39. In 2020, the COVID-19 pandemic strained HHS, its sub-agencies, and the U.S. healthcare industry in new ways. The CDC led the investigation into how the disease spreads, advised the public on pandemic precautions, and monitored healthcare delivery systems. The FDA played a similarly crucial role in development and approval for vaccines and COVID-19 treatments. And HHS administered necessary funding to healthcare providers under the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. No. 116-136, 134 Stat. 281.

40. By the first week of November 2020, COVID-19 infection rates had begun to surge upward in what would become, over the next two months, the worst wave of the pandemic to date.[5]

41. That same week, on November 4, 2020, HHS announced for the first time a massive deregulation effort that would affect the entire Department and its sub-agencies. HHS had never previously disclosed this scheme to the public, identified it as a Department priority, or listed it in the administration's Unified Agenda of Federal Regulatory and Deregulatory Actions.

42. That day, HHS issued a Notice of Proposed Rulemaking proposing that, subject to limited and vague exceptions, "*all* regulations" issued by HHS "in Titles 21, 42, and 45 of the CFR *shall expire*"—most in two years, the rest within ten years. Securing

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[4] In the Sunset Rule, HHS uses the word "regulation" to refer to an individual provision of the Code of Federal Register ("C.F.R."). *See* 86 Fed. Reg. at 5,720, 5,740-41. The Department estimates that "roughly five regulations on average are part of the same rulemaking," *id*. at 5,741, although the Sunset Rule does not say whether the average (*i.e*., the arithmetic mean) is representative of most rulemakings.

[5] *See COVID Data Tracker*, Trends in COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory, CDC (Mar. 6, 2021), https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases.

Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70,096, 70,097 (proposed Nov. 4, 2020) (the "Proposed Rule") (emphasis added). HHS acknowledged that the proposal was "unprecedented,"[6] and then-HHS Chief of Staff Brian Harrison later described it as "one of the most significant regulatory reform efforts in the history of the federal government."[7]

43. As authority, the Proposed Rule invoked the RFA's requirement that agencies publish a "plan for the periodic review of rules which have or will have a significant impact upon a substantial number of small entities." 85 Fed. Reg. at 70,097-98 (quoting 5 U.S.C. § 610(a)). HHS already operates under a 2011 plan for RFA review and has published an update on regulatory review every year through 2016.[8] The Proposed Rule also purported to rely on "the statutory authorities for the Department's existing regulations," although it did not identify the authorities associated with each regulation to be amended or how they authorized expiration dates. *Id*. at 70,103.

44. To avoid the scheduled expiration of a given C.F.R. section under the proposal, HHS would need to first perform an "Assessment" to determine whether the regulation has a significant impact on small entities under the RFA. *Id*. at 70,119. If so, HHS would need to conduct a "Review" to determine whether the regulation "should be continued without change, or should be amended or rescinded, consistent with the stated objectives of the applicable statutes, to minimize any significant economic impact of the

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[6] *HHS Proposes Unprecedented Regulatory Reform through Retrospective Review* (Nov. 4, 2020), https://www.hhs.gov/about/news/2020/11/04/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.html.

[7] Brian Harrison, *A new rule requires HHS to get rid of regulations that aren't helping the public*, Dallas Morning News (Jan. 14, 2021) https://www.dallasnews.com/opinion/commentary/2021/01/14/a-new-rule-requires-hhs-to-get-rid-of-regulations-that-arent-helping-the-public/.

[8] *Retrospective Review of Existing Rules*, HHS https://www.hhs.gov/open/retrospective-review/index.html (last visited Mar. 7, 2021). Notably, the Department's RFA plan is much more limited in scope. For example, it requires HHS to create and prioritize a list of regulations that actually need to be reviewed but does not require review of every HHS regulation.

Regulations upon a substantial number of small entities." *Id*. The Department envisioned a resource-intensive and time-consuming public notice-and-comment process, subject to judicial review, at both the Assessment and Review phases. *See id*. at 70,106-07, 70,110. The proposal would impose no obligation on HHS to undertake an Assessment and Review in the first place, and the proposed expiration dates would be self-executing if the Department failed to (or chose not to) complete the review process. *See id*.

45. The Proposed Rule neither explicitly identified the regulations HHS was proposing to amend, nor analyzed the harms and benefits of adding expiration dates to any particular regulation. Rather, it spoke in generalities and estimates. According to the proposal, HHS "has roughly 18,000 regulations, the vast majority of which it believes would need to be Assessed." *Id*. at 70,113. Further, "[t]he vast majority of these would need to be Assessed within two years." *Id*. HHS estimated that because some regulations are part of the same rulemaking, HHS would need to perform "roughly 2,480" Assessments in the first two years to prevent regulations ten years old or older from expiring. *Id*. And HHS offered no analysis of the impact on, or reliance interests of, regulated entities or the public from amending any of the roughly 18,000 individual regulations it proposed to amend.

46. The proposal also did not identify which regulations the Department believed to have "a significant economic impact upon a substantial number of small entities" such that they are subject to RFA review. *See* 5 U.S.C. § 610(a). Instead, HHS "conducted a random sample of its regulations." 85 Fed. Reg. at 70,112-13. HHS assumed, based principally on a cursory review of ten sampled rulemakings (*i.e*., less than a third of one percent) and an article written by an attorney with the American Petroleum Institute, that 11% of all HHS regulations would have a significant impact on small entities and thus fall under the requirements of the RFA. *Id*. at 70,115. Thus, although by the Department's own account the RFA does not apply to *any* of the 89% of the Department's regulations that HHS assumed lacked a significant impact on small entities, 5 U.S.C.

§§ 602, 610, HHS nonetheless proposed to add expiration dates to nearly all of those thousands of regulations. *See* 85 Fed. Reg. at 70,107.

a. HHS provides only 30 days for most comments, despite widespread concern that this was inadequate time to meaningfully respond to a proposal of this scope.

47. The APA requires that agencies provide "adequate time for comments" so that "interested parties [can] comment meaningfully." *Fla. Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988); *see* 5 U.S.C. § 553(c); Exec. Order No. 13,563, § 2(b), 76 Fed. Reg. 3,821 (Jan. 18, 2011) (comment period for typical rulemaking should be a *minimum* of 60 days); Exec. Order No. 12,866, § 6(a), 58 Fed. Reg. 51,753 (Sept. 30, 1993) (same). "90 days is the 'usual' amount of time allotted for a comment period." *Becerra v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153, 1176 (N.D. Cal. 2019) (quoting *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011)). HHS has previously recognized that 30 days can be "an insufficient amount of time" for comment on a complex rulemaking.[9]

48. Despite the unprecedented scope of the Proposed Rule, the public was given only 30 days, until December 4, 2020, to comment on the proposal as it related to all non-Medicare regulations (that is, as to the vast majority of the Department's regulations). 85 Fed. Reg. at 70,096-97. The public was given 60 days, until January 4, 2020 (a period that included three federal holidays), to comment on the Proposed Rule's effect on Medicare regulations. *Id*.

49. During the abbreviated comment period, hundreds of commenters representing virtually every type of entity with an interest in HHS regulations raised concerns about how the limited comment period affected their ability to meaningfully comment. For example, the Federation of American Hospitals explained that it was simply not possible to review a proposal of this magnitude "in a meaningful way with proper discussion and consideration" within the time allotted, particularly during a pandemic

[9] Adoption and Foster Care Reporting and Analysis System, 83 Fed. Reg. 11,450, 11451 (proposed Mar. 15, 2018).

when hospitals need "readily accessible guidance."[10] The Consumer Brands Association, an industry group representing "more than 1,700 iconic brands," reported that "stakeholders were not able to provide comments that are as thorough as necessary for a proposed rule of this scope" in the time allotted in part because "many businesses were closed or employees on leave" before the Thanksgiving holiday, and the Consumer Brands Association was busy "navigating the challenges of the COVID-19 pandemic," such as worker safety and supply chain issues.[11] The Service Employees International Union explained that a substantially longer comment period was necessary to give it a "meaningful opportunity to provide input" on a "rule of this magnitude."[12]

50. Many of these commenters requested more time. Plaintiff the County of Santa Clara explained that more time was needed to simply "ascertain[] all the HHS regulations that the County implements and depends upon" that would be affected by the Proposed Rule, which HHS itself had not identified.[13] The American Herbal Products Association reported that more time would allow it to provide examples of how HHS had already met the RFA's requirements for certain regulations.[14] Plaintiff ALA requested an extension because the "brief comment periods are an inadequate amount of time for us to prepare comments to appropriately respond" to the "wide range of complex and technical issues" raised in the Proposed Rule, "especially during the time of this COVID-19 pandemic."[15] Plaintiff CSPI requested 180 days to comment, explaining that "[s]uch a

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[10] Federation of American Hospitals, Comment Letter on the Sunset Rule at 2, 3 (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0196.

[11] Consumer Brands Association, Comment Letter on the Sunset Rule at 1, 3, 7 (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0280.

[12] Service Employees International Union, Comment Letter on the Sunset Rule at 3 (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0178.

[13] County of Santa Clara, Comment Letter on the Sunset Rule at 4 (Jan. 4, 2021) (footnote omitted), https://www.regulations.gov/comment/HHS-OS-2020-0012-0533.

[14] American Herbal Products Association, Comment Letter on the Sunset Rule at 3 n.4 (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0082.

[15] American Lung Association, Comment Letter on the Sunset Rule (Nov. 20, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0023.

sweeping proposal is inappropriate for HHS to consider completing in the rushed manner proposed, given its wide-ranging implications" and that "[s]aving lives" should instead be the focus of the Department's resources and attention.[16] Plaintiff NRDC urged HHS to "provide a *minimum* of 60 days for the public to comment on this proposal."[17]

51. During the comment period, the Department held only one public hearing on the proposal, on November 23, 2020, the Monday before Thanksgiving.[18]

52. At the public hearing, commenter after commenter explained how the Proposed Rule's timing and truncated comment period impacted their ability to adequately comment on a proposal of this breadth. The American Frozen Food Institute, which "represents America's frozen food and beverage makers" raised concerns that the proposal's scope, timing, and limited comment period "calls into question the fundamental fairness principles underlying the Administrative Procedure[] Act, assuring a reasonable opportunity to review and comment on new government actions."[19]

53. Similar concerns were expressed by such disparate groups as the American Medical Association,[20] the United Fresh Produce Association, which "represent[s] over 1,500 members of the fresh fruit and vegetable supply chain,"[21] and the National Confectioners Association, "the leading trade association representing the nearly $45 billion U.S. confectionary industry."[22] As the American Medical Association explained, it

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[16] Center for Science in the Public Interest et al., Comment Letter on the Sunset Rule at 1 (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0158.

[17] Natural Resources Defense Council, Comment Letter on the Sunset Rule at 10 (Dec. 4, 2020) (emphasis added), https://www.regulations.gov/comment/HHS-OS-2020-0012-0156.

[18] *See* Transcript, Public Hearing on the Securing Updated and Necessary Statutory Evaluations Timely Notice of Public Rulemaking, (Nov. 23, 2020), https://www.regulations.gov/document/HHS-OS-2020-0012-0501.

[19] *Id*. at 44, 46.

[20] *Id*. at 110-11.

[21] *Id*. at 70-71.

[22] *Id*. at 86, 88.

had been directing its resources "almost solely on the COVID-19 pandemic" and "advocating for appropriate policies that would address" it.[23] "[W]ith only 30 days to review the proposal and in the midst of everything else that's going on, it's extremely difficult for organizations and interested parties to evaluate it and meaningfully comment on it."[24]

54. Despite the overwhelming requests for additional time from all corners of the many industries affected by HHS, the Department refused to extend the comment period. 86 Fed. Reg. at 5,706. Indeed, the Department sent the draft final rule to the Office of Information and Regulatory Affairs on December 17, 2020, over two weeks *before* the end of the 60-day period for commenting on the proposal's impact on Medicare provisions.[25]

55. While HHS often receives tens of thousands of comments on a single rulemaking, the unjustifiably short comment period made a comparable response here impossible; instead, HHS received only 530 comments on a proposal to amend thousands of regulations.[26]

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[23] *Id*. at 111.

[24] *Id*.

[25] Final major federal rulemakings must be submitted to the Office of Information and Regulatory Affairs for inter-agency review, pursuant to Executive Order 12,866. 58 Fed. Reg. 51,735.

[26] *Compare, e.g.*, Nondiscrimination in Health and Health Education Programs or Activities, Rulemaking Docket HHS-OCR-2019-00007, https://www.regulations.gov/docket/HHS-OCR-2019-0007 (nearly 156,000 comments regarding a single proposed HHS rule), *with* Securing Updated and Necessary Statutory Evaluations Timely Rulemaking Docket HHS-OS-2020-0012 ("Sunset Rule Docket"), https://www.regulations.gov/document/HHS-OS-2020-0012-0001/comment# (530 comments regarding the expiration of approximately 18,000 regulations).

b. HHS refuses to consult with Indian tribes despite the proposal's effect on tribal programs and tribal funding.

56. HHS policy—and the federal government's trust relationship with sovereign Indian tribes[27]—requires the Department to consult with tribes "[b]efore any action is taken that will significantly affect Indian Tribes" or that has "Tribal implications."[28] Consultation is also required under Executive Order 13,175, Consultation and Coordination With Indian Tribes, which instructs agencies to "ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications." Exec. Order No. 13,175, § 5(a), 65 Fed. Reg. 67,249 (Nov. 6, 2000).

57. Plaintiff CTFC, representing 42 tribal governments and 3 statewide tribal leader associations, as well as other organizations representing tribes, raised concerns about the Department's failure to consult with tribes and requested immediate consultation. *See* 86 Fed. Reg. at 5,711. Plaintiff CTFC explained that the Proposed Rule "would affect literally hundreds of 'regulations'" that have tribal implications and substantial direct effects on tribes.[29] For example, the proposal would affect regulations under Title IV–E of the Social Security Act, which provides funds for states and tribes to provide foster care and transitional independent living programs for children; social programs of importance

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[27] The federal Indian trust responsibility is a legally enforceable fiduciary duty that has long been recognized by courts. *See Seminole Nation v. United States*, 316 U.S. 286, 295 (1942); Frequently Asked Questions, Bureau of Indian Affairs, https://www.bia.gov/frequently-asked-questions (last visited Mar. 7, 2021).

[28] HHS Tribal Consultation Policy at 3, *available at* https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf (last updated Dec. 12, 2010). "A unique government-to-government relationship exists between Indian tribes and the Federal Government. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, Federal case law, regulations, and executive orders that establish and define a trust relationship with Indian Tribes." *Id*. at 1-2.

[29] California Tribal Families Coalition, Comment Letter on the Sunset Rule at 2 (Dec. 4, 2020) ("CTFC Comment"), https://www.regulations.gov/comment/HHS-OS-2020-0012-0092; *see also*, *e.g.*, Native American Rights Fund and the National Congress of American Indians, Comment Letter on the Sunset Rule (Dec. 4, 2020), https://www.regulations.gov/comment/HHS-OS-2020-0012-0087.

to tribes under the Temporary Assistance for Needy Families and programs addressing mental health and care for the elderly; and laws that protect Indian children, such as the Indian Child Welfare Act.[30] CTFC and others explained the devastating effects that would result from automatic rescission of such regulations.[31]

58. Moreover, as CTFC explained, the proposal would set up an ongoing failure to consult because it "create[s] a process by which regulatory provisions directly impacting Indian Tribes could automatically terminate without notice to, or government-to-government consultation with, affected Tribes."[32] This "undermine[s] the federal government's trust responsibilities to Indian Tribes."[33]

59. Multiple tribes and tribal groups requested immediate consultation on the Proposed Rule. Nonetheless, HHS refused to consult with Indian tribes, despite acknowledging that monitoring and participating in the review process alone would impose $3 million in costs on Indian tribes. *See* 86 Fed. Reg. at 5,711. HHS claimed that the Rule "would have no direct impact on Indian Tribes" aside from monitoring costs because "HHS *intends* that all rules will be Assessed and (if necessary) Reviewed timely" such that they may not ultimately expire. *Id*. (emphasis added).

III. Under the Final Sunset Rule, Approximately 17,200 Regulations Are Set to Expire in 2026, but the Rule Does Not Specify Which Ones.

60. Of the 530 publicly available comments the Department received[34]—including 486 comments from a broad swath of "industry trade organizations, healthcare providers, businesses, legal/policy think tanks, nonprofit public interest groups, and members of the U.S. Congress," *id*. at 5,704—approximately 522 of them opposed the

[30] CTFC Comment at 2-3.

[31] *Id*.

[32] *Id*. at 1.

[33] *Id*.

[34] The Rule mentions 532 comments, 86 Fed. Reg. at 5,704, but only 530 comments reside on the public online docket, *see* Sunset Rule Docket.

proposal or advised HHS to withdraw it. Patient advocate groups like the American Heart Association, organizations representing hospitals like the Federation of American Hospitals, groups representing healthcare professionals like the American Medical Association and Plaintiff NAPNAP, insurers like Cigna and United Healthcare, business and industry groups like the U.S. Chamber of Commerce and the National Association of Manufacturers, and progressive advocacy organizations like Plaintiff CSPI all warned HHS of practical and legal problems with the Proposed Rule.

61. Despite nearly uniform public opposition, on January 19, 2021, HHS nonetheless published the final Sunset Rule without providing any further public process. *Id*. at 5,694, 5,704. HHS scheduled the Rule to take effect on March 22, 2021, less than five months after it was first mentioned to the public.

a. The final Rule requires that nearly all HHS regulations will expire unless HHS completes retrospective review for the thousands of affected regulations.

62. Under the finalized Rule,

> [S]ubject to certain exceptions, *all* regulations issued by [HHS] in Titles 21, 42, and 45 of the C.F.R. *shall expire* at the end of (1) five calendar years after the year that this final rule first becomes effective, (2) ten calendar years after the year of the Section's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed the Section, whichever is latest.

Id. at 5,694 (emphasis added). The only major substantive change from the Proposed Rule's core provisions is that the first expiration date is five years from the effective date of the Rule, instead of two. *See id*. at 5,705.

63. To avoid expiration of a given C.F.R. section, HHS must first perform an "Assessment" to determine whether "the Regulations issued as part of the same rulemaking . . . currently have a significant economic impact upon a substantial number of small entities." 86 Fed. Reg. at 5,720. If it determines that a regulation has a significant economic impact, HHS must then "Review" that regulation to determine whether it "should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of

the Regulations upon a substantial number of small entities." *Id*. Both Assessments and Reviews would involve a burdensome and time-consuming process involving notice-and-comment akin to reissuing the original regulations, and both would be subject to judicial review. *See id*. at 5,724, 5,732, 5,764.

64. If HHS does not undertake an Assessment and/or Review—which the Rule does not require it to do—the regulation automatically expires, without public comment or notice. The public will have no opportunity to participate if the Department chooses to let a regulation lapse without completing Assessment and/or Review, overlooks a regulation, or simply cannot keep up.

65. Although HHS refused to specify which regulations are exempted under the narrow exceptions from the Sunset Rule, *see infra* ¶ 69, it estimated that the "vast majority" of its 18,000 regulations must be Assessed to prevent their automatic elimination. *Id*. at 5,740. "[R]oughly 17,200" of these are more than five years old, meaning that "the vast majority of these would need to be Assessed within five years of [the Sunset Rule's] effective date" to avoid expiration.[35] *Id*. at 5,741.

66. The result is that approximately 17,200 regulations are scheduled to be automatically eliminated in 2026, unless HHS undertakes at least one notice-and-comment process per original rulemaking that is akin to a full-fledged rulemaking. The remaining hundreds will expire on a rolling basis in the five years after that. Using the Department's assumptions that a single rulemaking contains on average five regulations and that 11% of Assessments will lead to Reviews, this means that HHS must perform roughly 3,440 Assessments and 378 Reviews over the next five years to prevent the first round of scheduled expirations. *See id*. at 5,717, 5,741-42.

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[35] *See* List of HHS Rulemakings by Date of Promulgation, HHS https://www.hhs.gov/regulations/federal-registry/index.html (last visited Mar. 5, 2021).

b. The vague exceptions to the self-executing expirations make it impossible to determine which regulations have been amended and will expire without Assessment and Review.

67. HHS did not specify *which* regulations have been amended to include expiration dates, purportedly because figuring it out and informing the public would be "unnecessarily burdensome and resource intensive." 86 Fed. Reg. at 5,720. Instead, HHS declared that the Rule "'shall be deemed to amend' all regulations issued by" HHS unless subject to an exception. *Id*. But HHS also did not specify which regulations are excepted from the amendments.

68. In addition to exempting itself from expiration, the Sunset Rule exempts "Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section" and "Sections whose expiration pursuant to [the Rule] would violate any other Federal law."[36] *Id*. at 5,729, 5,764. The Rule does not further define these exceptions except to note that they apply to "a very small category." *Id*. at 5,731.

69. The Sunset Rule does not specify which regulations, in the Department's view, "are prescribed by Federal Law such that the Department exercises no discretion" or which ones constitute "Sections whose expiration pursuant to this section would violate any other Federal law," two often-litigated topics. HHS itself does not appear to know. Of its 18,000 regulations, HHS merely stated it believed "the vast majority" are not exempt and would need to be Assessed and/or Reviewed under the Rule to prevent expiration. *Id*. at 5,740.

70. Even the Department's assessment of the Rule's impact is based on a guess about the number of exempted regulations. "To help estimate the impact of this final rule, the Department conducted a limited randomized sampling of its regulations and assessed

[36] The Sunset Rule also includes exceptions for certain regulations related to internal personnel management, military or foreign affairs, procurement, and regulations issued jointly with other agencies, as well as a handful of regulations that are already subject to review more frequently than every ten years. *See* 86 Fed. Reg. at 5,729-31. HHS similarly declined to specify which regulations fall within those exceptions.

whether the sampled regulations would be exempt from this final rule." *Id*. at 5,741. HHS sampled ten rulemakings—less than 0.3% of the 3,600 rulemakings the Department estimates contain its 18,000 regulations—and found that "[n]one of the sampled regulations would be exempt from this final rule." *Id*. at 5,741-42. The Department's best estimate, based on unspecified data from a libertarian think tank,[37] is that "approximately 66 parts of the CFR," which accounts for "less than 1% of the Department's active parts" are exempt from the Rule. *Id*. at 5,741.

71. The Sunset Rule's identification of exempted regulations is so vague that it does not satisfy the basic APA requirement to tell the public what the Rule does. *See* 5 U.S.C. § 553(b)(3) (agency must provide notice of "the terms or substance" of the rule).

IV. The Sunset Rule Is Unlawful, and the Department's Purported Justifications Lack Basic Rationality.

a. The Sunset Rule schedules elimination of regulations regardless of their impact on small entities and without RFA review or considerations required under substantive statutes and the APA.

72. Regulations "must always be grounded in a valid grant of authority from Congress." *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000).

73. The Department purportedly issued the Sunset Rule to "enhance the Department's implementation of" the RFA requirements in 5 U.S.C. § 610(a) to review regulations significantly impacting small entities. 86 Fed. Reg. at 5,694. Indeed, the Department titled the Rule "Securing Updated and Necessary *Statutory* Evaluations Timely" and claimed that its purpose was to "effectuate the desire for periodic retrospective reviews expressed in the RFA." *Id*. (emphasis added); *see also id*. at 5,704.

74. However, the Rule's amendment to 18,000 regulations to add expiration dates is neither consistent with, nor authorized by, the RFA. The RFA requires that

[37] HHS relies on "an analysis from the Mercatus Center," a libertarian "free-market" think tank, and cites generally to a non-government database website called Quantgov.org. 86 Fed. Reg. at 5,741 n.233. It is unclear what information from that database the Department is relying on.

agencies review their regulations that have "a significant economic impact upon a substantial number of small entities" "*to determine whether*" those regulations should be "continued without change, or should be amended or rescinded." 5 U.S.C. § 610(a) (emphasis added). Any such review "shall consider" five statutory factors, such as the continued need for the regulation. *Id*. § 610(b). Nothing in the RFA authorizes HHS to eliminate regulations that have a significant impact on small entities *without* consideration of the five RFA factors. Nor does it authorize the Department to schedule the elimination of regulations that *do not* have a significant impact on small entities. Nonetheless, by the Department's own estimate, 89% of the regulations it amended do not affect a substantial number of small entities. *See* 86 Fed. Reg. at 5,742. Such regulations are thus outside the category of "Necessary Statutory Evaluations," *id.* at 5,694, that the RFA authorizes and the Rule purports to target.

75. HHS also claimed that it had authority for the Rule under "the statutory authorities for the Department's existing regulations." *Id*. at 5,703. As in the Proposed Rule, HHS did not purport to include an exhaustive list of the authorities for amending each regulation. Instead, the Department simply referred to "[s]ome of the Department's primary rulemaking authorities," which "include" 21 U.S.C. § 371(a) of the Federal Food, Drug and Cosmetic Act; 42 U.S.C. § 1302 and 42 U.S.C. § 1395hh of the Social Security Act; and the Secretary's general authority to "prescribe regulations for the government of his department" under 5 U.S.C. § 301. *Id*. at 5,703.

76. These statutes do not authorize the automatic *elimination* of regulations. To the contrary, on many occasions, Congress has expressly directed HHS to issue regulations to implement statutory provisions, often specifying the timeframe on which HHS must act. For example, 42 U.S.C. § 1396a of the Social Security Act directs HHS to issue regulations defining the requirements for state plans under the Medicaid program, leaving the Department considerable discretion in the regulations' content. HHS is required to issue such regulations, and they are necessary for states to be able to participate in Medicaid. 42 U.S.C. §§ 1396a, 1396b. In a similar example, 42 U.S.C. § 655(f) generally

requires HHS to issue regulations establishing requirements that must be met by an Indian tribe to be eligible for grants funding services for needy families with children. In another, 42 U.S.C. § 289 mandates that HHS issue regulations governing biomedical research involving human test subjects. It requires generally that HHS establish "a program" and "a process," *id*, but the details of that program and process are set forth by regulation, *see* 45 C.F.R. part 46. And in another example, the Federal Food, Drug and Cosmetic Act requires certain chain restaurants to disclose food calorie content on their menus and directs HHS to "establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations." 21 U.S.C. § 343(q)(5)(H)(iii), (v). Yet regulations under such statutory provisions apparently do not fall within the Sunset Rule's exception for regulations "prescribed by Federal law" because HHS has discretion "as to what is prescribed" by the regulations. *See* 86 Fed. Reg. at 5,729, 5,764.

77. When these regulations automatically expire, as designed under the Sunset Rule, HHS will immediately be out of compliance with the relevant statute. *See, e.g.*, *Oxfam Am., Inc. v. SEC*, 126 F. Supp. 3d 168, 172-73 (D. Mass. 2015); *Sierra Club v. Johnson*, 374 F. Supp. 2d 30, 32 (D.D.C. 2005). The Sunset Rule therefore expressly sets HHS on a path to violate numerous statutory mandates.

78. The mass amendment of thousands of regulations to schedule their automatic elimination is also inconsistent with the APA and the regulations' underlying enabling statutes. The APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015). Agencies changing their policies must consider the "facts and circumstances that underlay or were engendered by the prior policy," and any "serious reliance interests . . . must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

79. For many of the estimated 18,000 regulations encompassed by the Rule, "the terms of the enabling statute . . . indicat[e] what relevant factors the agency must

consider in making its decision." *C.K. v. N.J. Dep't of Health & Human Servs*., 92 F.3d 171, 182 (3d Cir. 1996); *see also Pension Benefit Guar. Corp. v. LTV Corp*., 496 U.S. 633, 646 (1990). For example, the Nutrition Labeling and Education Act mandates that food products bear critical serving size and nutritional information, such as calories. 21 U.S.C. § 343(q)(1). HHS may issue regulations to add and remove nutrient information from food labels, but only if it determines either that the nutrient information will "assist" or "is not necessary to assist consumers in maintaining healthy dietary practices." *Id*. § 343(q)(2). In another example, 21 U.S.C. § 341 requires HHS under certain circumstances to "promulgate regulations fixing and establishing for any food" a "standard of identity" and a "standard of quality" or "reasonable standings of fill of container." When doing so, HHS must consider certain factors, such as the "need for necessary packing and protective material" and "the differing characteristics of the several varieties of [a] fruit or vegetable." *Id*.

80. To amend each individual regulation to schedule automatic rescission, therefore, HHS was required to consider the original need for, considerations giving rise to, statutory requirements of, continuing need for, extent to which members of the public rely on, and impact of automatic rescission of the existing regulation. The Sunset Rule did none of this for any of the estimated 18,000 regulations affected.

b. The Sunset Rule is arbitrary and capricious because, among other reasons, it purports to "incentivize" the Department to review regulations at an infeasible pace HHS has never achieved by eliminating regulations relied upon by the general public.

81. The Department's justification for the Sunset Rule is that because regulatory review under the RFA has previously been "deprioritized and relegated to rainy day activities," "the Department believes a stronger incentive is needed to achieve the benefits of retrospective review." 86 Fed. Reg. at 5,699-,700. The "incentive" is that thousands of regulations—many of them required by Congress and needed by Plaintiffs and the public—will disappear with no further process if federal employees and political officials at HHS are unable to, or choose not to, complete review.

82. This justification is irrational on its face. It seeks to motivate career federal employees and political officials to do something by planting a timebomb set to eliminate regulations to the detriment of *someone else*, often the most vulnerable citizens among us.

83. For example, 45 C.F.R. § 164.512(b)(1)(i) authorizes healthcare providers to disclose protected health information without a patient's consent to a public health authority for certain public health purposes. This regulation has been vital during Plaintiff County of Santa Clara's public health response to the COVID-19 pandemic (as well as that of public health departments around the nation). The Rule's supposed "incentive" works by taking away this and many other regulations that government entities like the County rely on, unless the Department's employees choose to take optional, time-consuming action.

84. HHS also fails to acknowledge that there is no realistic probability that the Department will be able to conduct the number of reviews required to prevent automatic rescission. Under the Department's estimates, *supra* ¶ 66, HHS would need to "perform roughly 3,440 Assessments in the first five years" (688 per year, on average) plus 378 Reviews to avoid mass regulatory expiration of up to 17,200 regulations in 2026. 86 Fed. Reg. at 5,741.

85. By its own admission, HHS has never been able to conduct retrospective review at this pace. Despite a host of executive orders and agency initiatives, "the Department has only conducted retrospective review to a very limited extent" and never at the pace originally planned. *Id*. at 5,696. For example, "the Department planned 83 retrospective analyses in 2012 and completed 33 analyses with final action by August 31, 2013." *Id*. In another attempt, "[a]s of July 2016, the Department had 40 planned retrospective analyses and by April 2017 had completed analyses with final action on 19 of them." *Id*. HHS has not provided any information supporting its assumption that it can increase its rate of retrospective review 20-fold simply by artificially creating consequences for third parties. Indeed, in the time HHS took to issue the Rule, the Department could not even identify the regulations subject to its requirement because that

was too "burdensome and resource intensive." *Id*. at 5,720. There is no factual support for the conclusion that it can now reasonably identify all the relevant regulations and conduct thousands of Assessments and Reviews in the coming years.

86. The Department's estimate of the work needed to undertake the required reviews is similarly arbitrary. HHS "assumes" that some regulations will take "40 to 100 hours" to review while others will take "between 250 to 500 hours" to review, but it provides no basis whatsoever for these estimates. *Id*. at 5,743. It is inconceivable to assume without explanation that the Rule's estimates are meaningful.

87. Based on just this cursory estimate, the Department calculates that it would take up to 45.6 full-time employees five years to complete the necessary review. *Id*. But HHS does not explain where the personnel would come from even under that unreasoned and very conservative estimate or what the effect will be on other Department priorities. HHS dismissed commenter concerns about diverting resources during the COVID-19 pandemic, stating that it "believes the pandemic will be over by" 2026 when the first round of mass eliminations is scheduled, *id*. at 5,705, ignoring its own assumption that the task would take all five years. Nor does the Rule explain how HHS could devote dozens of employees to full-time retrospective review without compromising the Department's and its sub-agencies' many other crucial tasks, such as protecting the country from future pandemics, facilitating provision of and access to healthcare, and ensuring food and drug safety.

88. The Department also fails to rationally explain its decision to apply the "incentive" to nearly all HHS regulations. As discussed above, *supra* ¶ 73, the Department's justification relies on its claimed need to implement the RFA. Yet the Rule schedules the elimination of thousands of regulations HHS "found to not be subject to the RFA." *Id*. at 5,742. The Department's only explanation for why it scheduled automatic elimination for the 89% of its regulations it assumes are *not* subject to the RFA is that HHS must do more work to know whether the RFA applies. *See id*. at 5,717, 5,742. However, instead of doing that work to determine the regulations covered by the RFA—an obvious

and far less burdensome alternative—HHS has now required a full Assessment of thousands of regulations *not* subject to the RFA in order to avoid their artificial elimination deadline.

89. Even the sources the Department cites as purported support for regulatory expiration provisions in general do not support the assumption that the "incentive" would work as intended. For example, HHS relies on the "experience" of certain states like North Carolina and Idaho with automatic expiration provisions. *Id*. at 5,700, 5,745. But HHS states that the circumstances in Idaho were not comparable, *id.* at 5,745, and notes that North Carolina and many other states have repealed their "sunset" laws because they are "expensive, cumbersome, and disappointing" *id*. at 5,700 n.76 (internal citation and quotation marks omitted). In another example, one of the reports that HHS claims illustrates the "benefits of sunset provisions," *id*. at 5,700, actually concludes that

> the benefits of sunset laws are largely intangible and likely insignificant compared to the costs. Moreover, the burdens of such mandatory reviews can draw staff away from performing other vital oversight duties. Generally, sunset requirements produce perfunctory reviews and waste resources.[38]

HHS also claims that the Administrative Conference of the United States "called for" retrospective review, 86 Fed. Reg. at 5,700, but the cited document only endorses retrospective reviews where agencies tailor the "level of rigor of retrospective analysis . . . to the circumstances," and "identify[] regulations that are strong candidates for review" based on specific factors that do not include the regulation's age since promulgation.[39]

90. HHS did not conduct any serious review of the harm the Sunset Rule causes to the public. It dismissed concerns about harm caused by automatic rescission by asserting it "has no intention to rescind regulations that appropriately protect the public

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[38] Jason A. Schwartz, Inst. for Policy Integrity, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemaking* 23-24 (Nov. 2010), https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf (footnotes omitted).

[39] Administrative Conference of the United States, Adoption of Recommendations, 79 Fed. Reg. 75,114, 75,115-17 (Dec. 17, 2014).

health or consumers." 86 Fed. Reg. at 5,725; *see also id*. at 5,708, 5,712. But the Rule does not codify that intention; the only thing it requires is rescission, which will occur unless the Department takes separate final agency action to prevent it. And it allows the Department to abandon any regulation simply by doing nothing, whether or not the public considers it "appropriate."

91. The Department's assessment of the cost to the public simply to monitor the review process and determine which regulations remain in effect is also poorly supported and irrational. Despite the unprecedented scope of automatic rescission, the "Department believes the cost of monitoring Assessments will be relatively trivial" because "the regulated community already monitors Regulations.gov." *Id*. at 5,744. This conclusion is inconsistent with the record. It ignores the massive increase to that burden due to the unprecedented scope of the Rule and the unique nature of the automatic expiration provisions, as well as the burdens on the *non-regulated* public—all concerns commenters raised. For example, commenters explained that they do not typically monitor Regulations.gov to determine whether long-established regulatory schemes will be automatically rescinded due to Department inaction. And they explained that because they lack clarity on which regulations are exempted, their monitoring costs will go beyond merely monitoring a website and now must involve finding out whether regulations never subjected to Assessments or Reviews have expired or not.

92. With respect to Reviews, the Department's regulatory impact analysis is based on the broad and unsupported assumption that its pace of Review, and the public's interest in Reviews, will match what has occurred in North Carolina, a state that repealed its automatic expiration provisions as "disappointing" and "expensive. *Id*. at 5,745, 5,700 n.76, 5,745. HHS "expects it will receive less interest in regulations that are rescinded" because that is what occurred with respect to unspecified regulations in that state. *Id*. at 5,745. But HHS does not explain how the regulations or circumstances in the state context are comparable to the extensive regulations covering significant parts of the national economy (as well as protection of life and well-being) promulgated by HHS. *Id*. The

Department's estimate that cost to the public of monitoring is between $52.2 and $156.7 million is similarly grossly underestimated and insufficiently supported. *Id*.

93. The Department's justification is based on irrational incentives and infeasible factual assumptions and is arbitrary and capricious.

V. The Sunset Rule Harms Plaintiffs and the General Public.

94. Absent any stays, the Sunset Rule will go into effect on March 22, 2021.[40] *Id*. at 5,694.

95. The Sunset Rule harms all Plaintiffs by scheduling elimination of nearly all HHS regulations that structure Plaintiffs' operations and businesses, delineate their obligations and rights, or protect their members and the populations they serve. Absent further Department action finalizing review of individual regulations, 18,000 regulations *will* expire on a rolling basis, beginning in 2026. Expiration is automatic, and preventing it is left to the sole discretion and resource constraints of HHS in finalizing—or not—Assessments and/or Reviews of each regulation.

96. The Sunset Rule also harms all Plaintiffs by creating substantial confusion and uncertainty in every aspect of their work that relates to areas regulated by HHS. While some regulations may ultimately remain in place under the Sunset Rule, it is impossible for Plaintiffs to know *which* regulations will remain in place because it all depends on whether the Department will actually be able, and choose, to complete review on time. Leading up to the expiration period, individuals and entities affected by HHS regulations will not know whether any particular regulation will continue beyond the expiration date. Even

[40] President Biden's Chief of Staff issued a memorandum to all agency heads on January 20, 2021, instructing them to consider, for rules that have been published in the Federal Register but have not taken effect, postponing the rules' effective dates for 60 days from the date of the memorandum, consistent with applicable law and certain specified exceptions, "for the purpose of reviewing any questions of fact, law, and policy the rules may raise." Memorandum from Ronald A. Klain, Assistant to the President and Chief of Staff, to the Heads of Exec. Dep'ts & Agencies, Regulatory Freeze Pending Review (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/. As of the filing of this Complaint, HHS has not issued a stay in response to this memorandum.

where HHS undertakes an Assessment or Review, Plaintiffs will have no assurance that review will be completed before expiration. And for the regulations potentially subject to the exception for "Sections prescribed by Federal law" the Rule creates significant uncertainty because HHS has not published a list of which regulations are excepted. Plaintiffs cannot know whether HHS considers any particular regulation to be "prescribed by Federal law such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section" or one "whose expiration pursuant to this section would violate any other Federal law." *See* 86 Fed Reg. at 5,764. The scope of this uncertainty affects many (and for some, nearly every) aspect of Plaintiffs' missions.

97. The Sunset Rule will also harm Plaintiffs and their members by forcing them to divert significant time and finite resources to amass evidence concerning the benefits of regulations that most affect them even before review occurs so that they can adequately ensure that necessary regulations remain in place. HHS expects that the public will "remind the Department" to conduct a Review "if the Review deadline is nearing and the Department has not commenced the Review," monitor its progress to help "safeguard against accidental expirations," gather facts and cost-benefit information, and comment in support of relevant regulations. 85 Fed. Reg. at 70,117; 86 Fed. Reg. at 5,748. Plaintiffs such as the County of Santa Clara simply cannot devote all the resources that would be necessary to undertake this intensive process for the hundreds to thousands of relevant HHS regulations subject to the Rule.

98. The Rule will also force Plaintiffs to divert significant time and resources to track each relevant regulation's progress, educate the public on the patchwork of obligations and protections at risk of expiration, and revise their advocacy strategies to ensure that essential regulations remain in place and combat the ill effects of expiration. HHS explicitly envisioned that the public would incur between $52.2 million and $176.3 million in costs to monitor the regulations and participate in the review process. This

estimate, while implausibly low, clearly confirms that the Sunset Rule places a substantial financial burden on Plaintiffs and other entities.

99. The Sunset Rule will also harm members of the general public, including the elderly, children, doctors and other healthcare workers, tribal members, and anyone who needs medical care, is affected by pandemics or disasters, or simply eats food. These individuals will suffer worse outcomes in terms of health and well-being if they lose protections under HHS programs. This, too, will increase the economic costs to Plaintiffs, who will need to devote more time, energy, and resources to finding ways to assist individuals absent these protections from the federal government.

a. County of Santa Clara

100. Thousands of HHS regulations that the County of Santa Clara relies on to operate the County's Hospitals and Clinics, Social Services Agency, Public Health Department, Behavioral Health Services Department, Valley Health Plan, and Emergency Medical Services Agency are scheduled to be automatically rescinded under the Sunset Rule. Indeed, the Rule sets expiration dates for more regulations governing more significant issue areas than the County can currently identify and count. Yet even the expiration of a single regulation—such as 45 C.F.R. § 164.512(b)(1)(i), the HIPAA exemption that permits healthcare providers to share information for public health response purposes—will cause colossal chaos and harm to the County and the communities and patients that it serves.

101. If the Rule takes effect, it will require significant additional administrative, logistical, and operational contingency planning by the County, and make it harder for the County to embark on new plans and activities. The potential expiration of thousands of regulations that HHS has maintained for years fundamentally destabilizes the County's reasonably settled expectations, which it relies upon to budget and plan. The Rule will force the County to roll back new planned services and support to its community because of the substantial risk that federal funding that the County depends upon will diminish or disappear. It will disrupt its ability to make new long-term commitments in physical

infrastructure, budgets, programming, human capital, research, services, outreach, public education, electronic systems, and much more.

102. The Rule also requires the County to prepare to offer healthcare services with lower or no reimbursements because payments and requirements under federal programs are scheduled to expire while the County's existing obligations—many of which are the subject of highly negotiated, long-term, multi-entity, complex contracts that cannot be amended without substantial lead time—remain the same. The County may be forced to rent or own facilities that are no longer certified, purchase goods and services that cannot be used, run programs for which no one is eligible, employ a healthcare workforce that is suddenly uncredentialed, and fill in the costs from missing federal funding on which it depends. The uncertainty and harms will be all the more profound because of the immense technical complexity of the industries that HHS oversees, the substantive statutes that it administers, and the regulations that the Rule subjects to impending expiration.

b. California Tribal Families Coalition

103. CTFC's member tribes are affected by many of the HHS regulations scheduled to be automatically rescinded under the Sunset Rule. CTFC's member tribes are independent governments that administer programs related to foster care, child welfare, healthcare, and public health. They receive mandatory funding to operate programs under HHS regulations. Automatic rescission of any, or all, of these regulations will harm CTFC's member tribes and their tribal members by eliminating protections and funding that they are entitled to under the Indian Self-Determination and Education Assistance Act.

104. CTFC's member tribes are also affected by HHS regulations governing the distribution of emergency supplies to tribes and tribal health clinics. For example, under "Project TRANSAM," a cooperative program between the Indian Health Service and the Department of Defense, tribes are entitled to receive medical supplies and other assets from closed military bases.[41] HHS regulations governing this program address

[41] *About Project TRANSAM*, Indian Health Service, https://www.ihs.gov/transam/abouttransam/ (last visited Mar. 8, 2021).

maintenance of asset integrity through proper storage, security, inventory management and reports, coordination between HHS and tribes, and issues related to emergency response requirements. Without this regulatory framework, equipment, supplies, and assets may not be deployed at all, much less in a safe and orderly manner.

105. CTFC's member tribes will suffer immediate and substantial harm if the Sunset Rule takes effect because of the extreme and unprecedented uncertainty it creates, particularly with respect to funding. The Sunset Rule's scheme—and its vague exemptions—make it impossible for the tribes to know which regulations that they rely upon for funding and supplies will soon disappear. The regulatory foundation of their healthcare and social program funding will be destabilized, making it difficult for the tribes to budget, hire staff, enter into contracts, or develop programs to protect tribal members. The funding uncertainty will also have a trickle-down effect on other tribal programs, such as social service programs that work with the tribal courts to protect vulnerable tribal members.

106. This level of uncertainty is the antithesis of the goals of the Department's Tribal Consultation Policy and would not exist if HHS had consulted with CTFC's member tribes. Consultation would have given CTFC's member tribes the opportunity to determine the degree of harm to their government operations and propose feasible means to avoid or mitigate them.

107. CTFC is also directly harmed by the Sunset Rule. CTFC must now expend significant resources to monitor thousands of existing regulations to determine whether they are amended by the Rule and whether HHS will choose to Assess and Review them. This will divert significant resources from CTFC's primary goal of advocating for the inclusion of tribal concerns in regulations to promoting the retention and possibly re-issuance of the complex regulatory schemes the tribes already rely upon. CTFC will need to spend more resources than ever before to be able to advise tribes on their funding eligibility, the regulations they must abide by, and the programs available to them. This harm to CTFC is exacerbated because member tribes have their own regulations and

programs that may differ in how they interact with HHS; CTFC will have to advise different members differently and advocate to HHS on multiple fronts at the same time. It will be impossible for CTFC to adequately advocate for all member tribes with respect to all HHS regulations that are amended by the Sunset Rule.

c. National Association of Pediatric Nurse Practitioners

108. Thousands of HHS regulations that govern the businesses and operations of NAPNAP's members are scheduled to be automatically rescinded under the Sunset Rule. Federal protections that govern NAPNAP's pediatric advanced practice registered nurses and protect children's health are wide ranging. They include regulations that ensure access to vaccines and other critical preventive services, ensure safe and effective pediatric medicines and therapies, protect children from the harms of tobacco, and allow children to access high-quality, affordable health care coverage. By HHS's own estimate, the Sunset Rule schedules rescission of thousands of regulations under Medicaid and the Children's Health Insurance Program alone. These include, for example, Medicaid's Early and Periodic Screening, Diagnostic and Treatment benefits, which defines the standard of pediatric care and covers an array of services like developmental, dental, vision and hearing screenings, and early diagnosis and treatment of health problems. In addition, regulations governing Home and Community-Based Services waivers, which thousands of children and youth with special health care needs depend on, are subject to automatic elimination under the Rule.

109. The Rule also imperils regulations that directly protect child health, such as regulations under the 2009 Family Smoking Prevention and Tobacco Control Act that regulate tobacco products to protect children and adolescents from the harmful effects of tobacco and e-cigarette use. Another example is regulations under the Vaccines for Children Program, which plays a key role in protecting America's children from vaccine-preventable diseases. These and many other regulations germane to NAPNAP's mission are now subject to automatic rescission provisions.

110. The Sunset Rule will create regulatory chaos and confusion that will burden NAPNAP's members and other pediatric providers with an uncertain and unpredictable practice environment. Critically important children's health regulations could expire en masse, while underlying statutes remain. The result is that states, health plans, and other stakeholders will lack clear guidance on how to follow the law and implement important programs, making it virtually impossible for NAPNAP's members to provide care with the assurance that they are complying with the law.

111. The Sunset Rule will also harm NAPNAP directly. As a professional membership association, NAPNAP has an obligation to provide its members with comprehensive, accurate information to help them provide evidence-based, high-quality care for their patients. If the rule takes effect, NAPNAP will have to expend significant additional resources to monitor, review, and provide expert comments on thousands of regulations affecting its members' ability to practice. This effort would force the association to reallocate resources, which are already stretched by loss of conference revenue and other activities during the COVID-19 pandemic. It would thus reduce its ability to meet its members' need for educational and professional clinical resources. This degree of burden is directly caused by the Rule.

d. American Lung Association

112. Thousands of HHS regulations across multiple sub-agencies germane to ALA's healthcare mission are scheduled to be automatically rescinded under the Sunset Rule. Medicaid and the Children's Health Insurance Program, two critical programs that provide healthcare for millions of individuals with or at risk of lung disease, are administered based on thousands of regulations subject to the Rule. Regulations establishing health insurance marketplaces—the sole place where individuals can access federal financial assistance—and market reforms governing individual and group market coverage are now at risk of disappearing all at once. Without further HHS action to prevent expiration, key regulations implementing the ACA will expire, including regulations that guarantee issuance and renewal of insurance coverage, protections for

people with preexisting conditions, and requirements for comprehensive treatment. Individuals with or at risk of lung disease, the population that ALA supports and represents, rely on these and many other HHS regulations for the provision and assurance of quality, affordable healthcare. Without these regulations, the health and access of these individuals will suffer.

113. Regulations germane to ALA's lung disease prevention mission are also scheduled to be automatically rescinded under the Rule. For example, in 2016, the FDA finalized a regulation asserting its authority over e-cigarettes, cigars, hookah, pipe, dissolvable, and other forms of tobacco products. 81 Fed. Reg. 28,973 (May 10, 2016). Such products are used by millions of people, including youth and young adults. If this regulation expires, as is required under the Sunset Rule unless HHS takes further action, these products will become unregulated and millions of people will be at new risk of becoming addicted to tobacco. ALA's smoking cessation programs will become much more costly and difficult to operate, forcing ALA to divert resources from its other activities. More importantly, it would lead to more disease and death and billions of increased healthcare costs. And because of the nature of the regulation, automatic rescission could trigger a domino effect of undermining regulations that rely on the authority asserted in the 2016 regulation.

114. If it takes effect, the Sunset Rule will cause immediate and irreparable harm to ALA. ALA will need to divert its resources from advocating for more protections for the population it serves to simply trying to ensure that existing protections are not lost. It will need to expend significant time and resources to monitor the progress of relevant regulations through the retrospective review process and to discern which regulations are subject to the Rule's exemptions. Its ability to advise its target population on available protections and its ability to promote the health of its target population will be severely hampered. It will need to expend additional resources through its programs, including its Lung Helpline, to help new users end their addictions.

e. Center for Science in the Public Interest

115. The Sunset Rule conflicts with, impairs, and frustrates CSPI's mission and activities. CSPI will be forced to divert substantial resources from other organizational priorities to ensuring that thousands of regulations do not expire or otherwise change in a way that jeopardizes CSPI's mission and the health and safety of millions of Americans.

116. Approximately 2,000 FDA regulations germane to CSPI's mission are scheduled to be automatically rescinded under the Sunset Rule. More than 800 of these regulations determine the conditions, if any, under which certain additives may be safely added to food. For example, 21 C.F.R. § 172.345 mandates that certain grain cereals be enriched with folic acid and is widely credited with preventing approximately 1,000 neural tube birth defects each year.[42] Another example is the 2015 FDA ban on the addition of artificial trans fats, a regulation issued after a 25-year CSPI public health campaign.[43] *See* 80 Fed. Reg. 34,650 (June 17, 2015). Other regulations subject to the Sunset Rule govern food labeling and transparency and food safety. For example, regulations under the Food Safety Modernization Act require companies to take specific actions to prevent food contamination. Such regulations give consumers confidence that they can purchase food without contracting a deadly foodborne disease.

117. Under the Rule, CSPI must now divert significant time to, among other things: (1) confirming whether and when Assessments are scheduled; (2) tracking the relevant regulations' progress through the Assessment process; (3) drafting comments during the regulations' Assessments to explain why Review is not required; (4) encouraging the Department to complete Assessments on time to avoid the dire

[42] Jennifer Williams *et al.*, *Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification — United States, 1995–2011*, CDC Morbidity and Mortality Weekly Report (Jan. 16, 2015), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a2.htm.

[43] *A Final Farewell to Artificial Trans Fat: Partially Hydrogenated Oil Increasingly Hard to Find as Companies Face Monday Deadline to Eliminate It*, CSPI (June 13, 2018), https://bit.ly/2MVs4Hp.

consequences of expiration; (5) drafting comments for regulations undergoing Review to explain their benefits; (6) encouraging the Department to complete Reviews on time to avoid automatic expiration; (7) drafting comments for any such regulations the Department proposes to rescind or amend; and (8) petitioning for re-issuance of any such regulations that expire under the Rule.

118. Each such comment or petition will require substantial research, drafting time, and internal review, in addition to efforts to mobilize members and other partner organizations. In its cost analysis, HHS estimates that it will take between 5 to 15 hours to write a comment. 86 Fed. Reg. at 5,745. In CSPI's experience, that is a tremendous underestimate. CSPI routinely spends at least 40 hours drafting and finalizing a comment. On complex rules, CSPI can spend 100 hours or more on a comment.

f. Natural Resources Defense Council

119. Dozens of regulations germane to NRDC's public health mission are scheduled to "expire" under the Sunset Rule. These include regulations governing the use of antibiotics in animal agriculture, food additives, bottled water safety, and the protection of human subjects in scientific research.

120. NRDC devotes considerable resources to advocating for these and other health-protective regulations at HHS, and to educating its members and the public about these regulations. For example, NRDC has successfully advocated for regulations limiting the presence of arsenic and other contaminants in bottled water, 21 C.F.R. § 165.110, and has worked to ensure the effectiveness of regulations governing the safety of chemicals in food packaging, *e.g.*, 21 C.F.R. Part 170 Subpart B. These regulations and others safeguard the health of NRDC members and the public. NRDC is also actively advocating for new regulations and improved oversight on a wide range of public health issues. For example, NRDC petitioned HHS to withdraw its approval of the preventative use of livestock antibiotics.

121. Under the Rule, NRDC will be forced to divert its limited resources from these advocacy efforts to rehash issues that have already been addressed by HHS. Among

other things, to prevent the regulations that protect its members from expiring, NRDC will now have to (1) compile a list of HHS regulations it does not wish to see expire; (2) calculate when those regulations will turn ten years old; (3) interpret the Sunset Rule's confusing exemptions to confirm that a particular regulation is subject to termination; (4) monitor the Department's Assessments and Reviews to know whether a certain regulation is under review; and (5) at some undefined time when the expiration date is nearing, submit a reminder to HHS that the regulation is due to expire. If HHS chooses to undertake an Assessment and/or Review of one of these regulations, NRDC will have to divert resources to submit comments, engage its members and activists, and otherwise ensure that health-protective regulations remain on the books. And if HHS instead does nothing and allows a regulation to expire, NRDC will have to divert resources to educate its members about the new risks to their health caused by this expiration and to petitioning HHS to re-promulgate that expired regulation. This will in turn force NRDC to divert significant resources from its advocacy and public education efforts in order to ensure that HHS does not allow health-protective regulations to expire.

122. The Sunset Rule also harms NRDC's members. Absent further voluntary action by HHS, many regulations protecting NRDC members' health will expire, increasing NRDC members' and their families' risk of harm from, for example, consuming contaminated food, being inadvertently exposed to food allergens, or using unregulated hand and body wash products.

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CLAIMS FOR RELIEF

COUNT ONE
(on behalf of all Plaintiffs)

The Sunset Rule Is *Ultra Vires* and Issued in Excess of Statutory Authority, in Violation of 5 U.S.C. § 706(2)(C), and Contrary to Law, in Violation of 5 U.S.C. § 706(2)(A).

123. Plaintiffs repeat and incorporate by reference each of the preceding paragraphs.

124. Under 5 U.S.C. § 706(2)(C), courts shall hold unlawful and set aside agency action that is taken in excess of statutory jurisdiction, authority, or limitations.

125. Under 5 U.S.C. § 706(2)(A), courts shall hold unlawful and set aside agency action that is not in accordance with law.

126. As a federal agency, HHS has no power to act unless Congress confers that power, and actions that are unauthorized by Congress or inconsistent with congressional discretion are *ultra vires*.

127. The Sunset Rule is *ultra vires* and issued in excess of HHS's authority because it modifies and schedules rescission of approximately 18,000 regulations, in reliance on the RFA, without the process required by the RFA.

128. The Sunset Rule is *ultra vires* and issued in excess of HHS's authority because it modifies and schedules rescission of regulations whose review is not authorized by the RFA.

129. The Sunset Rule is contrary to law because it schedules the automatic elimination of regulations that are required by statute, including, among other things, regulations issued under 42 U.S.C. § 1396a, 42 U.S.C. § 655(f), 42 U.S.C. § 289, and 21 U.S.C. § 343(q)(5)(H).

130. The Sunset Rule is further contrary to law because it modifies and adds expiration dates to approximately 18,000 regulations without providing the same level of process provided for the original regulations, including, among other things, assessing the impact of the change to each regulation being amended, the underlying statutory

requirements for each regulation, and the impacts of the regulatory uncertainty created by the amendments.

COUNT TWO
(on behalf of all Plaintiffs)

The Sunset Rule Is Arbitrary and Capricious in Violation of 5 U.S.C. § 706(2)(A).

131. Plaintiffs repeat and incorporate by reference each of the preceding paragraphs.

132. Under 5 U.S.C. § 706(2)(A), courts shall hold unlawful and set aside agency action that is arbitrary or capricious.

133. The Sunset Rule is arbitrary and capricious and lacks a rational basis because, among other reasons, it (a) eliminates public health regulations as a purported incentive for the Department to conduct RFA reviews; (b) assumes that HHS will conduct RFA reviews at an implausible pace it has not shown that it can achieve; (c) does not consider the extreme degree of regulatory uncertainty the Rule creates; (d) underestimates the burden imposed on Plaintiffs for monitoring HHS regulations to ensure they do not expire; (e) fails to consider the specific regulations being amended to automatically expire; (f) does not clearly identify which regulations have been amended and does not consider the impact of that ambiguity; (g) amends regulations not subject to RFA retrospective review requirements while exempting the Sunset Rule itself because it is not subject to the RFA; (h) fails to respond meaningfully to significant comments; and (i) fails to address alternatives proposed by commenters.

COUNT THREE
(on behalf of all Plaintiffs)

The Sunset Rule Violates the APA's Requirements for Notice-and-Comment Rulemaking under 5 U.S.C. §§ 553 and 706(2)(D).

134. Plaintiffs repeat and incorporate by reference each of the preceding paragraphs.

135. The APA requires this Court to hold unlawful and set aside any agency action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

136. The Sunset Rule is a "rule" under the APA because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). With exceptions not applicable here, the "agency process for formulating, amending, or repealing [such] a rule," *id.* § 551(5), must comply with the requirements of notice-and-comment rulemaking, *id.* § 553.

137. The APA requires that agencies provide "adequate time for comments" so that "interested parties [can] comment meaningfully." *Fla. Power & Light*, 846 F.2d at 771.

138. The Sunset Rule failed to comply with the requirements of notice-and-comment rulemaking by providing a limited period for notice and comment that was wholly unreasonable under the circumstances including, among other factors, the scope and impact of the Rule and the ongoing COVID-19 pandemic, and by unreasonably denying requests to extend the comment period.

139. The Sunset Rule further violates APA notice-and-comment requirements because it fails to inform the public which regulations are amended by the Rule to include expiration dates.

COUNT FOUR
(on behalf of Plaintiff CTFC)

The Department's Refusal to Conduct Tribal Consultation Violates HHS Policy and Is Arbitrary and Capricious in Violation of the APA, 5 U.S.C. § 706(2)(A).

140. Plaintiffs repeat and incorporate by reference each of the preceding paragraphs.

141. The United States recognizes Indian tribes as sovereign nations. The HHS Tribal Consultation Policy requires that the Department consult with tribes "[b]efore any action is taken that will significantly affect Indian Tribes," including those that "impose[] substantial direct compliance costs on Indian Tribes." HHS Tribal Consultation Policy at 3-4.

142. The Sunset Rule amends regulations that significantly affect the tribal members of Plaintiff CTFC and other Indian tribes, including regulations implementing the Indian Health Care Improvement Act and title IV–E of the Social Security Act, and regulations governed by the Indian Self-Determination and Education Assistance Act. The automatic expiration of these regulations and the uncertainty regarding their continued existence will impose significant costs on CTFC, its members, and other tribes. The process created by the Sunset Rule will also impose millions of dollars in costs on tribes simply to participate in the review of regulations affecting tribes.

143. HHS violated its Tribal Consultation Policy by refusing to consult with tribes before issuing the Sunset Rule.

144. The Department's refusal to consult with tribes was also arbitrary and capricious because it relied on the assumption that regulations affecting tribes will not be allowed to expire when that assumption is speculative and wholly infeasible. Indeed, by its terms, the Rule allows regulations to expire automatically and thus without consultation.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

a) declare that the Sunset Rule is arbitrary, capricious, contrary to law, adopted without observance of required procedure or consultation, and issued in excess of HHS authority;

b) vacate and set aside the Sunset Rule;

c) award eligible Plaintiffs their reasonable costs and attorneys' fees for this action; and

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d) grant all other relief this Court deems appropriate.

Dated: March 9, 2021

Respectfully submitted,

By: */s/ Lorraine Van Kirk*

James R. Williams (CA Bar No. 271253)
Greta S. Hansen (CA Bar No. 251471)
Douglas M. Press (CA Bar No. 168740)
Lorraine Van Kirk (CA Bar No. 287194)
Office of the County Counsel
County of Santa Clara
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
lorraine.van_kirk@cco.sccgov.org
Telephone: (408) 299-5900

Counsel for the County of Santa Clara

Samara Spence* (DC Bar No. 1031191)
Jeffrey B. Dubner* (DC Bar No. 1013399)
Sean A. Lev* (DC Bar. No. 449936)
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
sspence@democracyforward.org
jdubner@democracyforward.org
slev@democracyforward.org
Telephone: (202) 448-9090

Counsel for All Plaintiffs

Lisa S. Mankofsky* (DC Bar No. 411931)
Matthew Simon* (DC Bar No. 144727)
Center for Science in the Public Interest
1220 L Street, NW, Ste. 300
Washington, DC 20005
lmankofsky@cspinet.org
msimon@cspinet.org
Telephone: (202) 777-8381

Counsel for Center for Science in the Public Interest

**Pro hac vice application forthcoming*