

1 Samara Spence* (DC Bar No. 1031191)
Jeffrey B. Dubner* (DC Bar No. 1013399)
2 Sean A. Lev* (DC Bar. No. 449936)
Democracy Forward Foundation
3 P.O. Box 34553
4 Washington, DC 20043
sspence@democracyforward.org
5 jdubner@democracyforward.org
slev@democracyforward.org
6 (202) 448-9090

7 *Counsel for Plaintiffs*

8
9 **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

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN JOSE DIVISION

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

Plaintiffs,

23 vs.

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

Defendants.

Case No. 5:21-cv-01655

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

Administrative Procedure Act Case

28

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

	<u>Page</u>
INTRODUCTION.....	1
PARTIES.....	4
JURISDICTION AND VENUE.....	8
LEGAL AND STATUTORY BACKGROUND	9
I. The Administrative Procedure Act (“APA”).....	9
II. The Regulatory Flexibility Act (“RFA”)	9
FACTUAL ALLEGATIONS.....	10
I. HHS Regulates Healthcare, Disease Control, and Food and Drug Safety...10	
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.	12
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.....	15
b. HHS refuses to consult with Indian tribes despite the proposal’s effect on tribal programs and tribal funding.....	19
III. Under the Final Sunset Rule, Approximately 17,200 Regulations Are Set to Expire in 2026, but the Rule Does Not Specify Which Ones.	20
a. The final Rule requires that nearly all HHS regulations will expire unless HHS completes retrospective review for the thousands of affected regulations.	21
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.....	23
IV. The Sunset Rule is Unlawful, and the Department’s Purported Justifications Lack Basic Rationality.	24
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.....	24
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.	27
V. The Sunset Rule Harms Plaintiffs and the General Public.	32
a. County of Santa Clara	34
b. California Tribal Families Coalition	35
c. National Association of Pediatric Nurse Practitioners	37

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

d. American Lung Association.....38
e. Center for Science in the Public Interest.....40
f. Natural Resources Defense Council.....41
CLAIMS FOR RELIEF43
 COUNT ONE.....43
 COUNT TWO.....44
 COUNT THREE.....44
 COUNT FOUR.....45
PRAYER FOR RELIEF.....46

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

5 **INTRODUCTION**

6 1. Plaintiffs bring this action under the Administrative Procedure Act
7 (“APA”), 5 U.S.C. § 500 *et seq.*, and the Regulatory Flexibility Act (“RFA”), 5 U.S.C.
8 § 601 *et seq.*, to challenge a final rule recently issued by the U. S. Department of Health
9 and Human Services (“HHS” or “Department”) entitled “Securing Updated and Necessary
10 Statutory Evaluations Timely,” 86 Fed. Reg. 5694 (Jan. 19, 2021) (“Sunset Rule” or
11 “Rule”). Under the guise of an RFA plan for periodically reviewing preexisting
12 regulations that significantly impact small entities, the Sunset Rule amends nearly all HHS
13 regulations to include self-executing expiration dates. The Rule’s impact is vast and
14 unprecedented. Absent separate Department action, approximately 17,200 regulations will
15 “expire” in 2026, with additional regulations automatically terminating afterward.

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

26 ///

27 ///

28 ///

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

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

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

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.