IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY, *Plaintiffs*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No.: 4:21-cv-00003-BMM-JTJ The Honorable Brian Morris, Chief Judge

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT (RELIEF REQUESTED BY JANUARY 28, 2021)

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INTRODUCTION

Last Wednesday, the Environmental Protection Agency published a sweeping new rule that cripples the agency's ability to protect public health and the environment by fundamentally transforming the ways in which it may consider and rely on scientific evidence. The rule, under the guise of promoting "transparency," limits the EPA's discretion to consider research for which the underlying data are not available for validation. Because legal and ethical rules prevent publication of this data when it involves human subjects, the rule's effect—and, indeed, the evident purpose for adopting it—is to hinder consideration of exactly the sorts of epidemiological and other studies that are most critical to the development of environmental and public-health standards.

Over the past two and a half years, the proposed rule generated enormous controversy and almost one million public comments—including comments reflecting the unanimous view of the nation's leading scientific, public-health, medical, and academic institutions that the rule disregards accepted scientific standards and severely impedes the agency's ability to protect the public. Undaunted, the EPA's leadership overrode the objections of the agency's own top scientists and pushed through a final rule in the administration's waning days.

But the EPA went further still this past week, necessitating this expedited motion: The agency took the unusual (and unlawful) step of making the rule effective

immediately upon its publication in the Federal Register. It did this just two weeks before Inauguration Day, in an obvious attempt to prevent the incoming administration from postponing the rule's effective date to allow time for a judicial challenge and agency reconsideration. In doing so, the agency violated the Administrative Procedure Act. The APA is clear: It requires that, absent a showing of "good cause" or another specified exception, the publication of a substantive agency regulation "shall be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). This minimum period of public notice via publication, which Congress deemed among the APA's most important requirements, protects principles of fundamental fairness by affording the public time to prepare for—and, if necessary, challenge—regulations that affect them. Given the importance of this requirement, courts closely guard its narrow exceptions, limiting them to emergency situations.

One presidential administration's bare desire to tie the hands of another is not, of course, an emergency situation. The EPA does not claim otherwise. Instead, the agency claims that this sweeping and transformational new rule is merely procedural and therefore exempt from the 30-day notice requirement. And it claims to have established the requisite "good cause" under section 553(d)(3) of the APA to make the rule immediately effective because the rule's "goals of ensuring transparency and consistency" in scientific research are "crucial for ensuring confidence in EPA decision-making." *Strengthening Transparency in Pivotal Science Underlying Significant*

Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469, 472 (Jan. 6, 2021). But merely claiming that a rule has important goals cannot demonstrate good cause for depriving the public of notice. All agency regulations purport to advance some beneficial purpose; if that were enough, they would all be exempt from the APA's requirement. Instead, the question under section 553(d) is whether the EPA has evidence of some crisis in "confidence" that urgently required it to put this rule into effect, following two and a half years of heated controversy, on the eve of a change in administration. It does not. To the contrary, the overwhelming scientific consensus reflected in the record is that the rule *itself* threatens confidence in the EPA's decisions by forcing the agency to regulate without giving due weight to the best-available scientific evidence.

In this expedited partial summary-judgment motion, the plaintiffs—Environmental Defense Fund, Montana Environmental Information Center, and Citizens for Clean Energy—do not yet challenge the rule itself. At this stage, they seek only to set aside the EPA's decision to make the rule immediately effective. That unlawful decision injures the plaintiffs by eliminating the 30-day notice period in which they could petition the agency to postpone the rule's effective date to facilitate judicial review.

Because the agency lacked any valid basis to forgo the public notice mandated by the APA, the Court should declare that the rule will not become effective until

February 5, 2021—30 days after its publication date—as section 553(d) requires. And because the plaintiffs can only meaningfully petition the agency to postpone the rule by filing their petition with the agency in advance of that February 5 effective date, we respectfully request that the Court grant a partial final judgment to that effect under Rule 54(b) by January 28, 2021. Otherwise, the plaintiffs will permanently lose the opportunity to exercise their rights under the APA.

BACKGROUND

A. Statutory background

For more than 80 years, the Federal Register has provided a uniform system for notifying the public of regulatory actions. *See* 44 U.S.C. § 1501. In the Federal Register Act of 1935, Congress required publication in the Federal Register of all documents with "general applicability and legal effect." *Id.* § 1505(a). In doing so, Congress sought "to eliminate the problem of secret law" by making federal rules available to those affected by them. *Cervase v. Office of Fed. Reg.*, 580 F.2d 1166, 1171 (3d Cir. 1978).

Congress significantly expanded agencies' publication obligations in the Administrative Procedure Act by requiring publication in the Federal Register of proposed and final regulations. *See* Randy S. Springer, *Gatekeeping and the Federal Register: An Analysis of the Publication Requirement of Section 552(a)(1)(d) of the Administrative Procedure Act*, 41 Admin. L. Rev. 533, 535–36 (1989). These requirements establish the

public's right to timely knowledge and uniform access to government decisions. *See id.* Congress viewed them as "among the most important, far-reaching, and useful provisions" of the APA, designed to "take the mystery out of administrative procedure" by providing that the "general public, rather than a few specialists or lobbyists, is entitled to know or to have the ready means of knowing" it. *City of Santa Clara v. Andrus*, 572 F.2d 660, 674 (9th Cir. 1978).

The APA requires two primary forms of notice. First, it requires that, "[w]hen an agency decides to issue a rule, it must first publish a notice of proposed rulemaking in the Federal Register, which is the guide for those members of the public … who want to participate in the rulemaking process." *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1484 (9th Cir. 1992); *see also* 5 U.S.C. § 553(b). A "window of time, usually thirty days or more, is then allowed for interested parties to comment." *Riverbend Farms,* 958 F.2d at 1484. After "consideration of the relevant matter presented," the agency may adopt a final rule that includes a "concise general statement of [its] basis and purpose." 5 U.S.C. § 553(c). "The gestation period from initial notice to final rule can be a couple of months, and often much longer depending on the time the agency allows for comments and the time it takes to digest those comments." *Riverbend Farms,* 958 F.2d at 1484.

Second, the APA requires the agency, once a rule has been finalized, to publish the final rule in the Federal Register "for the guidance of the public." 5

U.S.C. § 552(a)(1). If the rule is a "substantive rule," section 553(d) requires that the agency make the publication "not less than 30 days before its effective date." 5 U.S.C. § 553(d). Thus, "[i]n addition to the time required for the notice and comment procedures to run their course, an additional thirty days ordinarily must pass between the time the final rule is published and the time it takes effect." *Riverbend Farms*, 958 F.2d at 1484. "This is sensible; until the final rule is published, the public is not sure of what the rule will be or when the rule will actually be promulgated." *Id.* at 1485. Section 553(d)'s 30-day notice requirement protects "principles of fundamental fairness which require that all affected persons be afforded a reasonable time to prepare for the effective date" of a new rule "or to take other action which the issuance may prompt." *United States v. Gavrilovic*, 551 F.2d 1099, 1104–05 (8th Cir. 1977). Those actions may include petitioning the agency to reconsider the rule or to "postpone the effective date" while a legal challenge is pending. 5 U.S.C. § 705; *see also Nance v. EPA*, 645 F.2d 701, 708–09 (9th Cir. 1981).

Congress enumerated only three limited exceptions to the 30-day notice requirement: (1) for "a substantive rule which grants or recognizes an exemption or relieves a restriction," (2) for "interpretative rules and statements of policy," and (3) "for good cause found and published with the rule." 5 U.S.C. § 553(d). Given the importance of the public-notice requirement, these exceptions are "narrowly construed and only reluctantly countenanced." *Alcaraz v. Block*, 746 F.2d 593, 612

(9th Cir. 1984). In particular, courts have limited "good cause" for setting aside notice to "emergency situations," and "examine closely proffered rationales justifying the elimination of public procedures." *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1157 n.6 (D.C. Cir. 1981). "Congress intended to impose upon an administrative agency the burden of showing a public necessity for an early effective date," and an agency therefore "cannot arbitrarily find good cause." *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1320 n.16 (8th Cir. 1981).

B. Regulatory background

Reliance on the best-available scientific evidence has long been "central in the network of laws addressing environmental pollution in the United States." Jonathan M. Samet & Thomas A. Burke, *Deregulation and the Assault on Science and the Environment*, 41 Ann. Rev. Pub. Health 347, 348 (Apr. 2020), https://perma.cc/S2YZ-N8P8 . "This evidence-grounded starting point has been critical in addressing the myriad sources of environmental pollution … [and] reducing the burden of disease attributable to environmental factors." *Id.* In particular, the EPA relies heavily on epidemiological studies demonstrating the health effects of pollution, chemicals, and other environmental exposures in developing regulations that protect human health. *See id.* at 352.

In its newly promulgated rule, the EPA seeks to change that. Under an innocuous-sounding title, "Strengthening Transparency in Pivotal Science

Underlying Significant Regulatory Actions and Influential Scientific Information," the rule—in the words of the EPA's Director of the Office of Science Advisor—"significantly limit[s] scientific studies the EPA considers in regulatory decision-making" by restricting the agency's discretion to consider research for which the underlying data are not available for independent validation. Dr. Thomas Sinks, *EPA's scientific integrity in question over science rule*, The Hill, Nov. 29, 2020. The rule would limit agency consideration of "[t]housands of epidemiological studies" that are critical in setting standards to protect the public but that "rely on personal information that, if disclosed, would violate laws that protect study participants." *Id.* The rule, for example, could limit "consideration of the pivotal study of the health impacts of air pollution"—Harvard's seminal Six Cities study—"because its data remain unavailable to the public, despite the fact the data have been reanalyzed and confirmed." *Id.*

The effort to restrict studies relying on non-public data "dates back more than 25 years to a strategy developed by tobacco and fossil fuel industry advisers to fight national air quality standards." Marianne Lavelle, *EPA's 'Secret Science' Rule Meets with an Outpouring of Protest on Last Day for Public Comment*, Inside Climate News (May 19, 2020), https://perma.cc/537Y-USJJ. "Industry advisers took an approach of raising doubts about the original scientific studies on the grave health risks" of pollution. *Id.* The strategy—known as "weaponized transparency"—was taken up by chemical

companies and other polluting industries as a means of delegitimizing the science behind environmental regulations. Samet & Burke, *Deregulation and the Assault on Science and the Environment*, 41 Ann. Rev. Pub. Health at 354–55. After the EPA proposed banning a widely used insecticide linked to brain damage in children, for example, the pesticide company CropLife America petitioned the agency to halt regulatory decisions based on science for which the raw data are not available. *See* Lavelle, *EPA's 'Secret Science' Rule*.

For many years, the strategy was unsuccessful. As the EPA explained in rejecting a challenge to its air-quality standards for soot: "If governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment." *National Ambient Air Quality Standards for Particulate Matter*, 62 Fed. Reg. 38652 (July 18, 1997). The D.C. Circuit upheld that conclusion. *See Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002). "[R]equiring agencies to obtain and publicize the data underlying all studies on which they rely," the court wrote, would be both "impractical and unnecessary." *Id.*

In 2018, however, the EPA reversed course. It proposed to "change agency culture and practices regarding data access" by "exercis[ing] its discretionary authority to establish a policy that would preclude it from using [non-public] data in

future regulatory actions." *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18769 n.3 (proposed Apr. 30, 2018). The agency asserted—without evidence—that the new limit on its discretion would "lead to better outcomes, and strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions." 83 Fed. Reg. 18770.

The proposal was met with overwhelming opposition by scientists both inside and outside the agency. The EPA's own Science Advisory Board warned that the rule "risks serious and perverse outcomes." Gupta Decl., Ex. B at 27. "[T]here are legitimate legal, ethical, professional and financial reasons," it wrote, "why researchers may be unable or unwilling to fully share 'data'—including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data." *Id.* at 26. The board noted that the EPA and scientific institutions have "recognized that such constraints on availability of data do not prevent studies from being verified in other ways—or preclude those studies from being considered in regulatory decisions." *Id.* It concluded that the agency had provided "minimal justification … for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate," or for how the rule would "improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner." *Id* at 27.

Dr. Thomas Sinks, then the Director of the EPA's Office of the Science Advisor with 35 years of experience as a federal-government epidemiologist, wrote a rare "differing scientific opinion" predicting that the rule will "create chaos." Lisa Friedman, *E.P.A.'s Final Deregulatory Rush Runs Into Open Staff Resistance*, N.Y. Times, Nov. 27, 2020. "Human subjects research is the most predictive data for establishing the human health impact from environmental exposures," he wrote, and disregarding or diminishing that research means "setting aside relevant science"—leading ultimately to "poorly developed rules." Gupta Decl., Ex. C at 3–4. The result, he concluded, will be to "compromise the scientific integrity of our scientists, the validity of our rulemaking, and possibly the health of the American People." *Id* at 4.

The EPA also received hundreds of thousands of public comments opposing the rule. The nation's leading scientific and medical organizations weighed in, writing that the rule would "cripple the EPA's ability to create new air and water protections." Friedman, *E.P.A.'s Final Deregulatory Rush Runs Into Open Staff Resistance*. In one comment, 39 of the nation's top scientific, public-health, medical, and academic institutions—including the American Association for the Advancement of Science, the world's largest scientific society—warned that the rule will "diminish the critical role of scientific evidence in decisions that impact the health of Americans" by "de facto rejecting credible practices used by the scientific community and replacing them with … an unscientific standard to assess the validity of science."

Gupta Decl., Ex. E at 2. It would mean, for example, that the EPA "will likely be unable to cite important studies on topics relating to the levels of contaminants in water, air and land; epidemiological studies that describe clinical markers of exposure or effect; and many other studies that are fundamental in understanding and protecting human health." *Id.* at 3. The rule, the institutions wrote, is "not about strengthening science, but about undermining the ability of the EPA to use the best available science in setting policies and regulations." *Id.* at 1. The result is to "put[] public health and the environment at risk." *Id.*

Plaintiff Environmental Defense Fund also strongly opposed the rule, writing that it "lacks any legal or factual basis; would undermine the scientific integrity of the agency's decisions; and would do deep damage to public health by blinding the agency to life-saving research and hobbling the agency's ability to carry out our nation's bedrock health and environmental laws." Gupta Decl., Ex. D at 1. The EPA, it wrote, failed to consider "the costs of the proposal for researchers, EPA, and the public; the numerous practical, legal, and ethical constraints that make it difficult or impossible for researchers to disclose data and models in many cases; and the effectiveness of reasonable alternatives to EPA's draconian proposal, including traditional methods of peer review and consultation with expert advisory boards." *Id.* at 3.

On January 6, 2021—two weeks before Inauguration Day—the EPA published its final rule in the Federal Register. The final rule targets scientific research relying on "dose-response data"—that is, "data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect." 86 Fed. Reg. 492 (to be codified at 40 C.F.R. § 30.2). Such research is central to the agency's development of public-health standards but, because it provides information about threats to human health, is likely to rely on confidential data from human subjects that cannot be disclosed. The rule binds the EPA's discretion by requiring it to give less weight to "pivotal science where the underlying dose-response data" are not "available in a manner sufficient for independent validation." *Id.* at 472.

Because the EPA regarded the rule as "purely a procedural rule," it did not "rely[] on any substantive environmental statutes" like the Clean Air Act as a basis for its authority, but "exclusively on its housekeeping authority" under the Federal Housekeeping Statute, 5 U.S.C. § 301. 86 Fed. Reg. 471–72. And, for the same reason, the agency decided to forgo the APA's 30-day notice period, instead providing that the rule would become effective immediately upon its publication in the Federal Register. *See id.* at 472. The notice requirement does not apply to the rule, the agency wrote, because it is not a "substantive rule" covered by section 553(d), but a "rule of Agency procedure." *Id.*; *see* 5 U.S.C. § 553(d) (limiting the requirement's application

to "substantive rule[s]"). Even "assuming arguendo that the delayed effective-date requirement of the Act applied," the agency "determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making [the] final rule effective immediately" because the rule's "goals of ensuring transparency and consistency in how the agency considers dose-response data" are "crucial for ensuring confidence in EPA decision-making." 86 Fed. Reg. 472.

C. The plaintiffs

The plaintiffs are the Environmental Defense Fund, Montana Environmental Information Center, and Citizens for Clean Energy—three nonprofit organizations dedicated to the preservation and enhancement of the natural environment and the protection of human health through advocacy informed by the best available science.

Environmental Defense Fund (EDF) is a national membership organization that relies on science, economics, and law to advocate for informed policy and decisionmaking to restore the quality of air, water, and other natural resources nationwide. Its members include research scientists who conduct cutting-edge scientific research into the determinants of human health. It also employs its own scientists who conduct epidemiological and public-health research, and upon whose research EDF relies for its science-informed advocacy.

Montana Environmental Information Center (MEIC) is a member-supported advocacy and public-education organization that works to protect and restore

Montana's natural environment, including through assuring that state and federal officials comply with and fully uphold laws designed to protect the State's environment and people from pollution and fossil-fuel development.

Citizens for Clean Energy (CCE) is a nonprofit membership organization of Montana citizens whose objective is to convince decisionmakers to adopt clean-energy solutions in order to preserve Montanans' health, lifestyle, and heritage and to protect Montana's land, air, water, and communities from the consequences of fossil-fuel development.

ARGUMENT

I. The EPA violated the APA's 30-day notice requirement.

A. The APA imposes a nondiscretionary obligation on agencies to publish a substantive rule at least 30 days before its effective date.

Congress in the Administrative Procedure Act required agencies to provide the public with notice of new "substantive" rules by publishing them in the Federal Register at least 30 days before they become effective. 5 U.S.C. § 553(d); *see Riverbend Farms*, 958 F.2d at 1484. The mandatory nature of that 30-day notice requirement follows from the statute's plain language. Congress required agencies to publish new rules in the Federal Register. 5 U.S.C. § 552(a)(1)(D). And it mandated that, with limited exceptions, an agency's "required publication … of a substantive rule *shall* be made not less than 30 days before its effective date." *Id.* § 553(d) (emphasis added). Congress's "[u]se of the word 'shall' generally indicates a mandatory intent unless a

convincing argument to the contrary is made." *Newman v. Chater*, 87 F.3d 358, 361 (9th Cir. 1996). Here, there is no reason to read "shall" as carrying anything other than its ordinary, obligatory meaning.

That conclusion is bolstered by Congress's creation of specific, limited exceptions to the notice requirement. Congress enumerated just three circumstances in which the 30-day notice is not required: (1) for "a substantive rule which grants or recognizes an exemption or relieves a restriction," (2) for "interpretative rules and statements of policy," and (3) "for good cause found and published with the rule." 5 U.S.C. § 553(d). These exceptions are "narrowly construed and only reluctantly countenanced." *Alcaraz*, 746 F.2d at 612. Congress's "express enumeration" of specific, narrow exceptions "indicates that other exceptions should not be implied." *In re Gerwer*, 898 F.2d 730, 732 (9th Cir. 1990).

B. The EPA's rule is a substantive restriction on the agency's discretion and thus subject to the 30-day notice requirement.

In its final rule, the agency claims that the rule is "exempt from the … delayed effective-date requirement[]" because it is not a "substantive rule" under section 553(d), but a "rule of Agency procedure." 86 Fed. Reg. 472; *see* 5 U.S.C. § 553(d) (limiting the requirement's application to "substantive rule[s]"). This Court, however, "need not accept [the] agency's characterization at face value" of a highly controversial rule that received almost a million comments as being limited to

internal agency procedure. *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1125 (9th Cir. 2009). The "critical factor" in determining whether a rule is substantive is "the extent to which the challenged [rule] leaves the agency … free to exercise discretion to follow, or not to follow, the [rule] in an individual case." *Id.* at 1124. A rule that "merely provides *guidance* to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make individualized determination[s]" is procedural. *Id.* But when a rule "narrowly limits administrative discretion or establishes a binding norm," it "effectively replaces agency discretion with a new binding rule of substantial law." *Id.*; *see CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003).

Here, the EPA's rule creates a limit on the agency's discretion by adding new provisions to the Code of Federal Regulations that limit, for the first time, the weight that the agency is authorized to afford to studies that rely on non-public data. In particular, the rule provides that the "EPA *shall* give greater consideration to pivotal science where the underlying dose-response data" are "available in a manner sufficient for independent validation." 86 Fed. Reg. 492 (to be codified at 40 C.F.R. § 30.5 (emphasis added)). When data are not so available, the agency "*will* give [the science] lesser consideration." *Id.* (emphasis added). And although the rule grants the Administrator authority to "grant an exemption" to the requirement, exemptions must be made "on a case-by-case basis" for one of five specific, enumerated reasons

documented in the record. *Id.* at 493 (to be codified at 40 C.F.R. § 30.7). In other words, the rule forecloses the EPA from considering the studies the rule targets on an equal footing with other available evidence.

Such a rule—which "binds … the agency itself with the force of law"—is a "substantive" rule subject to the 30-day notice requirement. *CropLife Am.*, 329 F.3d at 883. In *CropLife*, for example, the D.C. Circuit agreed with the pesticide company that the agency's announcement that it would no longer rely on third-party human studies should have been subjected to notice-and-comment rulemaking. *Id.* at 878. By "deem[ing]" such studies "immaterial in EPA regulatory decisionmaking," the court held, the rule "clearly establishe[d] a substantive rule." *Id.* at 883. The same is true here—the EPA's rule restricts the agency's discretion by requiring the agency to treat studies to which the rule applies less favorably than other studies. It, too, is thus substantive—the "opposite" of procedural. *Neighborhood TV Co., Inc. v. F.C.C.*, 742 F.2d 629, 637 (D.C. Cir. 1984); *see also Batterton v. Marshall*, 648 F.2d 694, 706 (D.C. Cir. 1980) (holding that a rule was substantive where it "conclusively determine[d] the unemployment statistics" on which the agency could rely); *id.* (noting that a rule was substantive when it "promulgated standards" that "determined the nature of satisfactory tests needed to obtain … approval for new drugs").

C. The agency has not shown good cause to forgo the 30-day notice period.

As a substantive rule, the EPA's rule is thus subject to section 553(d)'s mandatory 30-day notice requirement unless one of the section's narrow exceptions applies. The EPA relies on just one of those exceptions here: section 553(d)(3)'s exception for "good cause found and published with the rule." *See* 86 Fed. Reg. 472.

"Because the good cause exception is essentially an emergency procedure … it is narrowly construed and only reluctantly countenanced." *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 777 (9th Cir. 2018); *see also United States v. Gavrilovic*, 551 F.2d 1099, 1103 (8th Cir. 1977) ("[T]he 30-day period should be closely guarded and the good cause exception sparingly used."). "As the legislative history of the APA makes clear," the exception is not an "'escape clause[]' that may be arbitrarily utilized at the agency's whim." *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1156 . Rather, application of the exception "is generally limited to emergency situations, or where delay could result in serious harm." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018). "As a result, successfully invoking the good cause exception requires the agency to overcome a high bar," usually by showing that "delay would do real harm to life, property, or public safety." *E. Bay Sanctuary Covenant*, 932 F.3d at

777. This narrow construction ensures that "the exception will not swallow the rule." *Buschmann v. Schweiker*, 676 F.2d 352, 357 (9th Cir. 1982).[1]

The agency claims that it has good cause to make the rule immediately effective here "because immediate implementation of the rule, with its goals of ensuring transparency and consistency in how the agency considers dose-response data … is crucial for ensuring confidence in EPA decision-making." 86 Fed. Reg. 472. That reason falls far short of satisfying the "exacting" good-cause standard, for several reasons. *Nat. Res. Def. Council*, 894 F.3d at 114.[2]

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[1] The APA provides a second "good cause" exception, applicable to the Act's notice-and-comment requirements. *See* 5 U.S.C. § 553(b)(B) (excusing notice-and-comment rulemaking "when the agency for good cause finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest"). Because "different policies underlie" the two exceptions, they can sometimes "be invoked for different reasons." *Riverbend Farms*, 958 F.2d at 1485. "[W]hat may constitute good cause to forego one notice requirement may not satisfy the other." *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1156. Nevertheless, the government commonly relies on the same rationale to satisfy both exceptions, and courts commonly address them together. *See E. Bay Sanctuary Covenant*, 932 F.3d at 777 n.15 (noting that the court's "reasoning applies to both" exceptions); *see also, e.g.*, *United States v. Valverde*, 628 F.3d 1159, 1164–65 (9th Cir. 2010).

[2] The agency's assertion that "the rationale for delayed effectiveness … does not apply" here because the rule is "a procedural rule that only applies internally" is not a separate basis for the agency's finding of good cause. 86 Fed. Reg. 472. Section 553(d)'s good-cause exception requires an agency to find that it has an urgent need to forgo the 30-day notice period—not just that it has no reason *not* to forgo it. To conclude otherwise would turn the APA's notice requirement on its head, allowing agencies to put rules immediately into effect unless they have good cause to provide notice. Regardless, as explained above, the rule's new limits on the EPA's discretion are not procedural, but substantive. The EPA itself recognizes that the rule's effects are not limited to the agency: "Across EPA programs, much of the science that informs regulatory actions is developed outside the Agency," and the rule is thus of

1. To begin with, any "emergency" here would be one "of the agency's own making." *Id.* at 115. The EPA issued its notice of proposed rulemaking in April 30, 2018, and a supplemental notice of proposed rulemaking on March 18, 2020, but did not publish its final rule until January 6, 2021. *See* 86 Fed. Reg. 473. Given that the agency took more than two and a half years to finalize the rule, it cannot credibly claim an urgent need to make it effective thirty days earlier. *See Valverde*, 628 F.3d at 1166 (holding that an agency had not shown good cause where it "let seven months go by" before promulgating its rule). "Good cause cannot arise as a result of the agency's own delay." *Nat. Res. Def. Council*, 894 F.3d at 114–15; *see W. Oil & Gas Ass'n v. U.S. EPA*, 633 F.2d 803, 812 & n.12 (9th Cir. 1980) (holding that an agency failed to establish good cause where "there was time within which the process could have worked"). "[O]therwise, an agency unwilling to provide notice … could simply wait" until the last minute to "raise up the 'good cause' banner and promulgate rules without following APA procedures." *Nat. Res. Def. Council*, 894 F.3d at 114–15.

2. In any event, ensuring "confidence" in EPA's rules is not the sort of "emergency situation[]" that justifies setting aside the APA's notice requirement. *Nat. Res. Def. Council*, 894 F.3d at 114. "[S]uch emergency situations are … rare," and

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"interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity." 83 Fed. Reg. 18769, 18770. As explained below, the plaintiffs and their members are among those significantly affected by the rule.

courts "examine closely proffered rationales justifying the elimination of public procedures." *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1157 n.6. "Examples of such circumstances under which good cause existed include an agency determination that new rules were needed to 'address threats posing a possible imminent hazard to aircraft, persons, and property within the United States,' or were 'of life-saving importance to mine workers in the event of a mine explosion,' or were necessary to stave off any imminent threat to the environment or safety or national security." *N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 766 (4th Cir. 2012). In *Hawaii Helicopter Association v. F.A.A*, for example, the Ninth Circuit held that the Federal Aviation Administration had good cause to issue an emergency safety regulation in response to seven helicopter crashes over nine months. *See* 51 F.3d 212, 214 (9th Cir. 1995).

Courts have also found good cause in "situation[s] in which the interest of the public would be defeated by any requirement of advance notice," such as where announcement of a rule would enable evasion of its requirements. *N.C. Growers' Ass'n*, 702 F.3d at 767. Good cause has been found, for example, in cases involving government price controls, where advance notice would invite the very hoarding and price gouging that the controls were meant to prevent. *See Nat. Res. Def. Council*, 894 F.3d at 114 n.13. Whatever the agency's claimed justification, the question is "whether the need is so great and the emergency so defined that it justifies administrative rule

making without according the public the ordinary notice required by law." *Gavrilovic*, 551 F.2d at 1105.

The agency's purpose of "ensuring confidence in EPA rulemaking" does not demonstrate that sort of compelling need. "This is not a situation of acute health or safety risk requiring immediate administrative action. And it is not a situation in which surprise to the industry is required to preempt manipulative tactics." *Nat. Res. Def. Council*, 894 F.3d at 115. All the EPA's rule does is restrict discretion that the agency has always had to consider studies relying on non-public data. The possibility that the agency's longstanding discretion will remain intact for an additional 30 days is, simply put, not an "emergency." *Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) (holding that the "impending operation of a statute intended to limit the agency's discretion" was not an emergency that justified making a rule immediately effective). If there really were critical reasons for giving lesser weight to particular studies during the 30-day period, nothing would prevent the EPA from invoking that discretion to do so.

Indeed, the EPA's "finding" of good cause here amounts to nothing more than a vague statement of the agency's "goals" in adopting the rule in the first place. *See* 83 Fed. Reg. 18770 (stating the rule's purpose is to "strengthen public confidence in the health and environmental protections underpinning EPA's regulatory actions"). An agency's "[m]ere restatement" of a rule's purpose "cannot constitute a reasoned

basis for good cause" to set aside normal notice requirements. *United States v. Reynolds*, 710 F.3d 498, 512–13 (3d Cir. 2013); *see also Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980) (good cause "must be supported by more than the bare need to have regulations"). "Presumably, agencies deem all their rules beneficial." *Zhang v. Slattery*, 55 F.3d 732, 747 (2d Cir. 1995). The APA's notice requirement would thus "be a dead letter if compliance could be excused whenever the beneficial effect would thereby be accelerated." *Id.*; *see Valverde*, 628 F.3d at 1166 ("If 'good cause' could be satisfied by an Agency's assertion that normal procedures were not followed because of the need to provide immediate guidance and information," the "exception to the notice requirement would … swallow the rule.").

Good cause requires more. The agency must "point to something specific that illustrates a particular harm that will be caused by the delay"—that is, the agency must "explain why the harm targeted by the regulation will worsen unless" the APA's ordinary procedures are dispensed with. *Reynolds*, 710 F.3d at 513–14. The EPA's statement of the rule's "goals" here fails that test because it does not identify anything "that would make a failure to immediately implement the rule especially harmful." *Id.* at 513–14; *see Nat. Res. Def. Council v. Evans*, 316 F.3d 904, 906 (9th Cir. 2003) ("good cause requires some showing of exigency beyond generic" assertions). Thus, assuming that the agency's general goals justify its adoption of the rule, those goals

cannot justify adopting it "without according the public the ordinary notice required by law." *Gavrilovic*, 551 F.2d at 1105.

3. Even if the agency's reasons could satisfy the good-cause exception in theory, the agency has not shown good cause here. An "agency's perception of urgency, without any supporting evidence, … cannot constitute a reasoned basis for good cause." *Reynolds*, 710 F.3d at 512. Rather, an "agency invoking the good cause exception must make a sufficient showing that good cause exists." *E. Bay Sanctuary Covenant*, 932 F.3d at 778. The "burden is on the agency to establish" that the APA's normal requirements should not apply. *Nat. Res. Def. Council*, 894 F.3d at 113–14.

The EPA has not come close to meeting its burden here. The agency's claim of good cause rests on a one-sentence assertion that the rule is "crucial for ensuring confidence in EPA decision-making." 86 Fed. Reg. 472. The "mere recitation that good cause exists," however, cannot satisfy its burden. *Zhang*, 55 F.3d at 746. The agency has not provided any evidence to substantiate its assumption that peer-reviewed studies relying on unavailable data lack sufficient reliability to inform agency decisions. Nor has it identified even a single example of a decision that was flawed because of its reliance on research using such data, much less a crisis in public confidence so severe that it requires the rule's immediate adoption. *See Valverde*, 628 F.3d at 1166 (agency lacked good cause where it "cited no crisis of confusion … and no reason whatsoever to support an urgent need for guidance"). In the absence of

such "specific evidence of actual harm," the agency has failed to show good cause for avoiding the APA's notice requirement. *United States v. Cain*, 583 F.3d 408, 422 (6th Cir. 2009); *see E. Bay Sanctuary Covenant*, 932 F.3d at 777–78 (rejecting an agency's good-cause finding as "only speculative"); *Valverde*, 628 F.3d at 1167 (rejecting "conclusory speculative harms").

4. Finally, the agency does not even attempt to argue good cause based on what is transparently its true motive for setting aside the 30-day notice period—its desire to put the rule into effect before President-Elect Biden is inaugurated on January 20, 2021. During the final months of presidential administrations, federal agencies typically issue a large number of new regulations in a last-minute effort to cement the administration's policy agenda. *See* Congressional Research Service, *Midnight Rulemaking: Background and Options for Congress* 1 (Oct. 4, 2016). The APA creates a mechanism by which the public can petition an incoming administration to postpone the effective date of a rule that has been published in the Federal Register but has not yet taken effect—giving the administration time to review and possibly reconsider it. *See* 5 U.S.C. § 705 (authorizing an agency, in certain circumstances, to "postpone" a rule's effective date). A rule that is already in effect, however, cannot be "postpone[d]," and the agency can change its effective date only by conducting time-consuming notice-and-comment rulemaking. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017); *Nat. Res. Def. Council*, 894 F.3d at 113.

Because the EPA did not publish its final rule until January 6, 2021, honoring section 553(d)'s mandatory 30-day notice period would mean that the rule would not go into effect until at least February 5—giving the incoming administration a chance to postpone it under section 705. By purporting to make the rule effective immediately, the agency would tie the new administration's hands. A desire to bind a future administration, however, is not good cause for the agency to deprive the public of the notice the APA requires. "Elections have policy consequences," and the new administration is entitled to postpone and reconsider the EPA's last-minute rules as provided by the APA. *Organized Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc). The outgoing administration has no legitimate interest in preventing it from doing so. Just as an incoming administration's desire to reconsider regulations is not good cause for setting aside the APA's requirements, *see Nat'l Educ. Ass'n v. DeVos*, 379 F. Supp. 3d 1001, 1021 (N.D. Cal. 2019), an outgoing administration's desire to *prevent* reconsideration of those regulations is not either.

Regardless, the EPA has not invoked its desire to bind the new administration as a basis for bypassing the APA's requirements. Section 553(d)(3) exempts a rule from the notice requirement only for good cause that is "found" by the agency and "published with the rule." 5 U.S.C. § 553(d). The agency is thus "limited to the explanations it provided." *Nat'l Educ. Ass'n*, 379 F. Supp. 3d at 1021; *see Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("[A] reviewing court … must judge

the propriety of [agency] action solely by the grounds invoked by the agency" when it acted.). Accordingly, the outgoing EPA Administrator's desire to insulate the rule from postponement cannot serve as good cause here.

II. The plaintiffs have Article III standing to challenge the effective date of the EPA's rule.

An organization has standing if a challenged action frustrates its goals and requires that it expend resources it would otherwise have spent in other ways. *Comite de Jornaleros de Redondo Beach v. City of Redondo Beach*, 657 F.3d 936, 943 (9th Cir. 2011). And an organization has associational standing to sue on behalf of its members if "'(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.'" *Oklevueha Native Am. Church of Haw., Inc. v. Holder*, 676 F.3d 829, 839 (9th Cir. 2012) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). The second and third associational-standing requirements are readily met in this case because the suit seeks to protect interests that are unquestionably germane to the plaintiffs' organizational purposes, *see supra*, at 14–15, and individual participation is unnecessary where (as here) the suit does not seek damages. *See United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996). So the only question here is whether the plaintiffs have properly alleged that they or any of their members have standing to sue in their own right.

The plaintiffs have cleared that threshold here. They have standing because they and their members have "suffered a concrete and particularized injury that is either actual or imminent," the injury is "fairly traceable" to the defendants' unlawful conduct, and "it is likely that a favorable decision will redress that injury." *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007). Specifically, they have standing based on two cognizable injuries that they have suffered or will suffer as a result of the final rule's non-compliance with section 553(d). *First*, the plaintiffs and their members will suffer a cognizable procedural injury if the rule is allowed to remain in effect during the 30-day period because it would strip them of their right to petition the incoming administration to postpone the rule's effective date as "justice so requires." 5 U.S.C. § 705. *Second*, the plaintiffs' members will also suffer a substantive injury because the rule's non-compliance with section 553(d) will impose immediate negative financial and professional consequences on them.

A. The plaintiffs have satisfied Article III's injury requirement.

1. The plaintiffs and their members will suffer a cognizable procedural injury from the rule's unlawful effective date because they will be deprived of their right to petition the EPA to postpone the rule's effective date.

We begin with the procedural injury caused by the rule's unlawful effective date. "To establish an injury-in-fact, a plaintiff challenging the violation of a procedural right must demonstrate (1) that he has a procedural right that, if exercised,

could have protected his concrete interests, (2) that the procedures in question are designed to protect those concrete interests, and (3) that the challenged action's threat to the plaintiff's concrete interests is reasonably probable." *California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018). Each of these requirements is met here.

First, had the EPA acted lawfully and complied with section 553(d)'s minimum 30-day mandate, the plaintiffs and their members would be able to exercise a procedural right that could protect their concrete interests. In that scenario, the rule, published on January 6, 2021, would not take effect until at least February 5, and the plaintiffs in the meantime would have the right to petition the incoming administration to immediately "postpone the effective date" of the rule under the APA. 5 U.S.C. § 705. In contrast, a rule that is immediately effective leaves the plaintiffs with no opportunity to file such a petition, because a rule that is already in effect cannot be "postponed." *See Clean Air Council*, 862 F.3d at 9; *Nat. Res. Def. Council*, 894 F.3d at 113. And as long as the rule is not yet in effect, the new administration would very likely grant such a petition. Most modern Presidents, upon taking office, have closely examined any not-yet-effective rules, *see* Congressional Research Service, *Midnight Rulemaking: Background and Options for Congress* 1, and that is especially likely for a significant environmental rule so controversial that it garnered almost a million comments. Were the incoming administration to postpone the EPA's rule here, it would protect the plaintiffs' concrete interests because, not only would the

rule not go into effect pending judicial challenges—thereby allowing the plaintiffs and their members time to obtain grant funding, complete ongoing research, or adapt it to the rule's requirements—but it would *never* go into effect if those challenges succeed.

Second, the procedural right conferred by section 553(e), as well as section 553(d)'s 30-day requirement, are plainly designed to protect the plaintiffs' concrete interests. The procedural right exists because Congress recognized that "interested person[s]" have a stake in agency rulemaking, 5 U.S.C. § 553(e), and wanted them to have the tools necessary to protect their concrete interests. And the "primary purpose" of section 553(d)'s 30-day period was "to permit petitions for reconsideration and to afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt"—including exercising the right to petition the agency to immediately postpone the rule's effective date. *Nance v. EPA*, 645 F.2d 701, 708–09 (9th Cir. 1981) (cleaned up); *see also Rowell v. Andrus*, 631 F.2d 699, 703 (10th Cir. 1980).

Third, "the challenged action will threaten [the plaintiffs'] interests." *Cal. ex rel. Imperial County Air Pollution Control Dist. v. U.S. Dept. of the Interior*, 767 F.3d 781, 789–90 (9th Cir. 2014). By depriving the plaintiffs and their members of the procedural right to petition the EPA to postpone the rule's effective date, the challenged action threatens two distinct types of interests: the (1) financial and (2) professional and

organizational interests of the plaintiffs and their members in the EPA's according full weight to the best available science as a basis for significant regulatory actions and influential scientific information.

Financial interests. EDF members who are research scientists have concrete financial interests in being able to conduct scientific research that can be considered by EPA on an equal footing as a basis for informing significant regulatory actions or influential scientific information. The rule threatens these scientists' interests by placing them in a difficult double bind. If they decline to conduct research that relies on rule-compliant dose-response data, they will lose access to grant funding. But if they attempt to conform their research to the rule to ensure it receives the weight it is due, they will face different costs: the risk of alienating research-subject communities and the expense of reworking their research agendas to try to develop rule-compliant methods.

Consider the grant evaluation process used by the institutes and centers of the National Institutes of Health (NIH), on which many environmental and environmental-health researchers depend. *See* Birnbaum Decl. ¶¶ 6, 9. As federally funded programs, these institutes treat the ability to "contribute to the regulatory decisionmaking of federal agencies" as an "important factor" in deciding whether to fund a given research proposal, weighed as part of the "Significance" of the research. *Id.* ¶¶ 8, 10, 13. Under this metric, if research is "unlikely or unable" to form the basis

for informing a range of EPA activities because the underlying data cannot be made available, an application to conduct that research would be "noncompetitive and highly unlikely to receive a grant." *Id.* ¶¶ 12–13.

Diminished access to NIH funding will impose immediate and far-reaching financial consequences on EDF members who are research scientists. Dr. Jeremy Sarnat and Professor Johnnye Lewis, for instance, are currently preparing applications to NIH institutes—due in February 2021—to fund research involving sensitive dose-response data that cannot be disclosed (either to the public or via restricted access) because of the nature of the data, the communities with whom the researchers are working, or both. *See, e.g.*, Sarnat Decl. ¶¶ 7, 9–11 (panel study collecting detailed biometric, geographic, and geospatial data); J. Lewis Decl. ¶¶ 21, 23, 25 (toxicity study examining uranium contamination impacts on Laguna Pueblo and Navajo Nation populations). Both researchers have had success obtaining such funding in the past. *See* Sarnat Decl. ¶ 12; J. Lewis Decl. ¶¶ 3, 20, 26. But because the rule will severely constrain EPA's discretion to rely on the research these grants support, they are now unlikely to be funded—costing Dr. Sarnat and Professor Lewis millions of dollars in research funding and creating an "immediate financial crisis" in their labs. *See* J. Lewis Decl. ¶¶ 23, 25–26 ($10 million at stake); Sarnat Decl. ¶ 13 ($3–5 million in funding less likely to be awarded). These harms are not unique: funding from NIH and its institutes is typically "critical to the continued financial

viability of environmental health research centers." Birnbaum Decl. ¶ 9; *see also, e.g.*, Balmes Decl. ¶¶ 15–19 (difficulty recruiting cohort of undocumented children as a result of the rule would risk nearly a dozen jobs); Karagas Decl. ¶¶ 2, 12–13 (95 percent of research led in 2020 depended on NIH funding).

But if researchers instead attempt to produce rule-compliant research, they will face a different set of costs. Most significantly, they risk losing the trust of disadvantaged communities with which they work, such as Indigenous people, immigrants, and racial minorities. Because of historical mistreatment, members of these communities can be "very reluctant" to participate in scientific research "out of fear of how [their] information may be used, or misused." J. Lewis Decl. ¶¶ 10–11 (discussing the denial of treatment to participants in the Tuskegee Syphilis Study and research that included unauthorized genetic tests on Havasupai Tribe participants' biological samples); *see also* Balmes Decl. ¶¶ 9–10, 17–18 (discussing concerns of participants who are undocumented immigrants). As a result, EDF member scientists have found that it is "critical" to be able to "assure study participants that their participation and associated data will remain confidential"—and have spent "years of work" with specific communities, like Native American Tribes, to develop their trust. J. Lewis Decl. ¶¶ 11, 13, 15–16; Balmes Decl. ¶¶ 9–10, 18. That trust hinges not just on protecting data, but also on study participants' belief that their involvement will impact decision-making that benefits their communities. *See* J. Lewis Decl. ¶¶ 17–18;

Balmes Decl. ¶¶ 12, 18. For EDF members who work in these communities, the very act of seeking consent to disclose study participants' sensitive information risks shattering the delicate trust relationships they have built over time—an immeasurable loss that imperils future scientific work in the affected communities. *See* J. Lewis Decl. ¶¶ 18–19, 28–29; Balmes Decl. ¶ 18.[3]

And even if EDF members can navigate these challenges, they must expend time and resources to rework their research agendas to develop rule-compliant methods. For members whose research methods are flatly incompatible with disclosure to the public or the government, that may mean the grueling work of shifting to different methods entirely. *See, e.g.*, Balmes Decl. ¶ 16 (explaining that it is not possible to disclose cohort data without identifying unique human subjects); Sarnat Decl. ¶¶ 6, 15 (noting the need to shift research priorities); Karagas Decl. ¶ 15 (similar). Moreover, for members currently preparing grant applications or developing research cohorts, the rule imposes "the immediate challenge of scrambling to figure out how to rebuild" noncompliant studies to "somehow be able to answer" the key research questions "while accommodating both EPA

[3] The rule's allowance for researchers to make data available via "restricted access," *see* 86 Fed. Reg. 492, does not resolve the concern of individuals—or Institutional Review Boards—that data be kept confidential in general, including from the government and its agents. *See* Balmes Decl. ¶ 10 (noting the difficulty of obtaining Institutional Review Board approval when data cannot be kept confidential); J. Lewis Decl. ¶¶ 12–15 (similar).

requirements" and community concerns—all in the course of a few weeks. J. Lewis Decl. ¶¶ 15, 25; *see also* Sarnat Decl. ¶ 14; Balmes Decl. ¶ 17.

Professional and organizational interests. Further, the loss of the procedural right conferred by section 553(e) threatens EDF members' concrete interests in professional opportunities—and MEIC, CCE, and EDF's related organizational interests in advocacy based on the best available science. *See Sierra Club v. Trump*, 963 F.3d 874, 885–86 (9th Cir. 2020) (loss of research opportunities amounts to a concrete injury).

First, EDF members have professional interests in conducting high-quality scientific research that can inform all levels of EPA decision-making. They entered their fields and set their research agendas with the goals of uncovering the scientific determinants of health so that their work can inform regulation and public policy and lead to better health outcomes in the communities they study. *See* Karagas Decl. ¶ 5; Sarnat Decl. ¶¶ 5, 8; Balmes Decl. ¶ 4. For example, members have intentionally designed research agendas that focus on under-studied communities and communities facing acute health risks in the hopes of discovering unknown and little-understood health determinants. *See, e.g.*, Hoppin Decl. ¶¶ 6–8; J. Lewis Decl. ¶¶ 19, 21, 25. For many researchers, the point of making these discoveries is to ensure that policymakers can act to protect impacted communities. *See, e.g.*, J. Lewis Decl. ¶ 29; Karagas Decl. ¶ 15.

The new rule threatens these concrete interests. By devaluing research that depends upon human-subject confidentiality, the rule makes it less likely that researchers' work will achieve one of the most important measures of scientific impact—influencing significant EPA decision-making. *See supra.* To ensure that their research has its intended impact, scientists would have to compromise a host of other professional values, such as sacrificing the trust of subject communities, *see* J. Lewis Decl. ¶ 17–18; Balmes Decl. ¶ 18, or abandoning optimal research methods in favor of methods in which they have less expertise or which present less acute scientific need, *see, e.g.*, Sarnat Decl. ¶¶ 6, 14–15; J. Lewis Decl. ¶ 19. In many cases, this will simply be impossible—scientists will be unable to conduct the kinds of research they entered their fields to pursue and that their fields consider scientifically valuable, and will suffer further professional and reputational setbacks. *See* Sarnat Decl. ¶¶ 11, 14–16; J. Lewis Decl. ¶¶ 25, 28–29; Karagas Decl. ¶ 15.

And, apart from their members, MEIC, CCE, and EDF independently have concrete interests in EPA's full consideration of the best available science as a basis for significant regulatory actions and influential scientific information. All three plaintiffs have organizational missions that include ensuring that chemicals, pollutants, and other health determinants are regulated rigorously and in a manner that aligns with the best available science. *See* Levitan Decl. ¶¶ 4–5; Stith Decl. ¶ 7; Hedges Decl. ¶¶ 2–4; Liebert Decl ¶¶ 2–4. To advance these missions, the plaintiffs

regularly employ the best available science in their advocacy, including before the EPA. McPartland Decl. ¶¶ 7–14; Levitan Decl. ¶¶ 4–5; Stith Decl. ¶¶ 5–7; Hedges Decl. ¶ 3–4; Liebert Decl ¶ 3–4. The rule, however, makes this process more costly and less effective, requiring each organization to divert resources to evaluate whether studies could form a basis for EPA action or are candidates for an exemption, *see* McPartland Decl. ¶¶ 15–22, Hedges Decl. ¶ 9; Liebert Decl ¶ 8, and diminishing the usefulness of research conducted by scientists the organizations employ or work with, *see* G. Lewis Decl. ¶¶ 1, 8, 13–19; Hedges Decl. ¶¶ 5, 9.

The plaintiffs have additional concrete interests the Rule threatens as well. Not only do they and their members have professional interests in ensuring that EPA actions are based on the best available science and accord that science its proper weight, but their members also have concrete health, safety, and recreational interests of their own in the EPA's doing so. *See, e.g.*, G. Lewis Decl. ¶ 4; Stith Decl. ¶¶ 7, 9; Hedges Decl. ¶ 7, 10–11; Liebert Decl. ¶¶ 6, 9–10.

2. The plaintiffs will suffer additional injury as a result of the rule's unlawful effective date.

The plaintiffs and their members will also face direct, substantive injuries as a result of the rule. For instance, as discussed above, EDF members in the process of applying for grant funding or developing cohorts will face immediate financial expenses in conforming their research agendas to the rule—including the expense of reviewing and revising grant application materials, redesigning their studies,

disrupting established relationships by seeking permission to adjust confidentiality arrangements with sensitive populations, and preparing their labs and research centers for the risk that they will no longer receive funding. These injuries are "concrete and particularized," *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000), because they will directly impact each organizational member who depends on grant-giving organizations for research funding and EPA consideration for professional advancement. And they are not "conjectural" or "hypothetical," *id.*; with grant applications due in a month or less, organizational members face the immediate expense of digesting and attempting to conform their research to the rule's requirements. *See supra.*

B. The plaintiffs have satisfied Article III's causation and redressability requirements.

The last two requirements of standing (causation and redressability) are also readily satisfied here. For the plaintiffs' procedural injury, "[r]elaxed standards apply to the traceability and redressability requirements." *California*, 911 F.3d at 571. As the Supreme Court has explained, "a person who has been accorded a procedural right to protect his concrete interests" may "assert that right without meeting all the normal standards for redressability and immediacy." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (emphasis omitted) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 572 n.7 (1992)); *see also E. Bay Sanctuary Covenant*, 932 F.3d at 767 n.8. "When a litigant is vested with a procedural right, that litigant has standing if there is some

possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts*, 549 U.S. at 518. The plaintiffs "need not prove that the substantive result would have been different had [they] received proper procedure; all that is necessary is to show that proper procedure *could* have done so." *California*, 911 F.3d at 571; *see also Massachusetts*, 549 U.S. at 518 ("A litigant who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." (cleaned up)); *Ctr. for Biological Diversity v. Mattis*, 868 F.3d 803, 818 (9th Cir. 2017) ("Plaintiffs alleging procedural injury can often establish redressability with little difficulty, because they need to show only that the relief requested—that the agency follow the correct procedures—may influence the agency's ultimate decision of whether to take or refrain from taking a certain action." (cleaned up)); *Nat'l Res. Def. Council v. Jewell*, 749 F.3d 776, 782–83 (9th Cir. 2014) (en banc).

The plaintiffs easily satisfy these requirements. The deprivation of their procedural right (and the risk that this presents to their concrete interests) is fairly traceable to the EPA's violation of section 553(d)'s 30-day mandate. That injury, moreover, would be redressed by a partial final judgment declaring that the rule's effective date is unlawful and the rule may not go into effect before 30 days after

publication, and by an injunction prohibiting the agency from treating the rule as if it were in effect during the 30-day period. And, if this Court grants relief in time, there is at least "some possibility" that the incoming administration, during that 30-day period, would grant the plaintiffs' petition to immediately postpone the rule's effective date, and thereby protect the plaintiffs' concrete interests. *See Massachusetts*, 549 U.S. at 518. Indeed, President-Elect Biden's transition team has already announced an interest in closely examining agency rules that will not have taken effect by Inauguration Day. *See* Jonathan Easley, *Biden aims to freeze Trump's 'midnight regulations,'* The Hill, Dec. 30, 2020, http://bit.ly/3bom4Xo.

By the same token, the plaintiffs' substantive injuries-in-fact also satisfy the ordinary causation and redressability standards applicable to such harms. *See Lujan*, 504 U.S. at 560–61. For instance, the expense of navigating the double-bind the rule imposes—including the expense of scrambling, with no warning and no time to prepare, to review and revise grant application materials, redesign studies, disrupt established relationships by seeking permission to adjust confidentiality arrangements with sensitive populations, and prepare their labs and research centers for the risk that they will no longer receive funding—on a precipitous timeline is the unavoidable result of EPA's violation of section 553(d)'s 30-day mandate. Had EPA complied with that mandate, EDF members would have had time to submit grant applications due before the rule took effect, consider other funding options, or obtain

immediate postponement of the rule's effective date—all of which would have avoided some of the rule's expense. *See Juliana v. United States*, 947 F.3d 1159, 1169 (9th Cir. 2020) ("Causation can be established even if there are multiple links in the chain, as long as the chain is not hypothetical or tenuous." (cleaned up)). And it is likely that a timely and favorable decision will redress this injury by delaying temporarily—and possibly forever—the need to adapt research to the new rule's requirements.

III. This Court should remedy the EPA's violation of the law by declaring the rule's effective date to be 30 days from its date of publication.

Because the EPA lacks good cause, or any other valid basis, for forgoing section 553(d)'s 30-day notice requirement, the agency violated the APA when it provided that its rule would be effective immediately upon publication. The remedy in cases like this one—where an agency has failed to comply with section 553(d)—is to "deny[] such a rule effectiveness for the mandated 30 days, allowing it to take effect in full thereafter." *Prows v. Dep't of Justice*, 938 F.2d 274, 275 (D.C. Cir. 1991); *see also Gavrilovic*, 551 F.2d at 1106 (holding that, where an agency's justification for "waiv[ing] the statutory waiting period under [section] 553(d) [was] inadequate," the rule was "not effective until 30 days after … publication in the Federal Register"); *Lewis-Mota v. Sec'y of Labor*, 469 F.2d 478, 482 (2d Cir. 1972) (declaring an agency decision "invalid until 30 days after it was actually published … but valid thereafter").

Accordingly, the Court should declare that the rule will not become effective until February 5, 2021—30 days after its January 6 publication in the Federal Register. Moreover, the only way for the plaintiffs to meaningfully petition the agency under the APA to further postpone, and ultimately to reconsider, the rule is by filing their petition before that February 5 effective date. To allow the plaintiffs an opportunity to do so, and the agency a sufficient opportunity to consider the petition, we therefore respectfully request that the Court "expressly determine[] that there is no just reason for delay," Fed. R. Civ. P. 54(b), and grant a partial final judgment on the plaintiffs' section 553(d) claim by January 28, 2021.

CONCLUSION

The plaintiffs' motion for partial summary judgment should be granted. The Court should hold unlawful and set aside the EPA's decision to make the rule effective immediately, and should declare that the rule is ineffective until 30 days from the date the rule was published in the Federal Register. To ensure that the plaintiffs have a meaningful opportunity to exercise their right to petition the EPA before the rule becomes effective, we respectfully request that the Court grant a partial final judgment under Rule 54(b) to that effect by January 28, 2021.

January 11, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2021, I electronically filed this brief in support of the plaintiffs' motion for summary judgment through this Court's CM/ECF system. I understand that notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

January 11, 2021

/s/ Derf Johnson
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