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.

COMPLAINT

EXPEDITED RELIEF SOUGHT

INTRODUCTION

This is an action under the Administrative Procedure Act challenging the lawfulness of a sweeping new rule published in the Federal Register last Wednesday, January 6, 2021. The new rule will cripple the Environmental Protection Agency's ability to protect public health and the environment by fundamentally transforming the ways in which the agency may consider and rely on scientific evidence. Under the guise of promoting "transparency," the rule will limit the EPA's discretion to consider research for which the underlying data are not publicly available. Because legal and ethical rules prevent making data involving human subjects available to the

public—or available through "restricted access"—the rule hinders consideration of exactly the sorts of epidemiological and other studies that are most critical to the development of public-health standards. Overriding the objections of the EPA's own top scientists, the agency's leadership pushed the rule through in the administration's waning days and took the unusual step of making it effective immediately upon publication. Both the rule itself and its immediate effective date exceed the agency's statutory authority.

First, as authority for enacting the rule, the EPA relied solely on the Federal Housekeeping Statute, 5 U.S.C. § 301, which the agency claims gives it the "authority to promulgate housekeeping regulations governing its internal affairs." Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469, 471 (Jan. 6, 2021). Although the EPA is not one of the Executive departments listed in that statute, it contends that such authority was later extended to it. *Id.* Moreover, the statute only authorizes agencies to enact rules that "govern internal ... affairs." Chrysler Corp. v. Brown, 441 U.S. 281, 309 (1979). The EPA's authority under the statute thus depends on two assumptions—that the rule "is a procedural rule within the scope of the EPA's housekeeping authority," and that the EPA has that authority in the first place. *Id.* at 472. But both assumptions are wrong. The critical question in determining whether a rule is procedural is whether it leaves the agency with discretion to disregard the rule in an individual case. The entire purpose of the EPA's new rule here is to *constrain* the agency's discretion to consider scientific research—a substantive restriction. And EPA lacks housekeeping authority in any event. Because the agency thus lacked authority to enact the rule under the housekeeping statute—the only source of authority it invoked—the rule is unlawful and this Court should set it aside.

Second, the agency took the unusual and unlawful step of making the rule effective immediately upon its publication in the Federal Register last Wednesday. But the Administrative Procedure Act requires that, absent a showing of "good cause" or another specified exception, the publication of a new "substantive" rule "shall be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). In concluding that the rule is exempt from this requirement, the EPA repeats its error of treating its sweeping and transformational rule as just "procedural" rather than substantive. It also claims to have established the requisite "good cause" under section 553(d)(3) because the rule's "goals of ensuring transparency and consistency" in scientific research are "crucial for ensuring confidence in EPA decision-making." 86 Fed. Reg. 472. 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 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 more than two and a half years, 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. Because the agency's decision to make the rule immediately effective thus violates the APA, the Court should declare that it will not become effective until February 5, 2021—30 days after its publication date. And the Court should ultimately set the rule aside.

PARTIES

- 1. Plaintiff Environmental Defense Fund is a national membership organization that relies on science, economics, and law to advocate for informed policy and decision-making to restore the quality of air, water, and other natural resources nationwide. Its members include 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.
- 2. Plaintiff Montana Environmental Information Center is a membersupported 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 environment and Montana citizens from pollution and fossil-fuel development.

- 3. Plaintiff Citizens for Clean Energy, Inc. is a nonprofit 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.
- 4. Defendant U.S. Environmental Protection Agency is an agency of the United States within the meaning of the APA. Defendant Andrew R. Wheeler is Administrator of that agency. He is sued in his official capacity.

JURISDICTION AND VENUE

- 5. Because this case arises under the APA, this Court has jurisdiction under 5 U.S.C. § 702 and 28 U.S.C. § 1331.
- 6. Venue is proper in this Court because plaintiffs Citizens for Clean Energy and Montana Environmental Information Center maintain their principal place of business in this district and are thus residents of this district for purposes of venue. *See* 28 U.S.C. § 1391(e)(1)(C). Divisional venue is proper in the Great Falls Division under L.R. 3.2(b) and Mont. Code. Ann. §§ 25-2-118, 25-2-125 because plaintiff Citizens for Clean Energy resides in this division at the time of the commencement of this action.

STATUTORY BACKGROUND

- 7. The Federal Housekeeping Statute provides that the head of certain Executive departments "may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301; see also id. § 101. The statute's purpose is to grant specified Executive departments the authority to enact rules that "govern internal ... affairs." Chrysler Corp. v. Brown, 441 U.S. 281, 309 (1979). Accordingly, the statute authorizes "what the APA terms rules of agency organization procedure or practice as opposed to substantive rules." Id. at 310 (cleaned up).
- 8. The Administrative Procedure Act requires an agency, once a new 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). Congress enumerated only three limited exceptions to this 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). The 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) (cleaned up). Those actions may include petitioning the agency to reconsider the rule or to postpone its effective date while a legal challenge is pending. *See* 5 U.S.C. § 705.

FACTUAL ALLEGATIONS

- 9. On April 30, 2018, the EPA published in the Federal Register a notice of proposed rulemaking for a new rule, titled "Strengthening Transparency in Regulatory Science." See 83 Fed. Reg. 18768, 18768 (proposed Apr. 30, 2018). The notice requested public comment on a rule that would "direct the EPA to ensure" that the scientific research "underlying its actions is publicly available in a manner sufficient for independent validation." 86 Fed. Reg. 473 (describing the 2018 proposal). As authority for the rule, the agency proposed relying on a variety of environmental statutes, such as the Clean Air Act, that it is charged with administering. See 83 Fed. Reg. 18773. The EPA published a supplemental notice of proposed rulemaking on March 18, 2020. See 86 Fed. Reg. 471–72; Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 15396 (proposed Mar. 18, 2020).
- 10. After signing a final rule on December 30, 2020, the EPA announced it on January 5, 2021, and published it in the Federal Register the next day. The final rule "describes how the EPA will determine the consideration to afford pivotal science of the EPA's significant regulatory actions and influential scientific

information." 86 Fed. Reg. 469. Specifically, the rule adds new provisions to the Code of Federal Regulations that limit, for the first time, the agency's discretion to afford appropriate weight to studies that rely on non-public "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." Id. at 492 (to be codified at 40 C.F.R. § 30.2). The new provisions provide that the "EPA" shall give greater consideration to pivotal science where the underlying doseresponse data" are "available in a manner sufficient for independent validation." Id. (40 C.F.R. § 30.5). When the underlying data are not so available, by contrast, the agency "will give them lesser consideration." Id. The rule grants the Administrator only limited authority to "grant an exemption" to the requirement, "on a case-bycase basis," for one of five specific, enumerated reasons documented in the record. *Id.* at 493 (40 C.F.R. § 30.7).

11. Research relying on dose-response data is central to the EPA's development of standards to protect public health. But, because that research provides information about threats to human health, it is likely to rely on confidential data from human subjects that cannot be publicly disclosed (or data that cannot otherwise comply with the rule). The new rule—in the words of a top EPA scientist—therefore "significantly limit[s] scientific studies the EPA considers in regulatory decision-making" by limiting the agency's discretion to consider "[t]housands of

epidemiologic studies" that are critical to public-health standards but that "rely on personal information that, if disclosed, would violate laws that protect study participants." Thomas Sinks, *EPA's scientific integrity in question over science rule*, The Hill, Nov. 29, 2020.

- 12. In contrast to the EPA's initial notice of proposed rulemaking, the agency in its final rule relied "exclusively on its housekeeping authority" under the Federal Housekeeping Statute, 5 U.S.C. § 301, as authority for the rulemaking. 86 Fed. Reg. 471–72. The agency deemed the rule as one that only "governs internal agency procedures for determining the consideration to afford various studies." *Id.* at 472. Because it thus viewed the rule as "purely a procedural rule ... within the scope of the EPA's housekeeping authority," the agency wrote that it was no longer "relying on any substantive environmental statutes as authority." *Id.*
- 13. Based on its view that the rule is purely procedural, the EPA also asserted that its rulemaking was "exempt from the ... delayed effective-date requirements set forth in" section 553(d) of the APA. *Id.* Accordingly, it provided that the "final rule is effective on January 6, 2021"—its date of publication in the Federal Register. *Id.* at 470.
- 14. Assuming "arguendo," however, "that the delayed effective-date requirement of the Act applied," the EPA stated that it "determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making this final rule effective

immediately." 86 Fed. Reg. 472. The agency claimed that "immediate implementation of the rule, with its goals of ensuring transparency and consistency in how the agency considers dose-response data underlying pivotal science to be used in significant regulatory decisions and influential scientific information, is crucial for ensuring confidence in EPA decision-making." *Id*.

of 30 days or more required by section 553(d)—can petition an agency to "postpone" the effective date of a rule that has been published in the Federal Register but has not yet taken effect. See 5 U.S.C. § 705. The plaintiffs had intended to exercise their right to do so by asking the EPA to postpone the rule's effective date to give it time to reconsider the rule. A rule that is already in effect, however, cannot be "postpone[d]." See Clean Air Council v. Pruitt, 862 F.3d 1, 9 (D.C. Cir. 2017); see Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin., 894 F.3d 95, 113 (2d Cir. 2018). The EPA's decision to make the rule effective immediately on publication therefore deprives the plaintiffs of the ability to seek postponement.

CLAIMS FOR RELIEF

COUNT ONE

(ACTION UNDER THE ADMINISTRATIVE PROCEDURE ACT FOR A DECLARATION THAT THE EPA'S RULE IS UNLAWFUL AND INJUNCTIVE RELIEF TO PREVENT ITS ENFORCEMENT)

16. This Court must judge the agency's action "solely by the grounds invoked by the agency" when it acted. SEC v. Chenery Corp., 332 U.S. 194, 196 (1947).

Here, the EPA relied "exclusively on its housekeeping authority" under the Federal Housekeeping Statute, 5 U.S.C. § 301, as authority for adopting the rule. 86 Fed. Reg. 471–72.

- 17. The housekeeping statute provides specified Executive departments with authority only to adopt "procedur[al]" rules—not "substantive" ones. *See Chrysler Corp*, 441 U.S. at 309–10. But the EPA is not one of those departments. *See* 5 U.S.C. §§ 101, 104. And because the EPA's rule "binds ... the agency itself with the 'force of law" by limiting the agency's discretion to consider scientific studies, it is a "substantive" rule. *See CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003). The agency therefore lacks authority to enact it. *See United States ex rel. O'Keefe*, 132 F.3d 1252, 1255 (8th Cir. 1998).
- 18. The agency's adoption of the rule is therefore "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" as well as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the APA. 5 U.S.C. § 706(2)(A), (C).

COUNT TWO

(ACTION UNDER THE ADMINISTRATIVE PROCEDURE ACT FOR A DECLARATION THAT THE EPA'S DECISION TO MAKE THE FINAL RULE EFFECTIVE ON PUBLICATION IS UNLAWFUL UNDER 5 U.S.C. § 553(d) AND INJUNCTIVE RELIEF TO PREVENT ENFORCEMENT UNTIL AT LEAST 30 DAYS FROM PUBLICATION)

- 19. The APA mandates that "[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date." 5 U.S.C. § 553(d).
- 20. The EPA's final rule is a "substantive rule" that is subject to the notice requirement.
- 21. The EPA, however, made the rule effective immediately on its publication in the Federal Register, rather than at least 30 days later.
- 22. None of the exceptions to section 553(d) applies. The EPA relies only on the exception for "good cause found and published with the rule." 5 U.S.C. § 553(d)(3). 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. But ensuring "confidence" in EPA decision-making is not the sort of emergency situation that justifies forgoing public notice. The agency's justification just restates the rule's purpose, which "cannot constitute a reasoned basis for good cause." *United States v. Reynolds*, 710 F.3d 498, 512–13 (3d Cir. 2013). All the more so because it is

the rule itself that threatens confidence in EPA decision-making by inhibiting the agency's consideration of the best available scientific evidence.

- 23. 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 than statutorily required. "Good cause cannot arise as a result of the agency's own delay." *Nat. Res. Def. Council*, 894 F.3d at 114–15.
- 24. The agency's decision to make the rule effective immediately and its finding of "good cause" to disregard section 553(d)'s mandatory 30-day period are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the APA. 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

The plaintiffs request that the Court:

- a. Declare that the EPA lacked authority to promulgate its final "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" rule, 86 Fed. Reg. 469, because the agency lacked authority under the Federal Housekeeping Statute, 5 U.S.C. § 301, and exceeded any authority it could have had;
- b. Hold unlawful and set aside the EPA's final rule, and enjoin enforcement thereof;
- c. Declare that the final rule violates 5 U.S.C. § 553(d) because its effective date is not at least 30 days after its publication in the Federal Register;
- d. Declare that the final rule's effective date is 30 days after the date that the rule was published in the Federal Register;

- e. Enjoin enforcement of the final rule until at least 30 days after its publication in the Federal Register;
- f. Award all other appropriate relief, including attorneys' fees and costs.

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Respectfully submitted,

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