No. 26-30203

IN THE
United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants-Appellees,

GENBIOPRO, INC.,
Intervenor-Appellee/Cross-Appellant,

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana
No. 6:25-cv-1491, Hon. David C. Joseph

BRIEF OF THE INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

Max Sarinsky
Katherine Welty
INSTITUTE FOR POLICY INTEGRITY
139 MacDougal Street, 3rd Floor
New York, NY 10012
(212) 992-8932
max.sarinsky@nyu.edu

Counsel for Amicus Curiae
Institute for Policy Integrity

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LOCAL RULE 26.1.1 SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

The Institute for Policy Integrity (Policy Integrity) is a nonpartisan, not-for-profit organization at New York University School of Law.[1] No publicly held entity owns an interest in Policy Integrity. Policy Integrity does not have any members who have issued shares or debt securities to the public.

DATED: July 22, 2026

Respectfully submitted,

/s/ Max Sarinsky
Max Sarinsky

Counsel for Amicus Curiae
Institute for Policy Integrity

[1] This brief does not purport to represent the views, if any, of New York University School of Law.

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INTEREST OF *AMICUS CURIAE* & AUTHORITY TO FILE

The Institute for Policy Integrity at New York University School of Law (Policy Integrity) is a nonpartisan, not-for-profit think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.[1] All parties consent to this brief's filing.

Policy Integrity has produced extensive scholarship on administrative law. Our faculty director, Professor Richard L. Revesz, is one of the nation's most cited administrative and environmental law scholars, having published more than 100 articles and books in these fields. Revesz and other Policy Integrity staff have published extensively on such administrative-law topics as statutory interpretation, the major questions doctrine, and, as most relevant here, the Administrative Procedure Act's (APA) standards of reasoned decisionmaking.

In this action, Plaintiffs argue that the U.S. Food and Drug Administration (FDA) did not engage in reasoned decisionmaking when modifying its Risk Evaluation and Mitigation Strategies for mifepristone

[1] Per Federal Rule of Appellate Procedure 29(a)(4)(E), no party's counsel authored this brief wholly or partly, and no person contributed money intended to fund its preparation or submission.

in 2023 (2023 REMS) to remove an in-person dispensing requirement. In support of that argument, Plaintiffs highlight a 2025 letter from the current Health and Human Services Secretary, Robert F. Kennedy, Jr., and then-current FDA Commissioner Martin A. Makary stating without explanation that there was a "lack of adequate consideration" underlying the FDA's prior REMS approvals, *e.g.* Pls.' Br. 69 (quoting ROA.2201), along with a companion social-media post from Secretary Kennedy, Pls.' Br. 20 (citing ROA.2190).

This Court's treatment of these statements could have significant implications for administrative law beyond this case. Policy Integrity therefore submits this brief to aid the Court by ensuring it has a complete and accurate understanding of the relevant doctrine regarding the treatment of *post hoc*, extra-record agency statements.

SUMMARY OF ARGUMENT

Several prior opinions in this case—from this Court, the District Court, and a Supreme Court dissent—have highlighted recent assertions from Secretary Kennedy and then-Commissioner Makary questioning the adequacy of the FDA's prior REMS approvals. But those *post hoc*, extra-record statements should receive no weight in this Court's analysis.

Courts review an agency's contemporaneous factual findings deferentially. But, as this brief explains, agency *post hoc*, extra-record statements about the sufficiency of evidence should bear no weight in an arbitrary-and-capricious analysis.

I. It is a bedrock principle of administrative law that courts review sufficiency-of-evidence claims based on the agency's "contemporaneous explanation," *Camp v. Pitts*, 411 U.S. 138, 143 (1973)—not its "*post hoc*" statements, *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168–69 (1962). While this principle is normally used to bar *post hoc* rationalizations aimed at supporting the challenged policy, it applies with equal force to agency statements questioning the challenged policy.

This parity reinforces the APA's procedural safeguards. It ensures that agency policy changes follow the "orderly functioning" of the judicial and administrative processes that Congress prescribed, *id.* at 169, and that "parties and the public can respond fully" to the agency's positions, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 23 (2020). Indeed, if these types of disclaimers received judicial consideration, an agency could seek to undo its prior deregulatory or regulatory actions by merely professing error in court—rendering "the

doctrine requiring agencies to give reasons" before revising prior actions a practical "dead letter." *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 557 (D.C. Cir. 2015).

II. Even setting aside their *post hoc*, extra-record nature, Secretary Kennedy's and then-Commissioner Makary's barebones disclaimers are particularly unpersuasive because they fail to grapple with the "facts and circumstances" that the FDA relied upon in modifying the 2023 REMS to remove the in-person dispensing requirement. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009). This Court rejects similarly "conclusory sentence[s]" from agencies, *Texas v. Biden*, 10 F.4th 538, 555 (5th Cir. 2021), and should do the same here.

For these reasons, this Court should give no weight to the agency's *post hoc*, extra-record statements when evaluating the sufficiency of the 2023 REMS.

ARGUMENT

I. Retrospective Statements On The Sufficiency Of Evidence Do Not Merit Judicial Consideration.

An agency's analysis is generally reviewed deferentially under the arbitrary-and-capricious standard. But courts are limited to the agency's

contemporaneous explanation for the decision under review—not after-the-fact agency statements.

The principle that judicial review of agency action is limited to the contemporaneous record is deeply established in Supreme Court caselaw.[2] For over eighty years, the Supreme Court has explained time and again that courts must review the sufficiency of evidence based on the agency's contemporaneous explanation. *See Sec. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 93–94 (1943); *see also, e.g.*, *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 587 (2025); *Michigan v. EPA*, 576 U.S. 743, 758 (2015). Thus, in an APA case, the court "is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Dep't of Com. v. New York*, 588 U.S. 752, 780 (2019); *accord Camp*, 411 U.S. at 143 (stating, in an APA arbitrary-and-capricious challenge, that the agency action must "stand

[2] This principle applies at a minimum to sufficiency-of-evidence claims such as APA arbitrary-and-capricious challenges. While *post hoc*, extra-record statements could be probative to claims alleging bad faith such as pretext, *see Dep't of Com. v. New York*, 588 U.S. 752, 781 (2019), such claims are absent here. And even for claims of bad faith, statements made years after the challenged decision from officials whose tenure postdated the determination are unlikely to be probative.

or fall on the propriety of [its] finding" considering only "the administrative record made" at the time of the challenged decision).

The corollary to this longstanding principle is that courts may not consider an agency's "*post hoc*" statements that did not form the "basis articulated" for its challenged decision. *Burlington Truck Lines*, 371 U.S. at 168–69; *see also Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 156–57 (1991); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988). This limitation applies to *post hoc* statements from not only agency staff or litigating attorneys, but also agency leaders. *Regents of the Univ. of Cal.*, 591 U.S. at 23 (explaining that "the problem is the timing, not the speaker"). Quite plainly, this longstanding principle requires that this Court not factor Secretary Kennedy's and then-Commissioner Makary's 2025 statements into its analysis.

To be sure, the caselaw described above generally arises in the context of an agency trying to buttress its action with additional, *post hoc* rationales—not, as here, question that action by impugning its analytical sufficiency. But the Supreme Court's core rationales for the limitation on considering *post hoc*, extra-record statements apply equally in the present context. For one, this limitation "vindicate[s] . . . the

administrative process" by promoting the "orderly functioning" that Congress laid out for the agency and judicial review of its actions. *Burlington Truck Lines*, 371 U.S. at 169; *see also Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 539–40 (1981) (rejecting "*post hoc* rationalizations" because "Congress gave [the agency] the responsibility . . . to explain its reasons" on the record). That rationale applies with equal force here: While the 2023 REMS "constitute[s] an exercise of the agency's delegated lawmaking powers" meriting judicial attention, *Martin*, 499 U.S. at 157, the agency's *post hoc*, extra-record statements do not. *See* 21 U.S.C. § 355-1(h)(2)(C) (requiring that the FDA publish any modifications to a risk evaluation and mitigation strategy in "an action letter describing the actions taken").

The Supreme Court has also recognized that limiting judicial review to the administrative record "promotes agency accountability" by "ensuring that parties and the public can respond fully and in a timely manner to an agency's exercise of authority." *Regents of the Univ. of Cal.*, 591 U.S. at 22–23 (internal quotation marks omitted). That rationale applies here, too: Attaching weight to the agency's 2025 statements about the sufficiency of the prior REMS approvals would circumvent the

statutory process for agency reevaluation and deprive regulated entities and the broader public of the opportunity for judicial review that would attach if the agency amended the 2023 REMS. *See* 5 U.S.C. § 702 (permitting judicial review of "agency action within the meaning of a relevant statute").

Indeed, crediting an agency's *post hoc*, extra-record disclaimer on the sufficiency of evidence would provide an end-run around the general requirement that agencies "use the same procedures when they amend or repeal" (or reinstate) an action as when issuing (or repealing) it "in the first instance." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 101 (2015). "If an agency could engage in rescission by concession, the doctrine requiring agencies to give reasons before they rescind [or reinstate] rules"—or follow statutorily-required procedures when doing so—"would be a dead letter." *Mexichem Specialty Resins*, 787 F.3d at 557. For this reason, the U.S. Court of Appeals for the D.C. Circuit, when faced with a largely analogous situation, did not heed "an agency's concession of a significant merits issue." *Id.*

In short, this Court should review the 2023 REMS under the APA's arbitrary-and-capricious standard based only on the contemporaneous

agency record. *Post hoc*, extra-record agency statements on that determination's sufficiency should bear no weight in that analysis.

II. The Statements Of Secretary Kennedy And Then-Commissioner Makary Are Particularly Unpersuasive.

Even if some *post hoc*, extra-record statements could be relevant to this Court's analysis, the barebones statements of Secretary Kennedy and then-Commissioner Makary still merit no weight. These "conclusory statements" with "unexplained inconsistenc[ies]" from the underlying REMS approvals do not provide the "reasoned explication" required when an agency reconsiders a prior action. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222, 224 (2016) (citation modified).

When an agency revisits a prior action, its analysis must be "supported by the record and reasonably explained." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 52 (1983). Specifically, the agency must supply "a reasoned explanation . . . for disregarding facts and circumstances that underlay . . . the prior policy." *Fox*, 556 U.S. at 516. It "cannot simply disregard contrary or inconvenient factual determinations that it made in the past." *Id.* at 537 (Kennedy J., concurring).

This Court has frequently recognized that "'conclusory statements' . . . do not constitute adequate agency consideration." *Louisiana v. Dep't of Energy*, 90 F.4th 461, 473 (5th Cir. 2024) (quoting *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1227 (5th Cir. 1991)); *see also Texas*, 10 F.4th at 555 (declining to defer to an agency's "single conclusory sentence," as "'belief' . . . is no substitute for a 'reasonable and reasonably explained' decision") (quoting "reasonable and reasonably explained" from *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). When revisiting a past decision, the agency must provide "analysis of its prior finding[s]" and "explain *why* it ha[s] changed its mind." *Nat'l Ass'n of Mfrs. v. Sec. & Exch. Comm'n*, 105 F.4th 802, 812 (5th Cir. 2024).

Given this precedent, the statements of Secretary Kennedy and then-Commissioner Makary—in both the 2025 letter and accompanying social-media post—merit no weight. In their letter, Kennedy and Makary assert that the FDA's decision to reconsider the 2023 REMS was informed "by the lack of adequate consideration underlying the prior REMS approvals." ROA.2201. They did not explain the basis for this conclusion or indicate what deficiencies they identified in any prior REMS approval. *Id.* Similarly, in a social-media post sharing the letter,

Secretary Kennedy suggested that the in-person dispensing requirement was removed in the 2023 REMS "without studying the safety risks," but identified no safety risk that the FDA omitted from its detailed analysis. ROA.2190.

In fact, the FDA's decision in the 2023 REMS to remove the in-person dispensing requirement for mifepristone was accompanied by a detailed analysis and explanation that neither Secretary Kennedy nor then-Commissioner Makary addressed. The FDA evaluated over a dozen published studies on the safety of dispensing alternatives. ROA.1027–39, 1041–44. In addition, the FDA compared safety data from periods when the in-person dispensing requirement was enforced and when it was not. ROA.373, 1024–27. This detailed evaluation went undiscussed in the 2025 letter and accompanying post.

Simply put, Secretary Kennedy's and then-Commissioner Makary's barebones disclaimers about the sufficiency of the prior FDA actions are irrelevant. They do not grapple with the "facts and circumstances that underlay" those actions or otherwise justify any contrary conclusion. *Fox*, 556 U.S. at 516. Rather, they are the sort of "conclusory statements" this

Court rejects. *Louisiana*, 90 F.4th at 473 (*quoting Corrosion Proof Fittings*, 947 F.2d at 1227). The Court should give them no weight.

CONCLUSION

For the foregoing reasons, the Court should disregard the *post hoc*, extra-record, and conclusory statements of Secretary Kennedy and then-Commissioner Makary.

July 22, 2026

Respectfully submitted,

/s/ Max Sarinsky

Max Sarinsky
Katherine Welty
INSTITUTE FOR POLICY INTEGRITY
139 MacDougal Street, 3rd Floor
New York, NY 10012
(212) 992-8932
max.sarinsky@law.nyu.edu[3]

Counsel for Amicus Curiae
Institute for Policy Integrity

[3] Policy Integrity gratefully acknowledges Kevin Hanley, a summer law clerk, for his research in preparation for this brief.

CERTIFICATE OF COMPLIANCE

Counsel hereby certifies that, in accordance with Federal Rule of Appellate Procedure 29(a) and 32(a), the foregoing brief contains 2,148 words, as counted by counsel's word processing system. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

DATED: July 22, 2026

Respectfully submitted,

/s/ Max Sarinsky
Max Sarinsky

Counsel for Amicus Curiae
Institute for Policy Integrity

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of July 2026, a true and correct copy of the foregoing Brief of the Institute for Policy Integrity at New York University School of Law as *Amicus Curiae* in Support of Defendants-Appellees was filed with the Clerk of the United States Court of Appeals for the Fifth Circuit via the Court's CM/ECF system. Counsel for all parties are registered CM/ECF users and will be served by the appellate CM/ECF system.

DATED: July 22, 2026

Respectfully submitted,

/s/ Max Sarinsky
Max Sarinsky

Counsel for Amicus Curiae
Institute for Policy Integrity