Nos. 23-235, 23-236

In The Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Respondents.

and

DANCO LABORATORIES, L.L.C.,

Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Respondents.

On Writs Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF OF *AMICUS CURIAE* SECRETARY DAVID LONGLY BERNHARDT IN SUPPORT OF RESPONDENTS

JOHN C. SULLIVAN
Counsel of Record
JACE R. YARBROUGH
S|L LAW PLLC
610 Uptown Blvd., Suite 2000
Cedar Hill, Texas 75104
john.sullivan@the-sl-lawfirm.com
469.523.1351 T
469.613.0891 F

Counsel for Amicus Curiae

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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INTEREST OF *AMICUS CURIAE*[1]

Amicus David Longly Bernhardt served as the 53rd United States Secretary of the Interior from 2019 to 2021. He began working for the Department of the Interior (DOI) in 2001 and served as the DOI's Solicitor from 2006 to 2009, and then as the Deputy Secretary of the Interior from 2017 to 2019. Secretary Bernhardt is the only individual to ever serve in each of those Senate-confirmed capacities.

Secretary Bernhardt's extensive experience in the DOI and working in several administrations has provided him with a unique perspective on how agencies should work and what takes place in practice. This "insider" knowledge paved the way for his recent book, DAVID BERNHARDT, YOU REPORT TO ME: ACCOUNTABILITY FOR THE FAILING ADMINISTRATIVE STATE (2023). There he provides firsthand accounts of problems with career employees understanding their proper role in the administrative state and seeking to undermine (or at least resist) the agendas of Presidents with whom they disagree. This problem is exacerbated by courts deferring blindly to agencies as the "experts" in a given field, not accounting for the fact that the entrenched bureaucracy often disregards the law in order to advance policy judgments over scientific ones.

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[1] Rule 37 Statement: No attorney for any party authored any part of this brief, and no one apart from *amicus curiae* and his counsel made any financial contribution toward the preparation or submission of this brief.

As a former Cabinet-level official, Secretary Bernhardt has a strong interest in seeing that agencies are properly constrained by the law and their own regulations. The administrative state is consistently failing the American people and will continue to do so until held accountable. The failure of the Food and Drug Administration (FDA) to follow the law in this case is just the latest in a long line of examples showing that deference from courts is unwarranted when employees are likely to value policy above the law, the agency's own regulations, or even the scientific evidence.

SUMMARY OF ARGUMENT

The administrative state fundamentally changed during the administration of Woodrow Wilson when "the progressive approach to governance put increasing power in the hands of 'experts' [since] ordinary citizens lacked the necessary knowledge and wisdom to weigh in on complex matters of law and policy." BERNHARDT *supra* at 17. President Wilson "therefore favored vesting more power in executive agencies staffed by experts and insulated from interference by an increasingly diverse electorate." *Ibid.* This reliance on experts paved the way for the modern administrative state and its demands on the judicial branch for broad deference in matters of policy.

The concentration of power in administrative agencies has effectively shifted the exercise of lawmaking power from the people's elected representatives to

unelected agency staff. But lawmakers often prefer to duck responsibility for negative consequences by punting difficult policy decisions to administrative agencies. And Secretary Bernhardt has seen firsthand that "agency career staff can leverage their delegated authority and the rulemaking process to run roughshod over the policy preferences of elected political leaders and the will of the American people." *Id.* at 78.

And while turning over decision making authority to the "experts" is one thing, it is another when that authority will be systematically exercised to advance policy agendas even at the expense of rules and regulations designed to limit agency discretion. As has been seen in the FDA on multiple occasions, science sometimes takes a backseat to policy goals or, even worse, regulatory capture. The result is an entrenched bureaucracy, working toward its own policy goals, that must be checked by the judicial branch. Thus the FDA's attack on the ruling below as a "judicial assault on a careful regulatory process," Pet.App. 104a, is absurd. The district court may have been a "non-expert" in this matter, but the FDA's disregard of its own regulations in approving mifepristone shows an entrenched policy preference rather than the measured "scientific judgment of the Food and Drug Administration." *Ibid.* As such, there is no reason to trust the opinion of the FDA on this matter and certainly no place for blind deference to the agency's conclusions.

The judgment of the Court of Appeals should be affirmed.

ARGUMENT

I. Agency Decisions Are Often Guided By Entrenched Employees Acting On Their Own Policy Preferences.

The Constitution and separation of powers dictates that the authority for executive agencies should come from the chief executive: the President. That means the decisions made by agencies, provided there is policy discretion available, should reflect the determinations of the President, not anyone else. In the administrative state, however, the decisions that end up being carried out by the agency often come from entrenched employees who act on their own convictions rather than the policy desires of elected officials (or even the text of a particular law or regulation).

Political appointees in the Trump Administration have provided numerous examples of employees attempting to resist the President's policies. Those career staff withheld information, refused to implement policies, intentionally delayed priorities, deliberately underperformed, leaked information, or even engaged in outright insubordination. James Sherk, *Tales from the Swamp: How Federal Bureaucrats Resisted*

President Trump, America First Policy Institute (Feb. 1, 2021), at 3.[2] As catalogued by James Sherk:

- Career employees at the Department of Justice Civil Rights Division refused to prosecute cases they ideologically disagreed with, even when the facts showed clear legal violations.
- Staff at the Department of Health and Human Services used Sharpie pens to adjust hiring dates to the day before President Trump took office in order to circumvent a hiring freeze.
- Career lawyers at the National Labor Relations Board routinely gave political appointees misleading legal analyses.
- Staff assigned to work on politically sensitive regulations at the Department of Education—including Title IX regulations—would produce either legally insufficient drafts of those regulations or ones that diverged from the Department's policy goals.

Id. at 1.

It has long been recognized that career employees in the agencies are overwhelmingly liberal. See, e.g., Jorg L. Spenkuch, Edoardo Teso, & Guo Xu, *Ideology and Performance in Public Organizations*, Nat'l Bureau of Economic Research (Apr. 2021), at 37.[3] This

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[2] Available at https://americafirstpolicy.com/assets/uploads/files/Tales_from_the_swamp.pdf.

[3] Available at https://www.nber.org/system/files/working_papers/w28673/w28673.pdf.

helps explain why intra-agency resistance was so pronounced during President Trump's tenure. See Christopher Flavelle & Benjamin Bain, *Washington Bureaucrats Are Quietly Working to Undermine Trump's Agenda*, Bloomberg (Dec. 18, 2017). But even Democratic political appointees have reported having difficulty restraining the progressive career staff. Sherk *supra* at 6. Overall, however, the liberal bent of the agencies means that there will be a consistent bias toward progressive policy positions within the bureaucracy.

Having entrenched employees willing to follow personal policy goals rather than the policy preferences of the President is troubling. That some are willing to work around the law in order to effect their own goals is worse. Though it is not everyone, many civil service employees in Washington advance their own policy views no matter which party is in power and no matter what their legal responsibilities entail. This even happens in areas where "expertise" from those employees is supposedly needed and relied upon.

As one example, during the COVID-19 pandemic, the career employee placed in charge of coordinating the Trump Administration's response was Dr. Deborah Birx. She details her actions in the book, DEBORAH BIRX, SILENT INVASION: THE UNTOLD STORY OF THE TRUMP ADMINISTRATION, COVID-19, AND PREVENTING THE NEXT PANDEMIC BEFORE IT'S TOO LATE (2022). One duty of the response task force was to draft weekly reports with recommendations for state Covid-mitigation measures that were edited by Senior White House

staff before being released. BERNHARDT *supra* at 46. Dr. Birx would often disagree with the White House edits and so applied a "work-around" where she deleted the redlined comments but then reinserted them elsewhere in the report in a less conspicuous location. *Ibid.* Using the terms "sleight of hand" and "subterfuge" to describe her actions, Dr. Birx's process was to "write, submit, revise, hide, resubmit." *Ibid.*

Secretary Bernhardt likewise saw this type of behavior firsthand at the DOI. When a regulation regarding the "critical habitat" of the northern spotted owl was in the process of being released, an employee at the U.S. Fish and Wildlife Service (FWS) did not agree with the Secretary's determination that the habitat area should be reduced by approximately one-third. *Id.* at 51. The FWS employee "appeared to believe that he was free to replace the words of a statute with other words he wished that Congress had written instead." *Ibid.* In particular, the employee wanted to replace the phrase "will result in extinction" with "more likely than not" or "has a high likelihood to result in the extinction of the species" because he considered those more appropriate in his estimation of the science. *Id.* at 52. Not only did that not match the text of the statute, there were good reasons to believe that the employee's "scientific" conclusion was wrong, too. *Id.* at 53. The employee's policy decision eventually carried the day, though, as Secretary Bernhardt's successor modified the rule that had been issued. *Ibid.*

Instances such as these underscore the need for agencies to follow closely their own regulations when

issuing decisions or revising rules. Too often entrenched employees will substitute their own (usually progressive) policy preferences into an agency's mission. This leads to administrative action that is contrary to both the will of the people and the laws/regulations in place to guide agency behavior.

II. Uncritical Deference By Courts Is Unjustified In The Face Of Entrenched, Policy Preferences Driving Agency Action.

It is not just the entrenched staff that cause problems, though—it is the policy preferences that ignore legal boundaries and then become entrenched within an agency. Tragically, these policy judgments not only lead to violations of agency regulations and the APA, they can ultimately cause costly mistakes by the agencies that harm the public.

This Court has recognized that "[t]he APA was framed against a background of rapid expansion of the administrative process as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *United States* v. *Morton Salt Co.*, 338 U.S. 632, 644 (1950). In other words, the APA was necessary to limit the zealousness of employees that would otherwise go too far in service of their own policy preferences. One would be naïve not to understand how policy drives the "science" at an agency, underscoring

the need for true judicial review of administrative decisions and not uncritical deference.[4]

It is not surprising to see that even a "science-based" agency like the FDA makes mistakes. After all, "scientists are human beings just like the rest of us. They're not perfect." Pet.App. 105a (Ho, J., concurring in part and dissenting in part). And as Judge Ho outlined in his opinion below, "the FDA has made plenty" of mistakes. *Ibid.* Some examples include:

- Using "bad science" to approve the drug Makena in 2011. See Christina Jewett, *F.D.A. Rushed a Drug for Preterm Births. Did it Put Speed Over Science?*, N.Y. Times (Mar. 25, 2022).
- Approving DES in 1941 to treat postpartum conditions and miscarriages even though it was known to cause cancer and other health problems that "initially led [the] FDA Commissioner . . . to reject the drug"—a position of precaution that was later abandoned. See Nancy Langston, *The Retreat from Precaution: Regulating Diethylstilbestrol (DES), Endocrine Disruptors, and Environmental Health*, 13 ENVIRONMENTAL HISTORY 41, 42 (2008). DES approval was not withdrawn until 2000. 65 Fed. Reg. 55264.
- Contributing to the opioid crisis by failing to properly enforce the Food, Drug, and Cosmetic

[4] The APA's judicial check is even more necessary for the FDA since it is not even nominally an "independent" agency.

> Act when approving extended-release oxycodone in 1995. See Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS 744 (2020). Subsequently, the FDA "continued to approve new opioid formulations for chronic pain based on efficacy trials utilizing a controversial methodology" and pursued only the interests of the pharmaceutical industry that had captured the agency. *Id.* at 745–46.

Pet.App. 105a–07a.

The real travesty is not that mistakes were made, but that they are often caused by things such as flawed policy or regulatory capture rather than science. Moreover, these issues seem to be amplified when it comes to matters that are charged in the public square. After all, the agency may not have so cavalierly disregarded its own regulations in the first instance if the underlying matter here did not revolve around abortion. See Pet.App. 89a–90a ("It's a longstanding principle that agencies must follow their own regulations. * * * The FDA violated that principle when it approved mifepristone under Subpart H—as even the drug's sponsor, the Population Council, admitted in 2000."). When that type of behavior takes place, it becomes apparent the agency action is being driven by policy considerations rather than agency expertise in an area. And then, once the initial determination is made, it becomes increasingly difficult for the agency to get away from it as the career employees feel bound to defend the agency's positions.

Having already shown that it cannot follow its own regulations on this topic, there is reason to question the accuracy of the FDA's position in this case. The measured "scientific judgment of the Food and Drug Administration" did not cause the agency to ignore its regulations in the first instance here. Pet.App. 104a. Thus no deference is owed the entrenched policy determination made by the FDA.

* * *

Judge Ho pointed out the obvious implications of Congress's decision not to exempt the FDA from judicial review of its approvals of drugs. Pet.App. 105a. And as shown above, Congress's decision was correct. Thus, "scientists at the FDA deserve our respect and our gratitude, but not our blind deference. That would defy Congress's clear directive that courts conduct independent legal review of FDA action under the APA." Pet.App. 109a. And when there is even more reason to distrust the scientific conclusions at issue—such as here when they stem from policy preferences—the need for independent legal review is even more pronounced.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

JOHN C. SULLIVAN
Counsel of Record
JACE R. YARBROUGH
S|L LAW PLLC
610 Uptown Blvd., Suite 2000
Cedar Hill, Texas 75104
john.sullivan@the-sl-lawfirm.com
469.523.1351 T
469.613.0891 F

Counsel for Amicus Curiae

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