United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

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VIA ELECTRONIC TRANSMISSION

The Honorable Robert Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Commissioner Califf:

As Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I write concerning the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, and the significant changes that federal agencies will make to their rulemaking and other processes in its aftermath. For 40 years, Congress and federal courts have ceded their respective responsibilities to write and interpret statutes to federal agencies. Under the Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, courts were required to give broad deference to agencies' interpretations of ambiguous provisions in statutes.[1] The Court has now overturned that deference, reinforcing that Congress and the courts are responsible for writing and interpreting the laws, respectively; not agencies.[2] The Court held that such deference defies the Administrative Procedure Act, and that agency interpretations are no longer entitled to deference.[3]

This decision is an opportunity for executive agencies to re-examine their role relative to Congress, and to return legislating to the people's elected representatives. For too long, *Chevron* deference has let agencies make broad decisions governing a diverse country of over 330 million people. Instead of engaging in the hard work of making tradeoffs and building coalitions needed to legislate, unelected agency bureaucrats exploit statutes to impose policy decisions that exceed their authority from Congress and exercise discretion far outside their core expertise and purpose.

Such unfettered agency power by the unelected is a perversion of the Constitution. *Loper Bright* makes clear that no agency is above the law or should be afforded special treatment when its authority is challenged. Moreover, the Court has separately confirmed that agencies need clear, specific statutory authorization from Congress to take action on issues of "vast 'economic and

[1] *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).
[2] *Loper Bright Enterprises v. Raimondo*, No. 22-1219, 2024 WL 3208360 (U.S. June 28, 2024).
[3] *Id.* at *3.

political significance.'"[4] Agencies cannot seize broad power based on authorities that Congress intended to be exercised narrowly—subtle, vague, or ambiguous statutory provisions provide no foundation for sweeping action.[5] Even then, Congress cannot delegate its Article I legislative powers to agencies.[6]

Congress is the most politically accountable branch in our government, and should be responsible for making the most important policy decisions that affect the American people. The Court also makes clear that Congress makes law, not agencies. When the Executive Branch does make law, such as promulgating new regulations, it does so to implement the laws Congress makes and only within the clearly established guardrails that Congress sets. In *Loper Bright*, the Court makes clear that the role of federal courts is to "independently interpret the statute and effectuate the will of Congress subject to constitutional limits."[7]

The impact of the Court's decision on the Food and Drug Administration (FDA) should not be cause for alarm. Congress has charged FDA with using its clinical and technical expertise to regulate products—drugs, medical devices, foods, dietary supplements, and cosmetics, among others—that Americans rely on every day. But FDA sometimes forgets that it exercises its expertise only to effectuate the laws that Congress enacts. Overturning the deference that FDA receives when interpreting statutes does not mean that courts will disregard FDA's expertise. Instead, courts will now give FDA's know-how appropriate consideration, yet reclaim their constitutional role of interpreting laws without putting a thumb on the scale in favor of the agency. Indeed, as the Court recognizes, an agency's know-how may be informative, but deferring to agencies is not necessary to ensure that resolving statutory ambiguities is "well informed by subject matter expertise."[8]

Despite the Court's decision, given your agency's track record, I am concerned about whether and how FDA will adapt to and faithfully implement both the letter and spirit of this decision. For example, FDA has unilaterally asserted jurisdiction over laboratory developed tests (LDTs) without Congress granting FDA that authority.[9] Indeed, Congress has made clear across multiple statutes that LDTs are not medical devices subject to FDA regulation.[10] FDA's lack of clear statutory authority is moreover evidenced by Congress' longstanding consideration of granting

[4] *See Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)).
[5] *See Whitman v. Am. Trucking Ass'ns, Inc*., 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").
[6] *See, e.g.*, *Gundy v. United States*, 588 U.S. 128, 135 (2019) ("Congress, this Court explained early on, may not transfer to another branch 'powers which are strictly and exclusively legislative.'" (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42-43 (1825))).
[7] *Loper Bright*, 2024 WL 3208360 at *2.
[8] *Id*. at *4.
[9] Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37286 (May 6, 2024) (to be codified at 21 C.F.R. 809).
[10] Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539; Clinical Laboratory Improvement Amendments of 1988, Pub. L. 100-578, 102 Stat. 2903.

FDA new authority over LDTs through legislation, which Congress has yet to pass.[11] How best to regulate products used in nearly every doctor's office and hospital in the country, especially where such products implicate the state-regulated practice of medicine, is a quintessential question of vast economic and political significance that Congress has yet to decide.[12] Unless and until Congress takes action, FDA cannot simply seize such vast authority for itself. The agency's decision to bypass Congress is an egregious overstep.

Additionally, FDA has ignored multiple court rulings on the Orphan Drug Act.[13] I was the original sponsor of the Retaining Access and Restoring Exclusivity (RARE) Act that, following the Eleventh Circuit's decision in *Catalyst*, amends the Orphan Drug Act to align with FDA's interpretation. Thus, I agree with FDA on this matter of policy. But contrary to FDA's brazen announcement that it would ignore the holding from the *Catalyst* decision, Congress has not yet enacted the RARE Act.[14] FDA may not simply pick and choose the laws it would like to follow based on its conception of what will "best serve public health."[15]

FDA's actions are made more brazen in light of the regular reauthorizations of the user fee programs that prompt Congress to examine and, as appropriate, update the agency's statutory authorities at least every five years. Regular reauthorizations, involving extensive agency and stakeholder feedback, offer a model to be emulated elsewhere, and give Congress an opportunity to respond to emergent issues, as needed. In fact, in the most recent user fee reauthorization legislation, Congress amended statutory provisions related to the classification of contrast agents as drugs versus medical devices after a D.C. Circuit decision that FDA lost.[16] Following this decision, where the court held that FDA acted in excess of its authority, Congress examined the issue and decided to grant FDA clear authority on this question. This is how our system of government should work.

But FDA guts this process, and thumbs its nose at the Constitution, every time it ignores the decisions that Congress makes through both laws it enacts and chooses not to enact. Congress' decision to enact provisions into law to address legal, scientific, or other developments, and not to enact provisions following others, must mean something. The Court's *Loper Bright* decision should impel FDA to more faithfully follow the law, and Congress to more attentively update the law, as warranted.

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[11] Verifying Accurate Leading-edge IVCT Development Act of 2021, S. 2209, 117th Cong. (2021).
[12] *See Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758 (2021) (per curiam) (holding that, absent clear statutory authority, the Centers for Disease Control and Prevention lacked the authority to take an action with billions of dollars of economic impact that intrudes on an area that is the "particular domain of state law.").
[13] *See Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021); Policy on Orphan-Drug Exclusivity; Clarification, 79 Fed. Reg. 76888 (Dec. 23, 2014) (to be codified at 21 C.F.R. 316).
[14] Clarification of Orphan-Drug Exclusivity Following Catalyst Pharms., Inc. v. Becerra; Notification, 88 Fed. Reg. 4086 (Jan. 24, 2023) (to be codified at 21 C.F.R. 316).
[15] *Id.* at 4087.
[16] The statutory provision is Section 3621 of the Consolidated Appropriations Act, 2023, Pub. L. 117-328, 136 Stat. 4459. The decision is *Genus Med. Techs., LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2021).

To understand how FDA will abide by and implement the Court's new framework, I ask that you answer the following questions, on a question-by-question basis, **by July 19, 2024**:

1. How will FDA change its current practices to enforce the laws as Congress writes them, and not to improperly legislate via agency action?

    a. Will FDA be conducting a systematic, action-by-action review of its ongoing activities to identify opportunities where FDA needs to make changes to comply with or otherwise account for the decision?

    b. Will FDA pause or stop any existing rulemaking activities in light of the Court's decision? If so, what rule(s) is FDA halting? If not, why does FDA feel it is legally able to continue existing rulemakings without considering the impacts of the Court's decision?

2. How does FDA plan to facilitate greater congressional involvement in policy issues under the agency's purview? Please be as specific as possible with respect to oversight responses, regular briefings, trainings and seminars, and other actions you plan to take.

3. What are your current policies about when your staff may or may not provide briefings to congressional staff? Under what situations would you refuse to brief congressional staff in response to a request for such a briefing? Where are such policies codified?

4. How do you plan on increasing FDA's responsiveness to oversight and technical assistance requests from Congress?

    a. For example, how do you plan to streamline FDA's process for clearing technical assistance to reduce response times to congressional requests?

5. Moving forward, will you commit to providing a substantive response to congressional oversight requests within 30 days of receipt of the request? If not, why not?

6. The legislative history of both the Food, Drug, and Cosmetic Act and the Clinical Laboratory Improvement Amendments of 1988 makes clear that Congress has not granted FDA clear authority over LDTs. In spite of this, FDA moved forward with rulemaking to assert such authority after the 117th Congress did not pass into law legislation that would have granted FDA the authority it has long sought. How will you apply the Court's *Loper Bright* decision to FDA's actions related to LDT regulation?

7. Following up on FDA's announcement regarding orphan drug exclusivity after the *Catalyst* decision, what criteria does FDA use to determine when it will follow or ignore the holding from a court decision? Please be as specific as possible, including how FDA will weigh the

status of the deciding court (i.e., district versus appellate) and any legislation that Congress has considered related to the underlying statute in question.

Thank you for your prompt attention to this important matter.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
U.S. Senate Committee on Health,
Education, Labor, and Pensions