No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF AMICI CURIAE OF THIRTEEN MEMBERS OF CONGRESS AND THE AMERICAN CENTER FOR LAW AND JUSTICE IN SUPPORT OF RESPONDENTS

JORDAN SEKULOW
Counsel of Record
DONN PARSONS
BENJAMIN P. SISNEY
NATHAN J. MOELKER
AMERICAN CENTER FOR LAW & JUSTICE
201 Maryland Ave., NE
Washington, DC 20002
(202) 546-8890
sekulow@aclj.org
Counsel for Amici

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulations

Other Authorities

INTEREST OF AMICI[1]

Amici are elected thirteen Members of the U.S. Senate and U.S. House of Representatives.

Amici Members of the U.S. Senate submitting this Brief are Ted Budd, Roger Marshall, M.D., Thom Tillis, and Tommy Tuberville.

Amici Members of the U.S. House of Representatives submitting this Brief are Rick Allen, Dan Bishop, James Comer, Dan Crenshaw, Jeff Duncan, Virginia Foxx, Andy Harris, M.D., Richard Hudson, and David Rouzer.

As the people's elected Representatives, Amici have special interests in protecting and promoting Congress's authority to make laws for the American people and in safeguarding the welfare of their constituents. As members of the U.S. Senate and U.S. House of Representatives, Amici have a perspective to offer this Court which is inherently different than that of the parties. Amici also have constituents affected by the FDA's arbitrary and unlawful actions. The Court's disposition of the issues here will affect the ability of Amici's constituents to earn a livelihood. As such, Amici have a particular interest in the issues in this case.

---

[1] Pursuant to Supreme Court Rule 37.6, amici curiae state that no counsel for any party authored this brief in whole or in part, and no entity or person, aside from amici curiae, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief.

Amicus Curiae, the American Center for Law and Justice ("ACLJ"), is an organization dedicated to the defense of constitutional liberties secured by law. ACLJ attorneys have appeared often before this Court as counsel for parties, *e.g.*, *Trump v. Anderson*, 601 U.S. 100 (2024); *Heritage Foundation v. Parker*, U.S. No. 21A249 (2021); and *Trump v. Vance*, 591 U.S. 786 (2020); or for amici, *e.g.*, *Fischer v. United States*, 144 S. Ct. 2176 (2024); *Janus v. AFSCME, Council 31*, 585 U.S. 878, 878 (2018); and *McDonnell v. United States*, 579 U.S. 550 (2016), addressing various constitutional and statutory issues, including those of improper or *ultra vires* governmental action. The ACLJ is devoted to the rule of law and defending both individual rights and liberties and the structural protections of our system of government.

SUMMARY OF ARGUMENT

Congress, not the FDA, should determine the major question of whether e-cigarette devices should be banned. The FDA has claimed to itself the authority to regulate e-cigarettes, known more precisely as electronic nicotine delivery systems ("ENDS"). After claiming that authority, it has then spent years putting the manufactures of such devices through a long elaborate review process where they were directly informed what materials were and were not required of their premarket tobacco product application ("PMTA"). Only after that process had concluded did the FDA then surprise manufacturers with totally new, arbitrary, and extra-statutory

requirements for these devices, a new requirement that imposed a *de facto* ban. It had no authority to do so.

Congress has carefully defined and limited the authority of the FDA. Balancing all competing interests, it denied the FDA the authority to ban an entire type of product. Instead, the FDA is supposed to review each PMTA on a case-by-case basis, considering each application on its own merits. The FDA, by its own admission, denied at least one million flavored e-cigarettes, like those at issue here. Accordingly, the FDA has implemented an across-the-board ban on all flavored products, in practice prohibiting manufacturers from making those devices.

There is a clear lack of authority for such a ban. Congress has specifically prohibited the FDA from banning products. Despite this, the FDA imposed a categorical prohibition. The statute expressly requires the FDA to engage in a case-by-case analysis, examining each proposed product to determine whether such a product "would be appropriate for the protection of the public health." 21 U.S.C. § 387j. Instead, the FDA has imposed a standard that functions as a practical ban by setting the bar so high, retroactively, that practically no products can meet it. Congress never gave the FDA authority to enact such a prohibition.

By curtailing the FDA's regulatory overreach, the Court can send a clear message that Congress, and not bureaucratic agencies, must make the laws that

govern the economy. Policy decisions should be restored to where they belong: the people's representatives.

At the core of the Constitution is Due Process. In contexts like this, Due Process encompasses the right to proper notice, such that an agency cannot pull the rug out from under the people via shifting obligations without proper notice. When this Court overruled *Chevron*, it emphasized that "*Chevron* fosters unwarranted instability in the law, leaving those attempting to plan around agency action in an eternal fog of uncertainty." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2272 (2024). This case illustrates the effects of those rapid changes in position, the fruit of the *Chevron* tree; agencies send the public on wild goose chases and then change their regulatory standard after the fact. Congress never intended or authorized such fluctuations or instability. And the Constitution does not allow it. Curtailing those surprises is necessary to ensure that the power to make laws returns to Congress, where it belongs.

ARGUMENT

It is Congress, not unelected bureaucrats, which has been granted the authority and responsibility to make laws for the American people. This case provides a crucial first opportunity for this Court to apply *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2247 (2024), to ensure that agencies no longer may send citizens "on a wild goose chase," *Wages &*

White Lion Investments, L.L.C. v. FDA, 90 F.4th 357, 362 (5th Cir. 2024), to try to figure out what novel obligation an agency might possibly impose on them. Instead, it is Congress which has the responsibility to make laws for the American people.

I. Under the Major Questions Doctrine, This Court should Curtail the FDA's Arbitrary Decision-making and Restore Authority to Congress.

Separation of powers is the essential safeguard of our constitutional structure. Just as Article III vests "[t]he judicial power of the United States" — and with it, the duty "to say what the law is" — in the independent federal courts, *Marbury v. Madison*, 5 U.S. 137, 177-78 (1803), Article I vests the federal legislative power of the United States in Congress, not any bureaucracy; the "text permits no delegation of those powers." *Whitman v. Am. Trucking Ass'ns,* 531 U.S. 457, 472 (2001). "[T]he lawmaking function belongs to Congress, U.S. Const., Art. I, § 1, and may not be conveyed to another branch or entity." *Loving v. United States,* 517 U.S. 748, 758 (1996). This principle protects one of the Constitution's most foundational precepts: the sovereignty of the American people and the political accountability of those who govern. When an unelected body of bureaucrats takes it upon itself to impose a *de facto* ban of a category of products, it is that authority which has been threatened.

A. The Major Questions Doctrine Reserves the Decision Whether to Ban E-Cigarettes to Congress, not Bureaucrats.

The Major Questions Doctrine ensures that agencies cannot dictate policy on issues of vast economic or political importance to our national life. If an agency seeks to claim for itself that power, it must properly identify clear authority from Congress for doing so. In such cases "the 'history and the breadth of the authority that [the agency] has asserted,' and the 'economic and political significance' of that assertion, provide a 'reason to hesitate before concluding that Congress' meant to confer such authority." *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-60 (2000)). Here, in these extraordinary cases, "both separation of powers principles and a practical understanding of legislative intent make [this Court] 'reluctant to read into ambiguous statutory text' the delegation claimed to be lurking there." *Id.* at 723 (quoting *Util. Air Regul. Group v. EPA*, 573 U.S. 302, 324 (2014)).

In recent years, this Court has had the need to apply this doctrine with rigor, invalidating administrative agency mandates of breathtaking scope because Congress did not clearly authorize them. *Biden v. Nebraska*, 600 U.S. 477, 489 (2023); *West Virginia v. EPA*, 597 U.S. 697 (2022); *NFIB. v. OSHA*, 595 U.S. 109 (2022) (per curiam); *Alabama*

Ass'n of Realtors v. HHS, 594 U.S. 758, 760 (2021) (per curiam).

In each of these cases, unelected, unaccountable bureaucrats seized for themselves the authority to regulate a major area that Congress had not seen fit to give them. In fact, these mandates were adopted to coerce policies that Congress had expressly *declined* to adopt. *See NFIB*, 595 U.S. 109, 122 (Gorsuch, J., joined by Thomas & Alito, JJ., concurring) ("Congress has chosen not to afford OSHA — or any federal agency — the authority to issue a vaccine mandate. Indeed, a majority of the Senate even voted to disapprove OSHA's regulation."); *West Virginia*, 597 U.S. at 724 ("Congress had conspicuously and repeatedly declined to enact" carbon dioxide emissions regulations that the EPA claimed authority to adopt); *Alabama Ass'n of Realtors*, 594 U.S. at 760 ("Concluding that further action was needed, the CDC decided to do what Congress had not."). The same thing has occurred here; Congress has expressly denied to the FDA the authority to impose a ban on particular products, but the FDA has chosen to impose a *de facto* ban of those products regardless.

The FDA is improperly claiming authority it does not possess. It is not the first time the FDA has done so — indeed, the modern understanding of the Major Questions Doctrine arose from another case of attempted FDA overreach, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-60 (2000). *Brown & Williamson* concerned whether the FDA could classify tobacco products as a "drug." For

the first time in its history, the FDA had asserted that it possessed authority to regulate tobacco products, despite the lack of any explicit congressional authorization.

This Court emphatically disagreed, rejecting the idea that Congress would leave the determination of whether the sale of tobacco products would be regulated, or even banned, to the FDA's discretion: "if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation." *Brown & Williamson Tobacco Corp.*, 529 U.S. at 143. This Court held that the FDA could not seize for itself authority to ban tobacco, as it simply had not been vested with that authority. In response to the FDA's claim to possess expansive authority, "we are obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power." *Id.* at 160.

Congress has since granted the FDA specific, enumerated authority to regulate tobacco products. 21 U.S.C. § 387a *et seq*. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. The TCA gave the FDA regulatory authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). But the FDA's authority remains intentionally and carefully circumscribed. In particular, Congress expressly

prohibited the FDA from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products[.]" 21 U.S.C. § 387g(3). For each category of device that Congress gave the FDA authority to regulate, Congress also carefully specified that the FDA has been granted *no* authority to impose a ban.

Accordingly, rather than permit the FDA to engage in a total ban of a category of product, the statute requires the FDA to follow a specified process for the review of tobacco products. 21 U.S.C. § 387j. A manufacturer may introduce a new tobacco product into interstate commerce only with authorization from the FDA. *See* 21 U.S.C. § 387j(a)(2)(A). An applicant for such authorization must show that the marketing of the new product "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

Congress delegated authority to the Health and Human Services (HHS) Secretary to subject tobacco products to the TCA through a regulatory deeming process. 21 U.S.C. § 387a(b). E-cigarettes, although Congress did not list them among the products to which the Act automatically applied, have been now included on that list by the FDA, according to a rule deeming e-cigarettes and e-liquids to be subject to the TCA. 81 Fed. Reg. 28,974, 29,028-29,044.

The issue in this case is not whether the FDA has authority to regulate e-cigarettes. Having promulgated this regulation, the FDA has now

imposed a *de facto* ban on an entire category of product. Despite the lack of any such authorization to do so, the FDA created a categorical ban on "flavored" e-cigarettes. *Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 384 (5th Cir. 2024). As the court below explained, the FDA did so by retroactively, after *years* of requesting certain kinds of information from manufacturers, creating a "categorical ban on using scientific data from unflavored products to support flavored PMTAs." *Id.* at 380. The court below explained in detail why these fluctuations in reasoning violated due process. But the additional crucial problem for this Court's consideration is that the FDA had no authority to impose such a *de facto* ban at all.

The FDA has implemented an "across-the-board ban on all flavored products, regardless of device type." *Id.* at 384. Despite the specific congressional legislation prohibiting the FDA from enacting such bans, the FDA did it anyway. But the statute expressly requires the FDA to engage in a case-by-case analysis, examining each proposed product individually to see whether it meets the required legal standard. 21 U.S.C. § 387j. Yet the agency imposed a "de facto ban on flavored e-cigarettes." *Wages & White Lion Invs.*, L.L.C., 90 F.4th at 384 n.5. It has no authority to do so.

The FDA's ban is *de facto*, not *de jure*. The FDA claims in its brief that it "accorded individualized consideration" to each application. Pet. App. 44. That claim is easily refuted by the fact that the FDA denied

over 946,000 flavored e-cigarette products in just over two weeks. *See* FDA, *FDA Makes Significant Progress in Science-Based Public Health Application for Review, Taking Action on Over 90% of More than 6.5 Million "Deemed" New Tobacco Products Submitted* (Sept. 9, 2021), https://perma.cc/4F69-MRUB. At the time of the Fifth Circuit's decision, the "FDA ha[d] not approved a single PMTA for a single one of the more than 1,000,000 flavored e-cigarette products submitted to the agency." *Wages & White Lion Invs., L.L.C.*, 90 F.4th at 370. The denial of a million flavored e-cigarette products in two weeks simply cannot be a "individualized assessment." Instead, it constitutes a *de facto* ban, as made clear by the fact that at the time of the Fifth Circuit's decision, no applications whatsoever had been granted.[2]

The FDA engaged in "regulatory switcheroos," *Wages & White Lion Investments, L.L.C.*, 90 F.4th at

---

[2] The FDA seeks to submit new evidence to this Court, not available to the Fifth Circuit, of four new products authorized while this Court's review has been pending. The FDA informs the Court that it granted a different manufacturer authorization to market four menthol-flavored e-cigarette products. App. Br. 47. These authorizations, after this case was already presented to this Court and while the FDA had strong incentives to make it appear that it has not imposed a *de facto* ban, is the exception that proves the rule. Indeed, these products were only authorized because the manufacturer submitted amendments over two years after the application deadline that included the studies FDA now demands. FDA, *TPL Review of PMTAs* 21, 62 (Jun. 21, 2024), https://tinyurl.com/3kh3u6t9; FDA, *TPL Review of PMTAs* 42, 72 (Jun. 21, 2024), https://tinyurl.com/srjecde3. The *de facto* ban of flavored e-cigarettes remains.

362, changing its requirements at the last minute in a manner that imposed a practical ban. According to the FDA's own briefing, as of this time, the "FDA has authorized the marketing of fewer than three dozen e-cigarette products, most of them tobacco flavored." App Br. 6. It also conceded that, "[b]y contrast, FDA has denied applications for authorization to market more than a million e-cigarette products with non-tobacco flavors." *Id.* The FDA has imposed a standard that sets the bar so high, *retroactively*, that practically no products can meet it.

Thomas Cooley defined legislative power as "authority, under the constitution, to make laws, and to alter and repeal them. Laws, in the sense in which the word is here employed, are rules of civil conduct, or statutes, which the legislative will has prescribed." Thomas M. Cooley, *A Treatise on the Constitutional Limitations Which Rest Upon the Legislative Power of the States of the American Union* 108 (5th Ed. 1883). The legislative power is "a predetermination of what the law shall be for the regulation of all future cases falling under its provisions." *Id.* It is this power that the Constitution vested not in the FDA but in Congress.

Congress has expressly denied the FDA authority to categorically ban products. 21 U.S.C. § 387g(3). The FDA has chosen to do so anyway. An authorization rate of four out of over 1 million flavored e-cigarette products is, for all meaningful purposes, a ban, only authorizing, at best, 0.0004 percent of those products. No authority has been granted to the FDA to legislate

such a ban. The Court has an opportunity to restore limitations on the bureaucracy by holding the FDA accountable. By curtailing the FDA's regulatory overreach, the Court will send a clear message that Congress, and not federal agencies, makes the law.

B. The FDA Does Not Have Authority to Perform Surprise About-Faces in Interpreting the Law.

At the core of the Constitution is Due Process. Due Process includes a right to notice: "[a]ll are entitled to be informed as to what the State commands or forbids." *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939). An agency cannot impose new requirements on someone without notice after the party relied on the agency's prior representations. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-156 (2012). Instead, a federal agency must give regulated entities "fair warning" of what the agency expects. *Id.* at 156. Agencies may not "depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

The *en banc* Fifth Circuit explained how the FDA repeatedly articulated clear and unambiguous expectations in its guidance to product manufacturers. The FDA specifically disclaimed the need for any specific study, including long-term studies, repeatedly telling manufacturers not to perform those studies. *Wages & White Lion Invs.,*

L.L.C., 90 F.4th at 363 (citing the FDA: "*No specific studies are required for a PMTA.*"). Only *after* receiving product applications, the FDA reversed course when adjudicating these applications—adopting a brand-new policy of requiring a scientific study. The FDA then ignored the evidence it had instructed manufacturers to provide: "after telling manufacturers that their marketing plans were 'critical' to their applications, FDA candidly admitted that it did not read a single word of the one million plans. Then FDA denied that its voluminous guidance documents and years-long instructional processes meant anything." *Id.* at 362.

This is part of the poisonous fruit of *Chevron*. Under *Chevron*, agencies had freedom to regularly change their positions and interpretation, and "change is not invalidating, since the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute." *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996). In fact, *Chevron* itself concerned an agency's change in interpretation, still given deference by this Court, reasoning that "the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 863-64 (1984). *Chevron* accorded equal deference to diametrically opposed agency interpretations, leaving agencies free to perform these rapid changes in their positions without direction from Congress.

Chevron ultimately gave agencies license to do exactly what they did here, fluctuating their expectations and standards for the public while still receiving ongoing deference in their determinations. That license has been terminated. When this Court overruled *Chevron*, it emphasized that

> [u]nder *Chevron*, a statutory ambiguity, no matter why it is there, becomes a license authorizing an agency to change positions as much as it likes, . . . *Chevron* thus allows agencies to change course even when Congress has given them no power to do so. By its sheer breadth, *Chevron* fosters unwarranted instability in the law, leaving those attempting to plan around agency action in an eternal fog of uncertainty.

Loper Bright Enters., 144 S. Ct. at 2272.

This case illustrates the ripple effects of those rapid changes in position; agencies send the public on wild goose chases and then retroactively change their regulatory standard, making it impossible for practically anyone to meet their obligations. Congress never granted the FDA authority to do so. This Court has emphasized the "risk that agencies will promulgate vague and open-ended regulations that they can later interpret as they see fit." *Christopher*, 567 U.S. at 158. That risk is on display here with all its dangerous consequences. It should be curtailed by

holding the FDA accountable and restoring legislative authority to Congress.

CONCLUSION

This Court should affirm the judgment of the Fifth Circuit.

Respectfully submitted,

JORDAN SEKULOW
Counsel of Record
DONN PARSONS
BENJAMIN P. SISNEY
NATHAN J. MOELKER
AMERICAN CENTER FOR LAW & JUSTICE
201 Maryland Ave., NE
Washington, DC 20002
(202) 546-8890
sekulow@aclj.org
Counsel for Amici