No. 22-1676

# IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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ASTRAZENECA PHARMACEUTICALS LP,

*Plaintiff-Appellee,*

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

*Defendants-Appellants.*

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Appeal from the United States District Court
for the District of Delaware
(No. 1:21-cv-27)
(District Judge Leonard P. Stark)

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## BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE AND AFFIRMANCE

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## INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* in important statutory-interpretation cases, to urge federal courts to vindicate Congress's exclusive lawmaking power by preventing federal agencies from rewriting federal law. *See, e.g.*, *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302 (2014); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

## INTRODUCTION & SUMMARY OF ARGUMENT

The goal of reducing health care costs, including lowering the cost of prescription drugs for uninsured and low-income patients, is a laudable one. Congress enacted the 340B Program as part of that worthwhile policy. But as the District Court rightly found, recent regulatory overreach has improperly expanded this well-intended cost-reduction program far beyond anything its statutory text can sustain. In our system of government, federal agencies like the Health

[*] No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties have consented to WLF's filing this brief.

Resources Services Administration do not wield the statutes they want; they must implement the statutes that Congress gives them. That bedrock constitutional principle is the chief focus of this brief.

Not only has HRSA misconstrued its statutory authority to take the action it attempted here, but the lack of any clear statement from Congress that it could do so precludes the agency from expanding manufacturers' statutory burdens under the 340B Program. By seizing on the 340B statute's silence alongside its overarching purpose, HRSA's latest regulatory overreach effectively grants the agency gap-filling authority that Congress never gave it. Because amending federal law is a task reserved solely for Congress, the Court should clarify that the 340B statute imposes no duty on manufacturers beyond "offering" covered entities the chance to "purchase" 340B-discounted drugs. 42 U.S.C. § 256b(a)(1).

"Agencies have only those powers given to them by Congress." *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022). The 340B statute, therefore, is not an "open book to which the agency [may] add pages and change the plot line." *Id.* HRSA has no "right, in the guise of construction of an act, to either add words to or eliminate words from

the language used by Congress." *King v. IRS*, 688 F.2d 488, 491 (7th Cir. 1982) (cleaned up). On appeal, it falls to this Court to determine "what Congress enacted." *Argentina v. Weltover*, 504 U.S. 607, 618 (1992). As at least two courts have held, 340B's statutory text, context, and history all confirm that Congress did not require manufacturers to deliver, much less sell, unlimited 340B-discounted drugs to uncovered entities like for-profit contract pharmacies. *See* JA31–JA50; *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, *9 (D.D.C. Nov. 5, 2021).

Above all, this is a "major questions" case. Whether to drastically expand the scope of the 340B Program in this way is a question of "such economic and political significance" that Congress would never commit it to the discretion of an agency without explicitly saying so. *West Virginia*, 142 S. Ct. at 2605 (quoting *Brown & Williamson*, 529 U.S. at 133). HRSA's contrary view, if embraced on appeal, would allow the agency to unilaterally transform the 340B Program from a sensible cost-saving measure into a constitutionally dubious wealth-transfer scheme. To prevail on appeal, then, HRSA must supply "something more than a merely plausible textual basis" for its newfound enforcement scheme; it "must point to 'clear congressional

authorization' for the power it claims." *West Virginia*, 142 S. Ct at 2609. This it cannot do.

Just as HRSA may not amend the 340B statute to its liking, neither may the federal courts. "Ours is a society of written laws." *Bostock v. Clayton Cnty., Ga.*, 140 S. Ct. 1731, 1754 (2020). Although a court is likely, now and then, to find itself unimpressed by "the written word" of the law before it, *id.* at 1737, that is no excuse to "abandon the statutory text" and "appeal to assumptions and policy," *id.* at 1749. These textualist principles are binding on the federal courts and, outside the rare absurdity or scrivener's error, there are *no exceptions*. Not even for well-meaning laws like the 340B statute.

## ARGUMENT

### I. HRSA'S VIOLATION LETTER WAS CONTRARY TO LAW.

As "creatures of statute," administrative agencies "possess only the authority Congress has provided." *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational & Safety Health Admin.*, 142 S. Ct. 661, 665 (2022) (per curiam). As the District Court rightly recognized, HRSA's enforcement discretion over the 340B Program is not unlimited. It is strictly bound by the text of the 340B statute Congress enacted.

That statute imposes only two duties on manufacturers like AstraZeneca. First, if AstraZeneca offers a covered drug to another purchaser at any price, it must "offer" that drug to covered entities. 42 U.S.C. § 256b(a)(1). Second, AstraZeneca must offer that drug to covered entities for "purchase" at the "ceiling price." *Id.* That is all. Apart from obliging manufacturers to "offer" a covered drug to covered entities for "purchase" at the "ceiling price," the statute imposes no other duty on them. It leaves the messy details of 340B transactions, including the terms of delivery, to the parties' free-market negotiations under the Uniform Commercial Code.

Indeed, "HRSA itself has long recognized that manufacturers are allowed to 'include provisions' in their contracts 'that address customary business practice.'" *Novartis*, 2021 WL 5161783, at *7 (quoting 59 Fed. Reg. 25,110, 25,114 (May 13, 1994)). This established practice confirms that HRSA's latest statutory reach—that the 340B statute bars AstraZeneca from having a policy of delivering 340B-discounted drugs only to a covered entity's in-house or wholly owned pharmacies or to a single, designated contract pharmacy—far exceeds the agency's grasp. The upshot is effectively to require manufacturers to sell and deliver

unlimited 340B-discounted drugs to any number of uncovered third parties. But the 340B statute says nothing of the kind.

Nor does 340B's overarching purpose justify HRSA's imposing its extra-statutory gloss on the statute. While it is true that the 340B statute aims to make 340B-discounted drugs widely accessible to eligible patients of covered entities, "[n]o law pursues its purposes at all costs." *Hernandez v. Mesa*, 140 S. Ct. 735, 741-42 (2020) (cleaned up). When an agency starts to exalt a statute's purpose alongside the statute's silence, it's often a tipoff that the Executive Branch effectively is about to take a red pen to the United States Code. Yet "even the most formidable argument concerning the statute's purpose" cannot supplant "the statute's text." *Kloeckner v. Solis*, 568 U.S. 41, 55 n.4 (2012).

Indeed, it "frustrates rather than effectuates legislative intent" simply to assume that "*whatever* furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam). This is especially so when, as here, Congress explicitly cabins that primary purpose by erecting barriers to ensure that 340B's steep discounts extend *only* to covered nonprofit entities and their eligible patients. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B)

(prohibiting the "transfer" of 340B-discounted drugs to anyone who is not an eligible "patient" of a covered "entity"); *id.* § 256b(a)(5)(A)(i) (prohibiting covered entities from receiving duplicate discounts). Bent on expanding manufacturers' 340B duties at all costs, however, HRSA sweeps aside these countervailing policy aims.

Nor can statutory silence supply words and meanings that Congress did not. True, as the District Court found, the 340B statute "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." (JA20) But mere silence is "no[t] ambiguity." *Ry. Lab. Execs. Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 664 n.5 (D.C. Cir. 1994) (en banc) (citations omitted). If anything, such "statutory silence, when viewed in context, is best interpreted as *limiting* agency discretion." *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 223 (2009) (emphasis added).

Put another way, "[t]he principle that a matter not covered is not covered is so obvious that it seems absurd to recite it." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012). Yet HRSA cannot resist the urge "to supply words or even whole provisions that have been omitted." *Id.* Lacking any statutory support

for its latest regulatory crackdown, HRSA insists that whatever duties Congress does not forbid the agency from imposing on manufacturers, it permits. But that can't be right.

"An agency cannot read a statute discussing topic X to confer power over unrelated topic Y just because the statute fails to mention topic Y." *Sun Wen Chan v. Att'y Gen. of U.S.*, 491 F.3d 100, 107 (3d Cir. 2007); *see, e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency"). Nor may HRSA read a statutory duty for manufacturers to *sell* 340B-discounted drugs to *covered* entities as a duty for manufacturers to *deliver* 340B-discounted drugs to *uncovered* entities. This Court "should not [so] lightly conclude that Congress enacted a self-defeating statute." *Quarles v. United States*, 139 S. Ct. 1872, 1879 (2019).

If Congress had wanted to authorize HRSA to force manufacturers to deliver 340B-discounted drugs to uncovered entities like contract pharmacies, it knew full well how to do so. Another part of the Veterans

Health Care Act of 1992, the very law that created the 340B Program, explicitly addresses pharmacies "operating under contract." Public Law No. 102-585, 38 U.S.C. § 8126(h)(3) (1992). So when Congress has provided for contract pharmacy arrangements, "it has done so clearly and expressly." *FCC v. NextWave Pers. Comms.*, 537 U.S. 293, 302 (2003). "But it did not do so in the 340B statute." (JA23)

What's more, Congress considered but ultimately rejected specific 340B language addressing drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with," covered entities. S. Rep. No. 102-259, at 2 (1992). And "where Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). Simply put, there is no gap here to fill.

"[J]ust as established practice may shed light on the extent of power conveyed by general statutory language, so the want of assertion of power by those who presumably would be alert to exercise it, is equally significant in determining whether such power was actually

conferred." *FTC v. Bunte Bros., Inc.*, 312 U.S. 349, 352 (1941). No surprise, then, that for nearly three decades—from 1992 to 2020—HRSA steadfastly maintained that manufacturers were free to impose delivery conditions on sales of 340B-discounted drugs. As the District Court found, the agency not only espoused the view that it lacked enforcement authority over manufacturers' delivery terms for contract pharmacies, but also applied that view when enforcing covered entity compliance. (JA12–JA16)

While it may be possible for an entire industry to violate federal law, for years, without some regulatory bureaucrat noticing, the "more plausible hypothesis" is that it has "been left alone" because it was fully compliant. *Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 510-11 (7th Cir. 2007). This is especially true when the agency's about-face creates an "unfair surprise" for regulated entities who, as here, had come to rely on the agency's earlier public pronouncements. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170-71 (2007).

Even worse is that HRSA now wants to use this unfair surprise to impose civil monetary penalties on manufacturers for "knowingly and intentionally" overcharging "covered" entities. Indeed, as construed by

HRSA, the 340B statute "fails to provide a person of ordinary intelligence fair notice of what is prohibited." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (cleaned up). But Congress "did not intend" a construction that "raises serious constitutional doubts." *Clark v. Martinez*, 542 U.S. 371, 382 (2005).

In sum, to allow HRSA to force manufacturers to deliver unlimited 340B-discounted drugs to any number of uncovered, for-profit third parties would be to create new statutory rights and burdens that Congress never approved. "Regardless of how serious the problem an administrative agency seeks to address," it cannot "exercise its authority in a manner that is inconsistent with the [statute] that Congress enacted into law." *Brown & Williamson*, 529 U.S. at 125 (cleaned up). And when "the express terms of a statute give . . . one answer and extratextual considerations suggest another, it's no contest. Only the written word is the law." *Bostock*, 140 S. Ct. at 1737.

## II. THE SWEEPING EXPANSION OF THE 340B PROGRAM IS A "MAJOR QUESTION" RESERVED SOLELY FOR CONGRESS.

If any doubt remains as to the 340B statute's reach, the "major-questions" doctrine resolves it. It "presume[s] that 'Congress intends to make major policy decisions itself, not leave those decisions to

agencies.'" *West Virginia*, 142 S. Ct. at 2609 (quoting *U.S. Telecom Ass'n v. FCC*, 855 F.3d 381, 422-23 (D.C. Cir. 2019) (Kavanaugh, J., dissenting from denial of rehearing en banc)). This is especially true when, as here, an agency asserts regulatory authority "beyond what Congress could reasonably be understood to have granted." *Id.* at 2620. Such "grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].'" *Id.* (quoting *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001)). The 340B statute is no exception.

### A. Only Congress may resolve a "major question."

Even when a statutory gap exists, an agency may fill that gap only when the "statutory circumstances" clarify that Congress meant to grant it such power. *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). The statutory scheme here precludes any suggestion that Congress meant for HRSA to resolve major ambiguities in the statute.

Given the 340B statute's limited scope and purpose, Congress gave HRSA only "specifically limited" authority. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014). Most importantly, "HRSA lacks the authority to issue a legislative rule." *Novartis Pharms. Corp.*, 2021 WL

5161783, at *8. And though HRSA has repeatedly asked Congress for "a statutory amendment" conferring "general rulemaking authority" since FY 2017, Congress has never obliged. *See* HHS, HRSA, *Fiscal Year 2023: Justification of Estimates for Appropriations Committees*, at 389 (2022) <https://bit.ly/3v5UXDx>.

Yet even when "Congress has delegated an agency general rulemaking or adjudicatory power, judges presume that Congress does not delegate its authority to settle or amend major social and economic policy decisions." William N. Eskridge Jr., *Interpreting Law: A Primer on How to Read Statutes and the Constitution* 288 (2016). Rather, Congress itself is "more likely to have focused upon, and answered, major questions." Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 370 (1986). That is why the Supreme Court "expect[s] Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Util. Air Regul. Grp.*, 573 U.S. at 324 (quoting *Brown & Williamson*, 529 U.S. at 160).

Consistent with this principle, federal courts may not extend the scope of a statute's regulatory reach over a "major question" without a *clear* congressional grant:

- In rejecting the Environmental Protection Agency's position that its Clean Power Plant Rule was the "best system of emissions reduction" under the Clean Air Act, the Supreme Court held that it was "not plausible that Congress gave EPA authority to adopt on its own such a regulatory scheme." *West Virginia*, 142 S. Ct. at 2616. "A decision of such magnitude and consequence rests with Congress itself, or an agency acting pursuant to a clear delegation from that representative body." *Id.*
- In vacating a Federal Communications Commission rule that would have exempted certain telephone companies from statutory rate-filing requirements, the Supreme Court found it "highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion." *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 231 (1994).

- In rejecting the Food and Drug Administration's attempt to regulate cigarettes as "drugs" or "devices" under the Food, Drug, and Cosmetic Act, the Supreme Court was "confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." *Brown & Williamson*, 529 U.S. at 146.
- In overturning an interpretative rule by the U.S. Attorney General that would have prohibited, under the Controlled Substances Act (CSA), physicians from prescribing drugs for assisted suicide, the Supreme Court rejected the "idea that Congress gave the Attorney General such broad and unusual authority through an implicit delegation in the CSA's registration provision." *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006).
- In vacating an EPA rule that would have subjected millions of previously unregulated greenhouse-gas emitters to onerous permitting requirements under the Clean Air Act, the Supreme Court expressed "skepticism" that the "long-extant statute" contained "an unheralded power to regulate so 'significant [a]

portion of the American economy.'" *Util. Air Regul. Grp.*, 573 U.S. at 324 (quoting *Brown & Williamson*, 529 U.S. at 159).

The major-questions doctrine not only makes sound practical sense as a rule of construction, but also serves a profound constitutional function. The "key reason" for the doctrine "is the strong presumption of continuity for major policies unless and until Congress has deliberated about and enacted a change in those major policies." Eskridge, *supra*, at 289. "Because a major policy change should be made by the most democratically accountable process—Article I, Section 7 legislation—this kind of continuity is consistent with democratic values." *Id.*

At bottom, the major-questions doctrine "supports a presumption of *non*delegation in the face of statutory ambiguity over major policy questions or questions of major political or economic significance." Abbe R. Gluck & Lisa Schultz Bressman, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part 1,* 65 Stan. L. Rev. 901, 1003 (2013). So even if the 340B statute were ambiguous, whether the 340B Program should be expanded as HRSA insists qualifies as a "major question."

### B. Whether to expand the scope of manufacturer duties under the 340B Program is a "major question."

Whether (and how) to expand 340B's already heavy burdens on drug manufacturers is a major question that only Congress can answer. Although the Supreme Court has not announced a bright-line test for when an agency's expansion of a statute's regulatory scope presents a major question, it has supplied some relevant factors. The doctrine applies in "cases in which 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*, 142 S. Ct. at 2608 (quoting *Brown & Williamson*, 529 U.S. at 159–60). Under any conceivable test, HRSA's extra-statutory expansion of the 340B Program raises a major question.

The economic impact of the 340B Program is enormous. Providing affordable medicine to poor and underserved communities comes with a hefty price tag. Discounted purchases under the 340B Program soared to $38 billion in 2020. *See* HRSA, FOIA response letter from Glen Voelker, Government Information Specialist, to Dr. Adam J. Fein, Drug Channels Institute (June 15, 2021) <https://bit.ly/3M7op2C>. That

amount is a staggering 27% increase over 2019 purchases, and more than quadruple all 340B purchases in 2014. *See* Drug Channels Institute, *The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019* (June 16, 2021) <https://bit.ly/3M7op2C>.

According to IQVIA, the list-price value of all 340B purchases in 2020 was more than $80 billion. *See* IQVIA, *Growth of the 340B Program Accelerates in 2020* (Mar. 31, 2021) <https://bit.ly/3M1jEaG>. This marked an 18.1% year-over-year growth versus 2019—"over four and a half times the overall pharma growth rate of 4.0%." *Id.* In fact, since 2017, the 340B Program's drug sales have swelled by 76%. *Id.* This explosion in sales has made 340B the second-largest federal prescription drug program, behind only Medicare Part D.

Given these stakes, the political significance of HRSA's novel construction of the 340B statute cannot be overstated. As HRSA's own audits have found, covered entities' increased use of unlimited contract pharmacy arrangements has produced a sharp rise in unlawful drug diversion and duplicate discounting. As recently as 2020, the Government Accountability Office reported that, for HRSA audits in FY 2012–2019, there were over 1,500 findings of 340B non-compliance by

covered entities. GAO, GAO-21-107 (Dec. 2020), at 13 <https://bit.ly/3hfFVD8>. Since 2017, more than 25% of covered entities audited by HRSA have had at least one finding of contract pharmacy non-compliance. *Id.* For manufacturers, this spike in unlawful practices means that a sizable percentage of valuable inventory is being unfairly sold at a loss.

By expanding the channels for unlawful practices, HRSA's latest construction of the 340B statute threatens to drive 340B costs higher still. For while HRSA auditors may tally instances of unlawful drug diversion and duplicate discounting, the agency has chosen to look the other way in remedying those violations. As the GAO report explains, "HRSA did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies . . . because the 340B statute does not address contract pharmacy use." *Id.* at 15–16. Put differently, HRSA believes that 340B's statutory silence unambiguously requires manufacturers—at threat of civil monetary penalties—to deliver unlimited 340B-discounted drugs to any number of for-profit contract pharmacies, yet that very silence also allows covered entities to flout explicit statutory prohibitions with abandon. That's absurd.

At bottom, HRSA's version of 340B would allow the agency to unilaterally transform the 340B Program from a sensible cost-saving measure into a misguided wealth-transfer scheme. Given the steep discounts the 340B Program provides, many covered entities and contract pharmacies have, in the wake of HRSA's revised guidance, come to rely on manufacturers' supply of 340B-discounted drugs as an added revenue stream by selling those drugs at a steep profit.

A recent analysis found that "340B covered entities and their contract pharmacies generated an estimated $113 billion in gross profits on 340B purchased medicines in 2018." Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program*, at 3 (Oct. 2020) <https://bit.ly/3w7Vs0L>. Indeed, contract pharmacies' average profit margin on 340B drugs "is an estimated 72 percent, compared with just 22 percent for non-340B medicines." *Id.*; Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy* (May 4, 2022), <https://bit.ly/399OKhD> (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"). This is far afield from Congress's stated purpose.

Whether manufacturers should be forced to give away product at deep discounts so that covered entities, along with their for-profit vendors, can generate operating revenue by reselling that product at market prices is far outside HRSA's expertise—much less its statutory charge. No agency may "forc[e] some people alone to bear public burdens which . . . should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960).

Such action also raises serious constitutional concerns, as it suggests that private property is up for grabs on the government's say-so. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) ("Government action that physically appropriates property is no less a physical taking because it arises from a regulation."); *Youngstown Sheet & Tube Co.*, 343 U.S. 579, 585 (1952) ("There is no statute that expressly authorizes the President to take possession of property as he did here."). Whatever else it may be, this is precisely the kind of "transformative expansion" of regulatory authority that belongs to Congress, not the agency. *Util. Air Regul. Grp.*, 573 U.S. at 324.

If embraced on appeal, HRSA's overhaul of the 340B Program would have profound economic and political consequences. In the face of

statutory silence, this Court can be confident that "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." *Brown & Williamson*, 529 U.S. at 146.

## III. IMPOSING EXTRA-STATUTORY REQUIREMENTS ON DRUG MANUFACTURERS WOULD CARRY THE COURTS FAR BEYOND THEIR PROPER ROLE.

Just as federal agencies may not rewrite federal law, neither may federal courts. The courts must leave the job of legislating to Congress. They may not "add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and [their] own imaginations." *Bostock*, 140 S. Ct. at 1738. As enacted, the 340B statute may well have many shortcomings; but the judiciary "is not the forum to resolve that policy debate." *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1906 (2022).

A court that agrees to expand a massive federal program does so in defiance of many blind spots. A court cannot know whether it is wise, despite the many other problems facing society (including the need to foster economic growth), to divert private capital in the way it thinks best. "The omnipresence of unintended consequences" for any public

policy "can be attributed, in large part, to the absence of relevant information." Cass R. Sunstein, *The Cost-Benefit Revolution* 79 (2018). Yet "the decisions that follow adjudication, involving a small number of parties," often "turn out to be inadequately informed." *Id.* at 86.

One corollary to the rule that courts cannot rewrite statutory law is that the political branches may do so when necessary. When the political branches are presented with a policy problem, they can collect data, study incentives, consider the diverse viewpoints of stakeholders, and then craft a systemic solution. They are better able to "collect dispersed knowledge" and "bring it to bear on official choices." *Id.* at 88. When, by contrast, a court is presented with a systemic problem, it (or a jury) can merely hear from a few witnesses, a few experts, and a few lawyers, and then impose remedies limited to the parties in the lawsuit. Litigation, with its inherent limitations (and frightful expense), is no way to go about crafting major public policy. A court is ill-equipped to grasp the many factors at play outside the confines of a given case or controversy.

Even if this Court could somehow craft a superior 340B Program, that would not justify such drastic judicial activism. The judge's power

to write laws mirroring the judge's sense of justice belongs to an era that lacked a popular branch of government. Judges can no longer justify creating law by claiming merely to "discover" it. "Judicial amendment flatly contradicts democratic self-governance." Scalia & Garner, *supra*, at 96. "Our preference for liberty and self-rule is undermined when the courtroom is opened up as an alternative forum for lawmaking." Diarmuid F. O'Scannlain, *Politics in Robes: The Separation of Powers and the Problem of Judicial Legislation*, 101 Va. L. Rev. Online 31, 34 (2015). That is not a role any member of this Court should embrace.

Engaging in judicial policymaking would also carry the judiciary far beyond its proper role—resolving discrete and tractable disputes rather than trying to manage wider social ills. Without this venerable constraint, "Judges are nothing more than politicians in robes, free to tackle the social problems of the day based on avant-garde constitutional theory or, worse yet, their own personal preferences. While such jurists may often be well meaning, their approach is inconsistent with our government's history, structure, and framework." *Id.* at 33.

In short, there is *no* authority permitting judges to settle public-policy disputes of the highest order. Despite HRSA's invitation on appeal, this Court cannot insist that the word "offer" means "deliver" any more than it can decide that an "uncovered" for-profit pharmacy is a "covered" 340B entity. A federal court has "no roving license" to "disregard clear language"—not even if the court is convinced that "Congress must have intended something" different. *Mich. v. Bay Mills Indian Cmty.*, 572 U.S. 782, 794 (2014) (cleaned up). This bedrock rule compels affirmance here.

## CONCLUSION

The Court should affirm the judgment below.

July 28, 2022

Respectfully submitted,

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## COMBINED CERTIFICATIONS

I certify that:

(1) both attorneys whose names appear on this brief are members of the bar of this Court;

(2) this brief complies with the type-volume limits of Fed. R. App. P. 29(a)(5) as it contains 4,715 words, excluding the parts exempted by Fed. R. App. P. 32(f);

(3) this brief complies with the typeface and the type-style requirements of Fed. R. App. P. 32(a) as it has been prepared in 14-point Century Schoolbook font;

(4) a virus check using Microsoft Defender Antivirus (version 1.371.607.0) detected no virus; and

(5) the text of the electronic brief and the hard copies are identical.

July 28, 2022

/s/ Cory L. Andrews
CORY L. ANDREWS

## CERTIFICATE OF SERVICE

I certify that, on July 28, 2022, I served all counsel of record via the Court's CM/ECF system.

/s/ Cory L. Andrews
CORY L. ANDREWS