Nos. 21-3128 & 21-3405

IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

ELI LILLY COMPANY and LILLY USA, LLC,

Plaintiffs-Appellants, Cross-Appellees,

v.

XAVIER BECERRA, et al.,

Defendants-Appellees, Cross-Appellants.

Appeal from the United States District Court
for the Southern District of Indiana
(No. 1:21-cv-00081-SEB-MJD)
(District Judge Sarah Evans Barker)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS AND PARTIAL REVERSAL

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June 1, 2022

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128 & 21-3405

Short Caption: Eli Lilly and Company v. Becerra

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Attorney's Signature: /s/ Cory L. Andrews Date: June 1, 2022

Attorney's Printed Name: Cory L. Andrews

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

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N/A

Attorney's Signature: /s/ John M. Masslon Date: June 1, 2022

Attorney's Printed Name: John M. Masslon

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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INTEREST OF *AMICUS CURIAE*[*]

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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 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,

[*] 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.

executive agencies like the Health 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' 340B burdens under the statute. The District Court's decision, by seizing on the 340B statute's silence alongside its "overarching purpose," blesses HRSA's latest extratextual rewrite and effectively grants the agency gap-filling authority that Congress never gave it. Because rewriting 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).

Federal agencies have 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 two other 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. *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *7 (D. Del. Feb. 16, 2022); *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021).

The District Court's contrary ruling, if allowed to stand, would allow HRSA to unilaterally transform the 340B Program from a sensible cost-saving measure into a constitutionally dubious wealth-transfer scheme. This it cannot do. Above all, whether to drastically expand the scope of the 340B Program in this way is a question of "such economic and political magnitude" that Congress would never commit it to the discretion of an agency without explicitly saying so. *Brown & Williamson*, 529 U.S. at 133.

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.

HRSA's enforcement discretion over the 340B Program is not unlimited. 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). Although it overturned HRSA's May 17, 2021 violation letter as arbitrary and capricious under the APA, the District Court found that HRSA's latest effort to force Lilly to deliver 340B-discounted drugs to for-profit uncovered entities "neither exceeds the agency's statutory authority nor is contrary to law." (R.144.50) That error warrants reversal.

The 340B statute imposes only two duties on manufacturers like Lilly. First, if a manufacturer 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, the manufacturer 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 manufacturers. 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)).

At HRSA's urging, however, the District Court went awry. "We cannot divine," the District Court stated, "whether Congress intended for drug manufacturers to have unlimited delivery obligations under the statute, untethered to the particular covered entity's actual distribution needs." (R.144.58) Despite this statutory silence, the District Court embraced HRSA's view that the 340B statute prohibits Lilly 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. (*Id.* at 144.59) 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.

The District Court's analysis did little more than cite 340B's "overarching purpose" (R.144.43) before adopting HRSA's extra-statutory gloss on the statute. Although 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). When a court starts to exalt a statute's "overarching purpose" alongside the statute's silence, it's often a tipoff that the Third Branch is effectively about to take a red pen to the United States Code.

Contrary to the District Court's view, "even the most formidable argument concerning the statute's purpose [can]not overcome . . . 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 true when, as here, the statute explicitly cabins that 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). The District Court simply ignored these countervailing policy aims.

Nor can statutory silence supply words and meanings that Congress did not. True enough, as the District Court found, the "340B statute is silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations." (R.144.41) 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).

If Congress had wanted to authorize HRSA to promulgate additional requirements for 340B deliveries to 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 addressed pharmacies "operating under contract." Public Law 102-585, 38 U.S.C. § 8126(h)(3) (1992). 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." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021).

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). "[W]here 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)); *cf. Boim v. Holy Land Found. for Relief & Dev.*, 549

F.3d 685, 689 (7th Cir. 2008) ("[S]tatutory silence on the subject of secondary liability means there is none.") Simply put, there is no gap here to fill.

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 confirmed, the agency "not only espoused the view that it lacked enforcement authority regarding contract pharmacy use but also applied that view in practice in addressing covered entity compliance." (R.144.54)

While it may be possible for an entire industry to violate federal law for many 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).

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

The *lack* of a statutory prohibition does not justify an agency's *imposing* that extra-statutory prohibition on regulated entities. *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"). This is especially so when the agency threatens to use that newfound prohibition to impose civil monetary penalties on manufacturers for "knowingly and intentionally" overcharging covered entities.

To allow HRSA to expand 340B to require manufacturers to deliver unlimited 340B-discounted drugs to any number of uncovered for-profit third parties would be to create new rights and burdens that Congress never approved. "Regardless of how serious the problem an administrative agency seeks to address . . . it may not exercise its authority 'in a manner that is inconsistent with the [statute] that Congress enacted into law.'" *Brown & Williamson*, 529 U.S. at 125 (quoting *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517 (1988)). 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.

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 asked Congress for "regulatory authority in the President's budget each year since FY 2017," Congress has never agreed. HRSA, HHS, *Fiscal Year 2021: Justification of Estimates for Appropriations Committees*, at 296 (2020) <https://bit.ly/3KPkxlp>.

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). Thus, 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, the Supreme Court has repeatedly refused to extend the scope of a statute's regulatory reach over a "major question" without a *clear* congressional grant:

- In vacating a Federal Communications Commission rule that would have exempted certain telephone companies from statutory rate-filing requirements, the 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 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 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 Environmental Protection Agency rule that would have subjected millions of previously unregulated greenhouse-gas emitters to onerous permitting requirements under the Clean Air Act, the 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).
- In refusing to defer to the Internal Revenue Service's view that the Affordable Care Act authorized billions of dollars each year in government subsidies to individuals who obtained health insurance through a federal exchange, the Court explained that, given the "deep 'economic and political significance'" of that

question, "[h]ad Congress wished to assign [it] to an agency, it surely would have done so expressly." *Burwell*, 576 U.S. at 486 (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324).

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). Whether the 340B Program should be expanded as HRSA insists is just such a "major question."

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

Whether and how to expand the already heavy burdens the 340B Program imposes 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 unilateral expansion of a statute's regulatory reach presents a major question, it has supplied some relevant factors. These include (1) "the amount of money involved for regulated and affected parties," (2) "the overall impact on the economy," and (3) "the degree of congressional and public attention to the issue." *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). 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 value 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.

Nor has Congress shown a lack of interest in the 340B Program. There are at least four 340B-related bills pending in Congress right now. *See* H.R. 4390 117th Cong. (2021); H.R. 3203 117th Cong. (2021); H.R. 7838 117th Cong. (2021); S. 773 117th Cong. (2021). Rather than reach for a novel judicial construction as the District Court did, this

Court should leave the task of amending the 340B statute to Congress, where it rightly belongs.

Given the stakes, the gravity of the District Court'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 noncompliance 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, the District Court's 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 contract pharmacies . . . because the 340B statute does not address contract pharmacy use." *Id.* at 15-16. So HRSA believes that 340B's statutory silence unambiguously requires manufacturers—at pain 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 without consequence. That's absurd.

At bottom, the District Court's version of 340B would allow HRSA 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 significant 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 intended purpose.

Whether manufacturers should be forced to give away product at steep discounts so that covered entities, along with their for-profit vendors, can generate operating revenue by reselling that product at or near market prices is far outside HRSA's expertise—much less its statutory authority. 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. Left to stand, the District Court's overhaul of the 340B Program will have enormous 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.

A court that seeks 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.

The corollary to the rule that courts should not rewrite substantive 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 diverse viewpoints from stakeholders, and then craft a systemic solution. They are better able to "collect disperses 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 simply ill-equipped to grasp the many factors at play outside the confines of a given case or controversy.

Even if the District 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).

Engaging in such judicial policymaking would not only undermine the democratic legitimacy of any new "law" but also carry the courts far beyond their 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. The District 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). This bedrock rule compels partial reversal here.

CONCLUSION

The judgments for Defendants-Appellees on Counts X, XI, and XIII should be reversed, and the District Court directed to enter judgment for Plaintiffs-Appellants on those counts.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify:

This brief complies with the type-volume limits of Fed. R. App. P. 29(a)(5) and Seventh Circuit Rule 29 because it contains 4,511 words, excluding the parts exempted by Fed. R. App. P. 32(f).

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