Nos. 21-3128 & 21-3405

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
Honorable Sarah Evans Barker

COMBINED REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AND RESPONSE BRIEF FOR PLAINTIFFS-CROSS-APPELLEES

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Constitutional Provisions

Other Authorities

INTRODUCTION

The government's brief lays bare the infirmity of its position. The government has almost nothing to say about the text of Section 340B. Instead, relying on admitted statutory silence about contract pharmacies, proposals Congress considered but declined to enact, vague notions of statutory purpose, and snippets from legislative history, the Department of Health and Human Services (HHS) asks this Court to impose an extra-statutory, multibillion-dollar requirement on outpatient-drug manufacturers that would transform the 340B program into the *second-largest federal drug program in existence*. In the government's view, if manufacturers do not acquiesce in delivering deeply discounted drugs to an unlimited number of third-party, for-profit contract pharmacies, without restriction—on the pretense that those entities are servicing non-profit covered entities—then manufacturers must either give up the right to participate in Medicare and Medicaid or face crippling penalties (or both). Never mind that the 340B statute says nothing of the kind; and never mind that the agency's atextual interpretation would effect a massive private wealth transfer from innovative pharmaceutical companies to for-profit pharmacy chains without congressional approval, must less just compensation. Worse, HHS's approach treats drug manufacturers as though they were instrumentalities of the federal government—only authorized to do what the government says they can do. That is exactly backwards. It is administrative agencies like HHS that "have only those powers given to them by Congress." *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022). When it comes to private entities, congressional permission is decidedly *not* required. *Accord Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000). The

government's contrary position rests on a serious misunderstanding of how regulation works in this country; it should be rejected.

As explained below, the text of Section 340B, its structure, and basic canons of statutory construction compel rejection of HHS's interpretation. Starting with the text, Section 340B of the Public Health Service Act simply requires drug manufacturers to "*offer* each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price"—nothing more. 42 U.S.C. §256b(a)(1). Indeed, all agree that is the "sum total of the statute's language regarding manufacturers' obligations." *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 193 (D.N.J. 2021). Yet, neither that provision nor any other in the statute purports to impose affirmative "delivery obligations"—much less the obligation to deliver drugs *wherever* or *to whomever* a covered entity might wish, rather than a covered entity itself. SA.41. Nor does the statute say a word about for-profit "contract pharmac[ies]," *id.*, let alone suggest that manufacturers are somehow obligated to deliver discounted drugs *to* an unlimited number of third-party, for-profit contract pharmacies, under opaque inventory management schemes, without restriction, wherever they might happen to be located.

Even the government concedes the statute is (at best for its position) *silent* as to manufacturers' delivery obligations and usage of for-profit contract pharmacies. *See* Gov't Br.30, 33. And every single district court to consider the question (including the one below) has agreed. *See* SA.34, 45; *AstraZeneca Pharms. LP v. Becerra*

("*AstraZeneca II*"), 2022 WL 484587, at *2, *6 (D. Del. Feb. 16, 2022); *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021); *Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 193 (D.N.J. 2021).

That should be the end of the government's case: Manufacturers cannot be required to deliver 340B-ceiling-priced drugs to (and thereby provide arbitrage opportunities and subsidies to) third-party, for-profit contract pharmacies that are not mentioned in the statute and that themselves plainly are not entitled to 340B-discounted drugs. Because, *as even the government acknowledges*, the text of Section 340B does not prohibit Lilly's contract-pharmacy initiative, *see* Govt.Br.34 (admitting that "[t]here is nothing in the 340B statute that explicitly prohibits" it), the question is not (as the government thinks) whether outpatient drug manufacturers are entitled to an *exception* from some broad delivery requirement that Congress affirmatively imposed. Congress said nothing about it. Rather, the question is whether statutory silence can be read to *create* the broad requirement to service contract-pharmacy arrangements that HHS now insists upon, backed by the threat of draconian monetary penalties. It cannot. It is well settled that "one is not to be subjected to a penalty unless *the words of the statute* plainly impose it." *Comm'r v. Acker*, 361 U.S. 87, 91 (1959) (quoting *Keppel v. Tiffin Sav. Bank*, 197 U.S. 356, 362 (1905)).[1] Yet subjecting Lilly "to a penalty" that no "words of the statute plainly impose" is exactly what the government seeks to do here. The government's analogy to "donut holes," Govt.Br.30, thus, misses the mark.

[1] All emphases are added unless otherwise indicated.

In any case, given the political and economic magnitude of the rule HHS wishes to squeeze out of the statute, congressional silence is not the government's friend here. *Compare West Virginia*, 142 S. Ct. at 2609, *with* Govt.Br. 33. The government's interpretation, if adopted, would grant it sweeping economic power and put manufacturers to the unconstitutional choice of either subsidizing for-profit pharmacies or foregoing participation in the ubiquitous Medicaid and Medicare Part B programs, which "touch[] the lives of nearly all Americans." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Under the government's approach, the 340B program, which was once a tail to the Medicaid rebate program, has now become a dog. But when an agency claims to "discover in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority," the Supreme Court demands not just implied congressional authorization, but "clear" congressional authorization. *West Virginia*, 142 S. Ct. at 2609-10. Both are lacking.

The government likewise grasps for arguments rooted in public policy and hypothetical slippery slopes. But those are unavailing. Even if some policy arguments could justify ignoring the text in some cases (a very big if), the government's policy arguments here are not among them, since they turn on a demonstrably false description of Lilly's contract-pharmacy initiative and position. The government repeatedly attempts to create the impression that covered entities cannot buy or access discounted drugs under Lilly's policy. That is simply not true. To be clear: Lilly makes all of its covered outpatient drugs available, in unlimited quantities, at discounted prices, to every covered entity, regardless of their contract-

pharmacy relationships—and even to contract pharmacies within certain reasonable limits. Lilly's policy merely requires delivery to a covered entity *itself* or a single designated contract pharmacy, rather than an unlimited number of contract pharmacy locations, which is exactly how the government restricted covered entities' use of contract pharmacies for nearly 15 years. Lilly also does *not* charge covered entities full prices for outpatient drugs—to the extent any covered entity claimed to have been charged (assertions Lilly had no opportunity to examine or rebut), it would be because it made purchases from or through pharmacies, not Lilly or its wholesalers, to circumvent Lilly's delivery policy.

Regardless of the outcome of this appeal, covered entities will be able to purchase discounted drugs from Lilly. The question presented here is *not* whether Lilly *offers* its outpatient drugs for purchase by covered entities; Lilly unquestionably does. Nor is the question whether patients will be able to obtain discounted drugs purchased by their covered entity; they unquestionably will. The question is whether HHS can force manufacturers, on pain of severe penalties, to comply with onerous obligations that Congress did not impose and that Congress likely could not impose without violating the Constitution. The answer to that question is plainly no. The Supreme Court has repeatedly cautioned against interpreting statutes to raise serious constitutional questions, which a massive forced wealth transfer from outpatient drug manufacturers to for-profit contract pharmacies plainly would.

In sum, Lilly was entitled to a declaration that its contract-pharmacy initiative does not violate the statute. The district court's finding to the contrary should be

reversed. Likewise, for those reasons and more, the government's May 2021 Violation Letter is not only contrary to law, but also arbitrary and capricious, and the government's arguments on cross-appeal and in support of its enforcement action should be rejected.

STATEMENT OF JURISDICTION

Lilly agrees with the government's statement of jurisdiction for purposes of the government's cross-appeal (No. 21-3405).[2]

ARGUMENT

I. Section 340B Does Not Require Manufacturers To Deliver Discounted Drugs To Third-Party, For-Profit Contract Pharmacies Without Restriction.

A. The Text of the Statute Precludes the Government's Position.

The government has no answer for the text of the 340B statute, which likely explains why the text makes precious few appearances in the government's brief. That speaks volumes in a statutory construction case. To recap, here is what 42 U.S.C. §256b(a)(1) says:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity … does not exceed [the ceiling price].
>
> Each such agreement … shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the

[2] A recent Fourth Circuit decision further confirms, for purposes of Lilly's appeal (No. 21-3128), that where "HRSA has taken action against" a participant in the 340B program based on its view of what Section 340B requires, "ongoing disagreement … between HRSA" and the participant "over how" to interpret the statute suffices to create "a definite and concrete controversy" that satisfies Article III. *Genesis Healthcare, Inc. v. Becerra*, 2022 WL 2375178, at *6 (4th Cir. July 1, 2022).

> applicable ceiling price if such drug is made available to any other purchaser at any price.

(Paragraph break added). This provision says nothing about any obligation to deliver discounted drugs to contract pharmacies; nor does it prohibit manufacturers from declining to deliver discounted drugs to an unlimited number of contract pharmacies.

That should be the end of this case, since no one disputes that Lilly in fact "offer[s]" to "each covered entity" the ability to "purchase," "at or below the applicable ceiling price," all "covered outpatient drugs" that Lilly "ma[k]e[s] available to any[one] at any price." 42 U.S.C. §256b(a)(1). In other words, no one disputes (or could dispute) that Lilly does exactly what the language of the statute requires of it.

Rather than confront the statutory language head-on, the government's brief blows by the statutory text as quickly as it can. It quotes the "offer" provision and then asserts, in a conclusory fashion, that the *real* "bottom line requirement" in Section 340B is that manufacturers "must sell their drugs to covered entities at a discounted price." Govt.Br.30-31. But putting aside for the moment that statutes do not pursue their "bottom line" at all costs, the government never explains how an obligation to "sell" (to "offer" "for purchase") discounted drugs to covered entities equates to an obligation to *deliver* discounted drugs *to third-party, for-profit businesses* on whatever terms covered entities demand, let alone to service an unlimited number of third-party, for-profit contract pharmacies based on their purported contractual arrangements to share proceeds with covered entities.

The government's argument—that the textual obligation to "offer" drugs "for purchase" to covered entities at a discounted "price" actually encompasses an implicit,

and far more onerous, obligation to deliver the drugs to for-profit third parties that are not mentioned in the statute—is unmoored from the statutory text. As Lilly explained in its opening brief, *see* Opening.Br.28-30, no one uses "offer" or "purchase" that way. The ordinary meaning of "offer" is to "present for acceptance or rejection"; "present for sale." Opening.Br.28; *accord, e.g.*, *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021). And the ordinary meaning of "purchase" is to "obtain in exchange for money or its equivalent; buy." Opening.Br.28. These ordinary meanings, which "govern[]" here because Congress did not define the terms, *see Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1750 (2020), do not encompass how or where delivery occurs—and especially not delivery to *someone other than the buyer*. Indeed, even if the statute explicitly required manufacturers not simply to "offer," but also to "sell" discounted drugs to covered entities, Govt.Br.30, the government's construction would still be wrong. After all, an obligation to "sell" drugs to covered entities at a certain "price" does not include an obligation to *deliver* drugs to *someone other than those entities*; nor does it prohibit conditions that do not render the offer (or sale) illusory. Opening.Br.31-32.

The government does not grapple with any of this, even though Lilly anticipated the government's arguments in its opening brief. Instead, in another rare nod to the language Congress enacted, the government pivots to quoting (at 29) the *first* sentence of 42 U.S.C. §256b(a)(1), which requires HHS to enter into contracts with manufacturers "under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity … does

not exceed" the ceiling price. But the government provides no more reason to derive a "deliver to anybody, wherever told" requirement from the "purchase by" provision than the "offer" provision. As a threshold matter, because the May 2021 Violation Letter did not rely on this statutory language, the government may not rely on it now to support its litigating position. *See DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020); Opening.Br.20, 45-46. In any event, as Lilly previously explained, Opening.Br.46, the "purchased by" language imposes requirements only on "[t]he Secretary"; it does not impose any obligations—let alone any delivery obligations—on manufacturers. 42 U.S.C. §256b(a)(1); *see also AstraZeneca Pharms. LP v. Becerra* ("*Astrazeneca I*"), 543 F. Supp. 3d 47, 59 (D. Del. 2021) (agreeing with this point). And to the extent the provision contemplates required action by manufacturers, it mandates only the price of 340B drugs: the "amount required to be paid" by "covered entit[ies]," *i.e.*, the price, may not "exceed" the ceiling price. 42 U.S.C. §256b(a)(1). The government provides no explanation for how this text—which, again, says nothing about delivery and nothing about contract pharmacies—can be understood to support an obligation to *deliver* 340B drugs anywhere and to anyone a covered entity demands, much less to an unlimited number of third-party, for-profit contract pharmacies.[3]

[3] To be clear, a covered entity's purchase price for purchases made from Lilly or its wholesaler will never intentionally exceed the ceiling price, and Lilly does not decline to offer its outpatient pharmaceuticals to covered entities at the ceiling price on the ground that a covered entity has multiple contract-pharmacy relationships. Lilly only declines to deliver (or instructs its wholesalers not to deliver) 340B-discounted drugs to locations other than the covered entity itself, contract pharmacies wholly owned by the covered entity, or a single designated pharmacy location.

The government also conspicuously ignores all the other textual and contextual evidence discussed in Lilly's opening brief and by other district courts. First and foremost, the government ignores the fact that Congress explicitly *did* account for contract pharmacy relationships and delivery obligations where it wanted to—including in the very next provision of the omnibus bill that enacted Section 340B into law. *See* Pub. L. No. 102-585, §603, 106 Stat. 4943, 4967 (1992). *But it did not do that in Section 340B*. As Lilly explained in its opening brief, Opening.Br.7, 30-31, courts generally presume that "Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)). And the "implications" of this general presumption "are strongest" when—as here—the disparate provisions were enacted "simultaneously." *Lindh v. Murphy*, 521 U.S. 320, 330 (1997); *see also West Virginia*, 142 S. Ct. at 2615 (similar). In sum, as Judge Stark explained, Congress plainly "kn[e]w[] how to write statutes that cover agents and contractors." *Astrazeneca I*, 543 F. Supp. 3d at 60. Yet Congress "did not do so in the 340B statute," *id.*, despite concededly being aware of these supposedly "common" "arrangements," Govt.Br.32. The government's failure to offer any response to that "intentional[]" choice, *Russello*, 464 U.S. at 23, speaks volumes.

The government likewise ignores that Section 340B contains a carefully circumscribed list of entities eligible to be "covered entities" entitled to 340B discounts. *See* 42 U.S.C. §256b(a)(4). Congress has expanded and contracted that

list over time—but what Congress has never done is add a for-profit entity to the list; nor has Congress ever given HHS (or any other agency) authority to expand the membership, let alone to include such entities. *See* Opening.Br.6-7. HHS's current attempt to drastically expand the universe of entities that can *receive* 340B drugs—via an atextual obligation for manufacturers to deliver 340B drugs to an unlimited number of for-profit contract pharmacies—is fundamentally inconsistent with the careful, reticulated regime Congress created. As Judge Stark put it, "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca I*, 543 F. Supp. 3d at 60.

Finally, the government fails to offer any textual (or other) explanation for why some supposedly "extra-statutory" manufacturer conditions (like requiring certain information from a customer) are admittedly permissible while others (like declining to deliver to unlimited third-parties) are not. Consistent with its past guidance, the government concedes that manufacturers can impose *some* conditions on their "offers" by, for example, "ask[ing] a covered entity for 'routine information necessary to set up and maintain and account.'" Govt.Br.39 (quoting 59 Fed. Reg. 25,110, 25,112 (May 13, 1994)). Lilly raised this inexplicable distinction in its opening brief (at 32-33), and Judge Friedrich relied on it in her decision, *see Novartis*, 2021 WL 5161783, at *7. Once again, however, the government fails even to engage with this objection to its position—or with a well-reasoned district court decision crediting the

objection—let alone demonstrate that Lilly's "offers" are any less *bona fide* than those with conditions HHS arbitrarily approves of.

Nor does Lilly's interpretation lead to what the government calls a "donut hole" in Section 340B. Lilly is not saying, as the government claims, that "Congress's failure to speak directly to a specific case … creates a tacit exception." Govt.Br.30. As the government itself acknowledges, that donut-hole theory applies *only where Congress has imposed a "broad rule*" that would otherwise cover this case to begin with. *Id*. So, for instance, the no-donut-hole theory guided the way in *Bostock*, where Congress imposed a broad rule against sex discrimination in the text of Title VII. To give effect to that broad rule *expressly articulated in the text of the statute*, the Court held that all forms of sex discrimination were prohibited under Title VII, even though the statute did not specifically enumerate every subtype. *Bostock*, 140 S. Ct. at 1747. That is not the case here. Section 340B does not impose a broad rule requiring manufacturers to get discounted drugs to covered entities and their designees, without limitation, and at all costs—let alone to retailers like contract pharmacies that may, or may not, end up dispensing discounted drugs to covered entities' patients. Had Congress actually enacted a statute that said, *e.g.*, "Manufacturers must 'ensur[e] that covered entities could consistently—and without hindrance—obtain drugs at a discounted price,'" *see* Govt.Br.34, then the lack of explicit textual reference to delivery might not "create[] a tacit exception" to the more general rule. *Bostock*, 140 S. Ct. at 1747 (addressing "Congress's failure to speak directly to a specific case that falls within a more general statutory rule"). But for all the reasons

already discussed, Congress did nothing of the sort. What the government is asking this Court to do, then, is *not* (as in *Bostock*) to give effect to a broad rule that Congress enacted by declining to create an atextual exception to a broad statutory rule. The government is asking the Court to *make up* a broad statutory rule that does not appear in the statutory text.

We therefore "end" where we "beg[a]n": "with the text." *Star Athletica, LLC v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017). As even the district court (at one point) recognized, *see* SA.61, nothing in the *text* of Section 340B imposes a requirement to deliver drugs to third-party, for-profit contract pharmacies without restriction. Lilly is therefore entitled to a declaration that its contract-pharmacy initiative does not violate the statute, and the district court's determination that the Violation Letter "does not exceed statutory authority," SA.71, should be reversed.

B. The Government's Reliance on Silence and Unenacted Proposals Cannot Overcome the Text of the Statute Congress Enacted.

Instead of addressing the textual problems with its position, the government attempts to revivify a long-discarded approach to statutory interpretation. Its brief expounds at length on inferences from statutory silence, legislative history, unenacted bills, and speculation about the consequences of taking the statute at its word. From these sources, the government urges the Court to discover an *implied* statutory delivery requirement Congress did not adopt. But as the Supreme Court has made clear, none of these atextual sources "gives … any reason to doubt the plain-text result in this case." *Simmons v. Himmelreich*, 578 U.S. 621, 627 (2016).

1. The government argues that manufacturers must be prohibited from placing (even the most sensible) conditions on their statutorily required "offers" to covered entities because nothing in the statute explicitly permits manufacturers to "add on … conditions" to their offers. Govt.Br.33. As Lilly pointed out in its opening brief (at 31), however, the Supreme Court rejected this exact argument in *Christensen v. Harris County*—a case the government yet again simply ignores.

In *Christensen*, an employer adopted a policy "requir[ing]" its employees "to use accrued compensatory time"—*i.e.*, to take paid time off, rather than be cashed out for the vacation hours they accrued by working overtime—when they hit a certain number of accrued hours. 529 U.S. at 588; *see id.* at 581. The Department of Labor took the view that this policy was unlawful because nothing in the Fair Labor Standards Act ("FLSA") explicitly "*permit*[*s*]" employers to make employees use accrued compensatory time instead of being cashed out. *Id.* at 588. The Supreme Court rejected this argument in unequivocal terms, calling it "exactly backwards." *Id.* The question, the Court explained, is not whether a statute *allows* employers to adopt a policy placing conditions on how employees can use compensatory time. The question instead is whether a statute *prohibits* it. "Unless the FLSA *prohibits* [the employer] from adopting its policy, [the agency] cannot show that [the employer] has violated the FLSA" by adopting said policy. *Id.* And because "the FLSA contains no such prohibition," the employer's policy was not unlawful—and the agency lost. *Id.*

Christensen's holding applies with full force here. The government's position in this case goes as follows: Section 340B says that manufacturers must offer their

drugs to covered entities at discounted prices; it does not say that manufacturers can put conditions on those offers (such as: "We won't ship our discounted drugs to more than one for-profit pharmacy that doesn't pass on the discounts to patients"). Ergo, the government says, manufacturers cannot put conditions on their offers. *See, e.g.*, Govt.Br.33. That argument is indistinguishable from the argument the agency made, and the Supreme Court rejected, in *Christensen*. Under *Christensen,* unless Section 340B *prohibits* Lilly from adopting its contract-pharmacy-distribution policy, Lilly's policy does not violate the statute. And because *even the government here agrees* that Section 340B contains no such prohibition, *see, e.g.*, Govt.Br.34, Lilly's contract-pharmacy initiative is not unlawful. After all, Lilly continues to offer every covered entity the ability to purchase all of Lilly's covered outpatient drugs at or below the 340B price, and to deliver all of its covered drugs to *every covered entity that orders them* (or at least one designated contract pharmacy per covered entity).

It therefore makes no difference that Section 340B does not explicitly say that manufacturers can "add on [delivery] conditions" to their offers under §256(b)(1). Govt.Br.33. Agencies may not infer from statutory silence an "implicit[]" prohibition on otherwise lawful practices. *Christensen*, 529 U.S. at 582; *see* Frank H. Easterbrook, *Statutes' Domains*, 50 U. Chi. L. Rev. 533, 544 (1983) ("[T]he domain of the statute should be restricted to cases anticipated by its framers *and expressly resolved in the legislative process*."). That bedrock principle, which Lilly discussed in its opening brief but the government (again) ignores, explains why *none* of the

government's cases held that a statute that did not explicitly require private parties to take a costly action could be read to implicitly require that result.

In any event, this case is even easier than *Christensen*. Unlike in *Christensen*, the agency here *concedes* that it lacks the power to fill any gaps in the relevant statute. *See* Govt.Br.8; Mot. Hr'g Tr. 51:23-25, *AstraZeneca v. Becerra*, No. 21-cv-00027 (D. Del. Oct. 22, 2021), Dkt. 103 (government counsel conceding that HHS "can't add to the statutory obligation" Congress enacted, because HHS lacks general rulemaking authority under Section 340B); *PhRMA v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014) (so holding). The only question, then, is whether the statute itself "*prohibits* [Lilly] from adopting its [contract pharmacy] policy." *Christensen*, 529 U.S. at 588. The answer to *that* question plainly is no.

Because the text of Section 340B does not *prohibit* Lilly's initiative, Lilly does not need the government to "authorize" its actions. *Contra* Govt.Br.37. At least where Congress does not say otherwise, a regulated entity is free to do what a statute does not prohibit; it is not, as the government would have it, restricted unless given permission—a notion antithetical to living in a free society. The government therefore misses the mark when it argues that Lilly cannot impose restrictions that have the effect of supplementing the government's own mechanisms for preventing diversion and duplicate discounts. Govt.Br.35-41. Nor do Lilly's motivations matter to the question of whether Section 340B prohibits Lilly's contract-pharmacy initiative. As long as a private party's actions are not unlawful—*i.e.*, not prohibited by law—a party's motivations are beside the point. *Cf. J.D. Edwards & Co. v. Podany*,

168 F.3d 1020, 1024 (7th Cir. 1999). In any event, *even the government acknowledges* that Lilly, far from being driven by an illicit purpose, adopted its contract-pharmacy initiative in part to help "prevent[] diversion and duplicative discounts" (which the statute explicitly prohibits). Govt.Br.35 (capitalization omitted).

2. The government's over-reliance on silence is also inconsistent with the Supreme Court's recent explanation of the "major questions" doctrine, *see West Virginia*, 142 S. Ct. 2587, which further refutes the government's effort to find in Section 340B a *multibillion-dollar* obligation to deliver 340B drugs to contract pharmacies that Congress did not impose at all, let alone clearly.[4]

The major questions doctrine stands for the commonsense proposition that courts should be skeptical when an administrative agency "'claim[s] to discover in a

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[4] The government claims (at Govt.Br.43) that Lilly raised the major questions doctrine for the first time on appeal. Not so. Here is what Lilly said in its district court briefing:

> Even the government admits that contract pharmacy arrangements capture billions of dollars in discounts every year.... Construing the statute, which says nothing about any such obligation, to require manufacturers to work through contract pharmacy arrangements would thus have massive consequences in simple dollars-and-cents terms. It would also threaten to transform the program from one that reduces existing costs to help low-income patients and the healthcare providers that serve them, to one that instead generates new revenue for covered entities, and is material to for-profit pharmacies' bottom lines.... That is fatal to the government's position, for it is black-letter law that Congress must "speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Utility Air Reg. Gp. v. EPA*, 573 U.S. 302, 324 (2014).

Dkt. 129 at 21 (emphases omitted); *see also, e.g.*, Dkt. 89 at 14. And recognizing that Lilly raised the doctrine in its briefing, the district court considered and rejected the argument in its decision. *See* SA.48-49. Neither Lilly nor the district court used the words "major questions." But neither did the Supreme Court until a few weeks ago. *See West Virginia*, 142 S. Ct. at 2609.

long-extant statute an unheralded power' representing a 'transformative expansion in [its] regulatory authority.'" *Id.* at 2610 (quoting *Util. Air Regul. Grp.*, 573 U.S. at 324). This case fits the doctrine like a glove. Indeed, the government does not meaningfully dispute that this case presents a major question. Nor could it. HHS spent nearly 30 years disavowing the power to require delivery to contract pharmacies, which it now says has been implicit in the statute all along. Opening.Br.35. That nowhere-expressed requirement would supercharge the already-explosive growth of the 340B program, which previously was a cost-savings program attached to Medicaid, but now, aided by the unfettered growth of contract-pharmacy arrangements, is poised to soon become *bigger than Medicaid*. Opening.Br.35-36; *see also West Virginia*, 142 S. Ct. at 2621 (Gorsuch, J., concurring) ("[A]n agency must point to clear congressional authorization when it seeks to regulate 'a significant portion of the American economy,' or require 'billions of dollars in spending' by private persons or entities."). And, perhaps worst of all, a decision upholding the government's atextual construction would give HHS the power to impose on private parties crippling penalties that the political branches did not clearly authorize—raising serious constitutional concerns. *See id.* at 2616 (explaining that the major questions doctrine "operates to protect foundational constitutional guarantees").

"Given these circumstances, there is every reason to 'hesitate before concluding that Congress' meant to confer on [HHS] the authority it claims under Section [340B]." *Id.* at 2610 (majority op.) (quoting *FDA v. Brown & Williamson Tobacco*

Corp., 529 U.S. 120, 159-60 (2000)). The total absence of statutory text requiring manufacturers to deliver discounted drugs to an unlimited number of third-party, for-profit contract pharmacies, without restriction, precludes the agency's attempt to impose that onerous and program-warping requirement on Lilly here. *See* Govt.Br.33 (conceding lack of "explicit prohibition" and the "possibility of clearer phrasing" (emphasis and quotations omitted).

The government's sole argument against operation of the major-questions clear statement rule is that "this case does not involve an agency's regulatory authority at all." Govt.Br.44. But there is no basis to limit the major questions doctrine to agency interpretations announced *in rulemakings* instead of adjudications. If anything, the fact that (as here) Congress chose *not* to confer rulemaking authority on an agency makes it even clearer that Congress's silence should not be viewed as a prohibition on private actors. Put another way, the fact that Congress declined to confer gap-filling authority with respect to the delivery of 340B drugs means that there are no gaps to fill, and this Court should enforce the text as written. That text does not purport to require manufacturers to deliver steeply discounted drugs to an unlimited number of third-party, for-profit contract pharmacies without restriction.

3. Because the text is silent, it is perhaps unsurprising that the government focuses so heavily on language that Congress *did not* enact. The government argues that "Congress considered but declined to enact a provision that would have confined [340B] discounts to covered entities that dispense drugs through in-house pharmacies." Govt.Br.1; *see also* Govt.Br.26-27. This "resort[] to that last

hope of lost interpretive causes," cannot save the government. *United States v. Thompson/Ctr. Arms Co.*, 504 U.S. 505, 521 (1992) (Scalia, J., concurring in the judgment).

To begin, the government fails to acknowledge, let alone refute, Lilly's argument and Judge Stark's conclusion that the draft bill the government invokes actually *undermines* the government's argument. *See AstraZeneca II*, 2022 WL 484587, at *6 & n.9; *AstraZeneca I*, 543 F. Supp. 3d at 60; Opening.Br.38-39. As Judge Stark explained, the cited bill included language that accounted for contract relationships. "The exclusion of that language indicates that Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *AstraZeneca II*, 2022 WL 484587, at *6.

In any event, legislative history can never displace clear text. *Milner v. Dep't of Navy*, 562 U.S. 562, 572 (2011). And as the Supreme Court has long explained, the (already limited) explanatory power of legislative history is at its absolute nadir when it comes to "failed legislative proposals" of the sort the government relies on here. *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994). "A bill can be proposed for any number of reasons, and it can be rejected for just as many others"—some of which may support a particular inference, some of which may undermine it, and some of which may have nothing to do with the issue at hand. *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001). In light of that reality, "'mute intermediate legislative maneuvers'"

(such as merely not enacting certain proposed language) "are not reliable indicators of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (quoting *Trailmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947)); *see also Ratzlaf v. United States*, 510 U.S. 135, 148 n.18 (1994) (Ginsburg, J.) (rejecting reliance congressional reports issued "in connection with an unenacted version of [a bill]"); *Gulf Oil Corp. v. Copp Paving Co.*, 419 U.S. 186, 200 (1974) (similar). And that is even more true where, as here, the legislative history is (at best for the government) ambiguous and susceptible to competing interpretations. *See Milner*, 562 U.S. at 572.

That is reason enough to reject the government's position. But there is a deeper problem with the government's theory that the true meaning of the 340B statute is found *not* in the text of the statute Congress enacted, but in bills that died in committee or things Congress left unsaid. "[B]icameralism and presentment make lawmaking difficult *by design*." *Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 61 (2015) (Alito, J., concurring) (quoting John F. Manning, *Lawmaking Made Easy*, 10 Green Bag 2d 191, 202 (2007)). It is thus always dangerous to credit a litigant's claim that omissions or proposed-but-not-enacted language provide the key to understanding a statute that actually passed through the Article I gauntlet. And that danger is multifold when—as here—the litigant is a government actor and its claim is that the real meaning of a law Congress enacted is found in a proposed bill *that would have expanded its enforcement authority* but did not pass, or in statutory silence *that gives it more power to regulate* than the enacted text countenances. The Constitution makes lawmaking difficult for a reason: "to protect liberty." *INS v.*

Chadha, 462 U.S. 919, 950 (1983); *see id.* at 950-51 (expounding the "essential constitutional functions" served by the "finely wrought and exhaustively considered" Article I requirements).

These principles apply with special force here because the authority the government claims carries with it a further authority to impose crippling penalties on private parties. As noted at the outset, the Supreme Court has long held that "one is not to be subjected to a penalty unless *the words of the statute* plainly impose it." *Acker*, 361 U.S. at 91 (quoting *Keppel*, 197 U.S. at 362). It cannot be disputed here that Congress *has not* clearly expressed an obligation to deliver 340B drugs to contract pharmacies. Yet under the government's view, a manufacturer that declines to do so faces severe "civil monetary *penalties*," Govt.Br.2, plus debarment from Medicaid and Medicare Part B. *See* 42 U.S.C. §§256b(d)(1)(B)(vi), 1396r-8(b)(4)(B). If Congress wants manufacturers to face such punitive consequences simply for declining to deliver 340B drugs to contract pharmacies, it needs to say so—clearly.

C. The Government's Reliance on (its View of) Congress's Underlying Purpose Cannot Overcome the Text of the Statute.

Unable to find support in the text—either explicit or implicit—that Congress actually enacted, the government pivots to mischaracterizing Section 340B and invoking vague notions of "purpose."

1. The government claims that "Congress created the 340B Program to ensure that covered entities could obtain discounted drugs under the conditions that Congress established." Govt.Br.30 (emphasis omitted). But even putting aside that the "conditions Congress established" do not include a requirement to deliver 340B

drugs to contract pharmacies, the government's theory that Section 340B must be construed to "implied[ly]" require parties to do "everything necessary … to attain[] [the government's claimed] end," Govt.Br.30-31 (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012)), could not be *less* consistent with Supreme Court and Seventh Circuit precedent.

The Supreme Court has held time and again that "it is quite mistaken to assume, as [the government] would have us, that 'whatever' might appear to 'further[] the statute's primary objective must be the law.'" *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017) (first alteration added) (quoting *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam)). This Court has long held the same. *See, e.g.*, *Hill v. Madison Cnty.*, 983 F.3d 904, 907 (7th Cir. 2020); *First Bank v. DJL Properties, LLC*, 598 F.3d 915, 917-18 (7th Cir. 2010); *Hrubec v. Nat'l R.R. Passenger Corp.*, 49 F.3d 1269, 1270 (7th Cir. 1995). The Supreme Court and this Court have further explained that "no legislation pursues its purposes at all costs," *Rodriguez*, 480 U.S. at 525-26, and that the government's "simplistic[]" mode of purposive analysis "frustrates rather than effectuates legislative intent," *Cont. Courier Servs., Inc. v. Rsch. & Special Programs Admin., U.S. Dep't of Transp.*, 924 F.2d 112, 115 (7th Cir. 1991) (quoting *Rodriguez*, 480 U.S. at 526); *see* Opening.Br.40.

It is difficult to overstate this point: What the government is asking this Court to do—to presume "that any result consistent with [the government's] account of the statute's overarching goal must be the law"—is exactly the opposite of what courts are supposed to do when reading statutes. *Henson*, 137 S. Ct. at 1725. "An agency

cannot treat a statute as authorizing an indefinite march in a single direction." *Cont. Courier Servs.*, 924 F.2d at 115. It should therefore come as no surprise that the government cites *zero* cases, from any court, to support its theory that Section 340B must be construed to pursue at all costs what the government claims is its ultimate objective. In fact, the government cites (at 32) a decision that affirmatively *refutes* its attempt to use "vague notions of a statute's 'basic purpose'" to "overcome the words of its text." *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 220 (2002) (quoting *Mertens v. Hewitt Assocs.* 508 U.S. 248, 261 (1993)).

It perhaps should also be unsurprising that the government misrepresents the treatise it relies on. Justice Scalia and Professor Garner never endorsed a purpose-at-all-costs theory of statutory interpretation. In fact, they squarely reject it. *See, e.g.*, Scalia & Garner, *supra*, at 18 (decrying as "destructive" any method of interpretation that "goes around or behind the words of the controlling text to achieve what [a party] believes to be the provision's purpose"). The quotation the government plucks out of context comes in a discussion of the "predicate-act canon," which—as Justice Scalia and Professor Garner explain just a few sentences later—carries a critical "limitation[]" that the government here elides: "'where the means for the exercise of a granted power are given, *no other or different means can be implied*, as being more effectual or convenient.'" *Id.* at 193.

That "limitation" makes the result here clear. Under Section 340B, HHS has the power to require manufacturers to "offer" to "covered entities" the ability to "purchase" discounted drugs. 42 U.S.C. §256b(a)(1). Or, put differently, covered

entities have the power to "purchase" drugs at discounted "ceiling price[s]." *Id.* Those are the only powers that Congress "granted." Scalia & Garner, *supra*, at 193. Not even the government tries to argue otherwise. As a result, "no other or different means" of furthering (what the government claims is) the statute's purpose "can be implied," even if (the government believes) some other means would "more effectual[ly]" further that purpose. *Id.* The government's plea for this Court to stretch Section 340B well beyond what its duly enacted text can bear, in the name of furthering (what it says is the statute's) "purpose," has no basis in law. *See id.* (emphasizing that the predicate-act canon "must be applied with caution, lest the tail of what is implied wag the dog of what is expressly conferred"). This Court should reject it.

2. To make matters worse, the government's purpose-at-all-costs argument also relies on an overly simplistic characterization of the statute, which does not account for the statutory structure.

In the government's telling, the point of Section 340B is to "ensur[e] that covered entities could consistently—and without hindrance—obtain drugs at a discounted price." Govt.Br.34. In reality, the statute itself places a variety of "hindrances" on covered entities. For one thing, Section 340B expressly prohibits covered entities from "resell[ing] or otherwise transfer[ring]" a covered drug to "a person who is not a patient of the entity." 42 U.S.C. §256b(a)(5)(B). The statute also expressly prohibits covered entities from claiming "duplicate discounts or rebates" by requesting, e.g., a Medicaid rebate for a drug a covered entity purchased at (or below)

the 340B price. *Id.* §256b(a)(5)(A)(i). It would certainly be easier for covered entities to "obtain drugs at discounted prices," Govt.Br.34, if they did not have to account for what they do with them or for the other federal discounts they receive. But Congress nevertheless still imposed these "hindrances."

As a result, the government's simplistic description does not match the statute that Congress actually enacted. Indeed, in the government's view, pharmaceutical manufacturers are obligated to go along with whatever arrangements for-profit contract pharmacies enter into with covered entities, even if those contract pharmacies are pocketing 99 cents out of every dollar that is realized from arbitraged sales of the discounted drugs. That cannot have been what Congress intended in requiring an "offer" of discounted prices to covered entities, particularly in a statute that says nothing endorsing such contract-pharmacy relationships.

Contrary to the government's narrative, Section 340B simply requires manufacturers to "offer" to sell *to a covered entity* (no one else) at the statutorily-mandated price—nothing more. *See* 42 U.S.C. §256b(a)(1). And the reality is that Lilly's policy does further the goal of ensuring that *covered entities* "obtain lower prices on the drugs that they provide to their patients." H.R. Rep. No. 102-384, pt. 2, at 7 (1992). It is thus the government that now seeks to add to the "conditions that Congress established," Govt.Br.30, by reading the word "offer" both to require manufacturers to *deliver* discounted drugs to third-party, for-profit contract pharmacies and to *prohibit* all restrictions on such delivery or sale.

3. Unable to change what the enacted statute says, the government shifts to arguing that recent industry practice must somehow reflect what Congress meant to achieve (without saying so) in 1992. According to the government, because "covered entities have relied on outside pharmacies (known as 'contract pharmacies') to dispense the drugs purchased at the 340B price" "[f]rom the inception of the 340B Program," Govt.Br.1, Congress must have meant to account for them in the statute, even if it did not say so explicitly.

There are several problems with this argument. First, the government's description of history is at best misleading. From 1992—"the inception of the 340B Program" (Govt.Br.1)—until at least 2010, there were heavy limitations on covered entities' use of contract pharmacies *imposed by the government itself*. A covered entity could only use a contract pharmacy to dispense 340B drugs if the covered entity lacked "'in-house' pharmacy services." A covered entity that lacked the ability to dispense drugs in-house could use *at most* "*one*" contract pharmacy. And the pharmacy with which such a covered entity contracted could use "*only one site* … for the contracted service" (namely, dispensing 340B drugs to the covered entity's patients). 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996); *see also id.* at 43,551 (rejecting objections to the one-pharmacy limitation). Even after HHS issued revised guidance in 2010, which explicitly disclaimed that it was creating any "new obligations and burdens on manufacturers," 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010), covered entities were still required to *maintain title* to discounted drugs purportedly obtained on their behalf—something the government now seems to disregard in endorsing the

fiction that for-profit contract pharmacies are now engaged in: purchasing discounted drugs, treating them as part of a pharmacy's general inventory, and selling them to any patient indiscriminately. Lilly pointed all of this out in its opening brief (at 10-11, 13, 29, 34). Again, the government has no response. The government's assertion that covered entities from the beginning have relied on contract pharmac*ies* plural is revisionist history.

Second, as Lilly also pointed out in its opening brief, the government's volte-face has led it to say that the limitations *HHS itself imposed for nearly 15 years* rendered the statute a "dead letter," "frustrat[ed] Congress' manifest purpose," and were unlawful. Govt.Br.31 (quotations omitted); *see also* Oral Arg. Tr. 67:6-12, *AstraZeneca v. Becerra*, No. 21-cv-00027 (D. Del. May 28, 2021), Dkt.76; Opening.Br.18. That is nonsense (and left unexplained by the government). Whatever else may be said about the wisdom of the government's newfound position, it strains credulity to suggest that the statute compels this result despite the 340B program's effective operation for decades under limitations far more restrictive than Lilly's policy. *See* Opening.Br.15-16.

Third, the government's focus on what the legislature must have meant, rather than what the statute it enacted actually says, is a basic category mistake. The government assumes that "Congress simply must have wanted" covered entities to be able to use contract pharmacies. *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1078 (2018). "But this Court has no license to 'disregard clear language' based on an intuition that 'Congress must have intended something broader.'" *Id.*

(quoting *Michigan v. Bay Mills Indian Cmty.*, 572 U.S. 782, 794 (2014)). Once Congress has "enact[ed] a statute, '[courts] do not inquire what the legislature meant; [they] ask only what *the statute* means." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1631 (2018) (quoting *Schwegmann Brothers v. Calvert Distillers Corp.*, 341 U.S. 384, 396, 397 (1951) (Jackson, J., concurring)).

D. The Government's Speculation about the Purported Consequences of the Plain-Text Reading Cannot Overcome the Text of the Statute.

Left with nothing else, the government resorts to a slippery-slope parade of horribles, contending that if manufacturers are allowed to reject demands to transfer their drugs to unlimited numbers of contract pharmacies, then there are no constraints on what a manufacturer could do. Thus, the government argues, manufacturers could "offer their drugs to covered entities … but only if the covered entity agreed to purchase the manufacturer's drugs whenever possible, and never a competitor's." Govt.Br.34.

This slippery-slope argument does not save the government. *See generally Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 447 n.5 (2010) ("Judges and lawyers live on the slippery slope of analogies; they are not supposed to ski it to the bottom."). As Lilly previously explained, the "offer" provision does not permit all manner of restrictive conditions that would effectively render a manufacturer's "offer" illusory. *See Novartis*, 2021 WL 5161783, at *6 (referring to "meaningful, *bona fide* offers"); *see also* Opening.Br.32. The type of condition the government imagines may well prevent a covered entity *itself* from obtaining the

drugs at the discounted price and therefore render an "offer" illusory (not to mention potentially violate antitrust or consumer-protection laws). But that is not this case.

The government is doubly wrong when it asserts Congress could not possibly have meant for §256b(a)(1) to be interpreted consistent with its ordinary meaning, because (according to the government) that ordinary meaning leaves open the possibility that covered entities would need to arrange "to pick up … 340B drugs from [a manufacturer's] headquarters." Govt.Br.34 (quoting *Quarles v. United States*, 139 S. 1872, 1879 (2019)). Lilly has *never* required anyone (including covered entities) to pick up 340B drugs from its (or its wholesalers') warehouses. Lilly will arrange to deliver as many 340B drugs as a covered entity wants *to the covered entity*, wherever located, to all contract pharmacies wholly owned by a covered entity, or to a single contract pharmacy. Nothing about the word "offer," however, *requires* that. Lilly does so, as is consistent with industry practice, even though, in the case of many discounted 340B sales, it results in a net *loss* for Lilly. Lilly could reasonably require its purchasers to make their own arrangements for delivery. To be sure, Lilly could not render its offer illusory by, for example, providing solely for a pick-up on the lunar surface—notwithstanding HHS's absurd invocation of that location in its now-discredited Advisory Opinion. A.7. The government cannot justify its effort to impose crippling civil monetary penalties on Lilly, *see* SA.3, based on hypothetical conditions Lilly has never imposed.

The modest conditions Lilly imposed—in response to documented contract-pharmacy abuses—still permit covered entities to purchase as much of Lilly's covered

outpatient drugs as they need, at the discounted 340B price. Lilly is simply declining requests to go beyond the statutory requirement and transfer its drugs to third-party, for-profit contract pharmacies at locations around the country in an unlimited, unrestricted manner, when the statutes says not a word about servicing such contractual relationships. This point is critical. Although the government goes to lengths to create the impression that covered entities cannot buy or access covered drugs, *see, e.g.*, Govt.Br.1, 4, 17, 23, 31-33, 38, that is simply false. Under Lilly's contract-pharmacy initiative, Lilly continues to make all of its covered outpatient drugs available, in unlimited quantities, to every covered entity. Lilly will even deliver 340B drugs to a contract pharmacy of a covered entity's choosing, plus any contract pharmacy that shares a corporate parent with a covered entity. Those allowances are more generous than the agency itself permitted until 2010. The notion that Lilly's policy is unlawfully harming covered entities (or patients) blinks reality.

To be sure, the government claims that Lilly's and other manufacturers' contract-pharmacy initiatives have caused a decline in total sales of discounted drugs. *See* Govt.Br.17-20. But if that is right, that only confirms the abuses that have been undermining the integrity of the 340B program. And it ignores the massive explosion in 340B discounts commanded in just the past few years, as contract pharmacies have milked the program at the singular expense of outpatient drug manufacturers (raising serious Takings concerns, as discussed below). As Lilly explained at length in its opening brief, the 340B program has grown dramatically for the benefit of contract pharmacies, *without any evidence of corresponding growth in patients or*

increases in charity care, much less evidence of any increase in discounts provided to patients. *See* Opening.Br.13-14.

The government also suggests—but never says directly—that Lilly's contract-pharmacy initiative (and other manufacturers' similar policies) might harm patients or deny them access to medications. *See* Govt.Br.17-20 (discussing "covered entities[']complain[ts]"). But the May 2021 Violation Letter the government issued Lilly cites nothing to show that limiting distribution to covered entities themselves, wholly owned contract pharmacies, or a single contract pharmacy (nor any other restriction) prevents patients from accessing their medications. What is more, the most significant risks of abuse flow in exactly the opposite direction. If the government can read new obligations into the statute that Congress never enacted, then there is no limit to what it may impose on manufacturers, based on nothing more than bare assertions about Congress's supposed "purposes."

At bottom, the government wants to advance an absurdity argument: It asserts that it would "defy common sense" to interpret Section 340B consistent with its ordinary meaning. Govt.Br.34. But, as just noted, the government's "absurd" consequences are hyperbolic, and there is nothing absurd about the plain-text reading Lilly advances, which at least two district courts have thus far adopted. *See AstraZeneca II*, 2022 WL 484587, at *5-6; *Novartis*, 2021 WL 5161783, at *6-7.

Courts have exceedingly limited license to decline to give effect to the plain-text reading of a statute. They may do so only in rare cases where it is necessary to avoid an outcome that is "so gross as to shock the general moral or common sense,"

Crooks v. Harrelson, 282 U.S. 55, 60 (1930), or "so bizarre that Congress 'could not have intended' it," *Demarest v. Manspeaker*, 498 U.S. 184, 191 (1991) (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982)); *see also Sturges v. Crowninshield*, 17 U.S. (4 Wheat.) 122, 202-03 (1819) (Marshall, C.J.) ("[T]he plain meaning of a provision" is not "to be disregarded" unless "the absurdity and injustice of applying the provision to the case, would be so monstrous, that all mankind would, without hesitation, unite in rejecting the application. The government has not come close to clearing that high bar. There is nothing absurd, or even "self-defeating," Govt.Br.34 (citation omitted), about a statute that requires manufacturers to offer discounts to a select group of non-profit safety-net providers but does not require manufacturers to deliver discounted drugs to an unlimited number of for-profit retailers without restriction. Nor is it absurd to think that, when Congress created the 340B program, it expected manufacturers to provide discounted drugs only to covered entities (*i.e.*, the only entities eligible for 340B discounts), not to third-party, for-profit pharmacies (which sell drugs to their customers at non-discounted prices and can pocket the difference as pure profit). Nor is it absurd to conclude that, while Congress granted covered entities a right to purchase manufacturers' drugs at deeply discounted prices, it did not also grant them a separate right to require manufacturers to ship discounted drugs to whomever and wherever covered entities demand, without restriction. Indeed, the statute itself prohibits covered entities from "resell[ing] or otherwise transfer[ring]" a covered drug to "a person who is not a

patient of the entity." 42 U.S.C. §256b(a)(5)(B). The notion that 340B-priced drugs *must be sent* to third-party, *for-profit* retailers turns the statute upside down.

What would be absurd is to read the statute to prohibit Lilly from providing for distribution only to covered entities or a single contract pharmacy of a covered entity's choosing, when that was *exactly* what HHS itself restricted covered entities to from 1996 to 2010.[5] Lilly's offer to covered entities—under which Lilly (1) will sell to each covered entity as much as its covered outpatient drugs, at or below the ceiling price, as each covered entity wishes, and (2) will arrange for delivery to covered entities and/or a contract pharmacy of a covered entity's choosing—plainly is not illusory. Nor has the government ever argued that it is. The government's attempt to use the absurdity doctrine as a get-out-of-text-free card fails.

E. The Government's Atextual Construction of Section 340B Raises Serious Constitutional Issues.

The government's interpretation of Section 340B would also violate the canon of constitutional avoidance. If the government were right about what the statute means, then manufacturers of outpatient drugs would have been singled out either

[5] The fact that HHS later instituted a "pilot" program (with rigorous audit requirements it has since abandoned, U.S. Gov't Accountability Office ("GAO"), GAO-21-107, at 1 (Dec. 2020), https://bit.ly/3wl7UcA) and ultimately lifted its restriction on covered entities using more than a single contract pharmacy (in non-binding guidance that expressly disclaimed the notion it was altering any obligations, no less), is of no moment. The *statute* says nothing to prohibit manufacturers from limiting distribution to covered entities themselves (which are the only entities that can make "ceiling"-price purchases). *See Novartis*, 2021 WL 5161783, at *7 ("[N]either … the 'Shall Offer' provision nor any other language in Section 340B prohibit[s] manufacturers from placing any conditions on covered entities."). Nor can the text be read to *require* distribution to an unlimited number of for-profit contract pharmacies without restriction, based on the fiction that they are working in conjunction with a covered entity. *See AstraZeneca II*, 2022 WL 484587, at *6.

to subsidize for-profit pharmacy chains, or else to lose access to and "reimburse[ment] under Medicaid or Medicare Part B." Govt.Br.1. Those programs are now ubiquitous and, given the structure of health care in this country, necessarily account for large portions of manufacturers' bottom lines. That is a textbook violation of the Takings Clause and the unconstitutional-conditions doctrine—and that is true regardless of whether a manufacturer's initial choice to participate in 340B was coerced. *See Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (noting that manufacturers have little choice but to "opt into" the 340B program).

The 340B program originated as a means to allow manufacturers to provide discounts to covered entities, and thereby increase low-income Americans' access to life-saving treatments, while exempting those discounts from Medicaid rebate calculations (so as to not penalize manufacturers for offering them). *See* Opening.Br.37-38. The program was never intended to enrich pharmacy chains like CVS and Walgreens. Yet the government's new interpretation does just that by forcing a private wealth transfer from one set of for-profit private parties to another, regardless of whether the latter even pass on the discounts they receive to patients. Whether or not that is a rank taking of property without just compensation, that upside-down requirement has no "'essential nexus' or 'rough proportionality'" to the interest 340B is designed to serve. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). And because it does not "further the end advanced as the justification" for the statute, the government's proposed condition—which the government only recently purported to

discover after nearly three decades of (correctly) claiming that the statute required no such thing—amounts to "an out-and-out plan of extortion," which the Constitution does not tolerate. *Nollan v. California Coastal Comm'n*, 483 U.S. 825, 837 (1987).

The government's casual dismissal of these constitutional principles, *see* Govt.Br.41-43, is of a piece with its backwards statutory interpretation. The government proceeds from the assumption that the baseline is that Lilly cannot do anything without Congress's explicit permission when it comes to selling its own drugs. That is as wrong as wrong gets. Our "law has most carefully protected the ownership of personal property." *Shaw v. R.R. Co.*, 101 U.S. 557, 565-66 (1879). The baseline under the Fifth Amendment is that Lilly is free to keep its property (*i.e.*, the drugs it manufactures) and, if it chooses to sell, to sell at the prevailing market price. Under these principles—and settled precedent the government elides—Congress's failure to "speak directly" to a requirement that manufacturers deliver discounted drugs in unlimited quantities to for-profit contract pharmacies across the country—an unquestionable interference with manufacturers' common-law property rights—means that those preexisting property rights remain intact. *United States v. Texas*, 507 U.S. 529, 534 (1993) (discussed at Opening.Br.42); *see also U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849-50 (2020) (rejecting the view that agencies can, "without a word from Congress," alter "the power of the Government over private property").

The only ways the government could move from that baseline, consistent with the Takings and Due Process Clauses, would be (1) to exercise eminent domain *and*

pay market value for the drugs (*i.e.*, to effect a taking and pay just compensation), or (2) to try to induce Lilly to choose to provide discounts on its property by offering Lilly some valuable benefit in exchange. The government insists Congress did the latter here by requiring outpatient drug manufactures to participate in the 340B program as a condition of participating in Medicare and Medicaid. Of course, given the ubiquity of Medicare and Medicaid, *see Allina*, 139 S. Ct. at 1808, that is hardly a "benefit," and is instead more of a "gun to the head," *NFIB v. Sebelius*, 567 U.S. 519, 581-82 (2012). More fundamentally, the terms of the deal Congress struck did not include any requirement to deliver discounted drugs to third-party, for-profit contract pharmacies like CVS and Walgreens. Rather, the deal Congress authorized the government to make imposes a singular requirement on manufacturers: the obligation to offer covered entities—*non-profit* safety-net care providers all, *see* 42 U.S.C. §256b(a)(4) (exhaustively cataloguing the universe of covered entities)—the opportunity to purchase manufacturers' drugs at a discount.

Although that requirement may originally have been proportional to the benefit of participating in other government programs, the burdens HHS now seeks to impose through reinterpretation of the statute are not. The government may not "hold hostage" the right to do business in a particular industry only "to be ransomed by the waiver of constitutional protection." *Horne v. Dep't of Agric.*, 576 U.S. 350, 366 (2015); *see* U.S. Const. amend. V, cl. 5; Opening.Br.47-53. In any event, this Court need not weigh the relative benefits and burdens of the new "deal" HHS seeks to strike, because *Congress* has not put manufacturers to the constitutionally dubious

"choice" of subsidizing for-profit pharmacy chains to the tune of tens of billions of dollars or else lose coverage under ubiquitous federal healthcare programs.

Rather than construe the 340B statute to put manufacturers to a Hobson's choice they never saw coming (and could not have foreseen), which raises serious constitutional issues, the Court should simply give effect to the text that Congress enacted. The Court should reject the government's overreach, vacate the district court's declaration that Lilly's policy "directly conflicts with the statutory requirement[s]," SA.46, and grant Lilly its requested relief: a declaration that Lilly has no statutory obligation to deliver discounted drugs to contract pharmacies without limitation and that Lilly's policy, thus, does not violate the 340B statute.

II. The Violation Letter Is Arbitrary And Capricious.

If the Court agrees with Lilly's interpretation of the statute and grants Lilly's requested relief, then the Court need not reach the issues raised in the government's cross-appeal, *see* Govt.Br.44-46, because the government may not lawfully compel Lilly to deliver 340B drugs to contract pharmacies. But regardless, the agency's failure to explain its 180-degree change in position vis-à-vis its ability to enforce such an obligation provided an adequate reason to vacate the May 2021 Violation Letter as arbitrary and capricious, as the district court held. SA.52-58. And the agency's failure to explain its 180-degree change in position vis-à-vis its statutory interpretation of manufacturers' obligations to service an unlimited number of contract-pharmacy arrangements provides an independent reason to vacate the May 2021 Violation Letter as arbitrary and capricious. *Bay v. Cassens Transp. Co.*, 212 F.3d 969, 972-73 (7th Cir. 2000) ("[W]e may affirm on a ground other than that relied

on by the district court so long as it is adequately supported in the record and the law."). Thus, if the Court reaches the merits of the cross-appeal at all, it should therefore affirm the district court's vacatur.

Regulated entities have "serious reliance interests" in regulating agencies' articulated interpretations of governing statutes. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016). As a result, an agency that "changes its existing position … must at least 'display awareness that it is changing position'" to comply with its procedural obligations under the APA. *Id.* at 221 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)). "It follows that an unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Id.* at 222 (alteration adopted and quotations omitted); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 56 (1983) ("While the agency is entitled to change its view on the acceptability" of a regulated entity's practice, "it is obligated to explain its reasons for doing so.").

The May 2021 Violation Letter flunks this basic requirement. To start, all agree that the agency's 1996 guidance "limited covered entities to using no more than a single contract pharmacy." *AstraZeneca I*, 543 F. Supp. 3d at 56; *see also Novartis*, 2021 WL 5161783, at *8 (similar); SA.26 (similar). But shortly before Congress added the "shall … offer" provision to the 340B statute in early 2010, the agency changed course, stating that "HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Yet, in

announcing this shift, HRSA hastened to add that covered entities' newfound ability to use multiple contract pharmacies did not "impose[] additional burdens upon manufacturers." *Id.*; *see also* VLTR.7590 (again emphasizing, in 2020, that the 2010 "contract pharmacy advice" was "not binding" on manufacturers).

The agency made this position crystal clear to all in July 2020, when it advised a 340B-focused news publication that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020); *see also Am. Hosp. Assoc. v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting a July 2020 email from HRSA's Communications Director saying the same thing). The agency represented the same thing *again* to the GAO as late as December 2020: "HRSA officials reported that … the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use." GAO-21-107, "Highlights"; *see also id.* at 15-16. Covered entities certainly had no difficulty understanding the agency's position. *See, e.g.*, VLTR.3655.

That all changed in December 2020, when the HHS General Counsel released an Advisory Opinion announcing, for the first time, that the 340B statute purportedly (although not textually) created a legally enforceable obligation on the part of manufacturers to deliver their "covered outpatient drugs to … contract pharmacies and to charge … no more than the 340B ceiling price" where "contract pharmacies are acting as agents of a covered entity." A.5.

The Advisory Opinion—which the agency has since withdrawn in light of manufacturers' successful APA challenges, *see AstraZeneca I*, 543 F. Supp. 3d 47; SA.22—was followed shortly by HRSA's May 2021 Violation Letter to Lilly. In the Violation Letter, the agency pivoted once again. Gone was the Advisory Opinion's tenuous "agent" limitation; now, the agency opined simply that the 340B statute required manufacturers to "offer[] … covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." A.3.

As courts have repeatedly held, these gyrations on the part of the agency—going first from one permitted contract pharmacy (and one site) per covered entity (and only if the covered entity lacked an in-house dispensing pharmacy) to multiple contract pharmacies without limitation, and then from no enforceable manufacturer obligation vis-à-vis contract pharmacies to a statutorily-compelled one—"establish that the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has *not* remained constant but has, instead, materially shifted." *AstraZeneca I*, 543 F. Supp. 3d at 56; *accord Novartis*, 2021 WL 5161783, at *8 (concluding that the agency's "position has in fact shifted over time"); SA.52-58 (similar). And far from evincing any "awareness" of a change in position, *Encino*, 579 U.S. at 221, the violation letter affirmatively claims that this newly-announced obligation on the part of manufacturers has actually been the agency's "plain" and "consistent[]" position "since the issuance of its 1996 contract pharmacy guidance." A.2. Never mind that the sole statutory provision the violation letter cites was not added to the statute until 2010, and therefore could not possibly have been

the basis for the agency's purported position since 1996. *See* Affordable Care Act, Pub. L. No. 111-148, §7102(b), 124 Stat. 119, 827 (Mar. 23, 2010). And never mind that the government has since taken the position that the 1996 guidance itself was in error. *See* Oral Arg. Tr. 67:6-12, *AstraZeneca v. Becerra*, No. 21-cv-00027 (D. Del. May 28, 2021), Dkt. 76. Regardless, the Violation Letter points to no such "plain" statement of manufacturers' duties vis-à-vis contract pharmacies at any prior point in the agency's history. That is likely because there is none.

In its brief on cross-appeal, the government gives its wheel of legal theories yet another whirl. This time, rather than attempt to harmonize its past contract-pharmacy guidance with its present position, the government directs the Court to pay no attention to the guidance behind the curtain: Because "HHS has consistently recognized that its guidance is unenforceable," or so the government says, the Court need not consider the agency's decades of contrary guidance at all. Govt.Br.44.

That is not how administrative law works. As an initial matter, the argument that HHS's past contract-pharmacy guidance has no relevance to manufacturers' legal obligations stands in stark opposition to what HHS said in the Violation Letter. The agency there claimed that the contract-pharmacy obligations it announced were a mere reiteration of its prior contract-pharmacy guidance: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [340B] purchases regardless of the dispensing mechanism." A.2. Having taken that view in its final agency action, HHS cannot now change tacks. "[A] court may uphold agency action only on the grounds

that the agency invoked when it took the action," *Michigan v. EPA*, 576 U.S. 743, 758 (2015), not some "different legal theory" advanced by "the agency's appellate lawyers" after the fact, *Philadelphia Gas Works v. FERC*, 989 F.2d 1246, 1250 (D.C. Cir. 1993).

As the district court here explained, the government's current theory is similarly inconsistent with the agency's past statements of its position. *See* SA.57. If the purported statutory "no conditions" principle the government now touts had truly required manufacturers to deliver 340B drugs to contract pharmacies all along, then there would never have been cause for the agency to opine that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies," Mirga, *supra*, or that it could only "strongly encourage[]" manufacturers to do so because it lacked "regulatory authority … to develop enforceable policy." *Am. Hosp. Ass'n*, 2021 WL 616323, at *3 (quotations omitted); *see also* VLTR.3655 (covered entity asking HRSA to abandon its position that it could not force manufacturers to sell to contract pharmacies). The government's new position "clearly conflicts with HRSA's representations to the GAO just a year before." SA.57.

Finally, taking its new logic at face value would only confirm that the agency did indeed materially change positions on the extent of manufacturers' obligations. If manufacturers have always been statutorily required to acquiesce to all permissible contract pharmacy arrangements, then the government's "exponential expansion" of permissible contract pharmacy usage over time has in turn exponentially expanded manufacturers' obligations. SA.53. As Judge Stark put it:

> In this context, it is inaccurate to insist that manufacturers' duties have never changed, solely on the grounds that the government has always

> required manufacturers to accommodate all contract pharmacy arrangements that the government has permitted. Again, because the government has changed what covered entities *may* do, it has consequently changed what drug manufacturers *must* do.

AstraZeneca II, 2022 WL 484587, at *7 n.12 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 57); *see also Novartis*, 2021 WL 5161783, at *8 (similar). The government may not escape that result by now claiming that its past contract-pharmacy guidance was merely "advi[ce]" to covered entities, Govt.Br.45, rather than a statement of permission: The 1996 guidance "*permitted* covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy." 75 Fed. Reg. at 10,272; *see also id.* (stating that the 1996 "guidelines *permitted* a covered entity to use a single point for pharmacy services"). Under the 2010 guidance, as the agency explained at the time, "[c]overed entities will be *permitted* to use multiple pharmacy arrangements." *Id.* at 10,273; *see also id.* ("HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site.").

No matter how the government slices it, the Violation Letter constituted a material, unexplained change in the agency's previously-articulated position that it could not compel manufacturers to deliver 340B drugs to contract pharmacies. Should this Court reach the issue, the determination that the Violation Letter was arbitrary and capricious under the APA should therefore be affirmed.

CONCLUSION

The judgment should be reversed in part and the case remanded with instructions to declare that Lilly's contract-pharmacy initiative does not violate the statute. At the very least, the Court should affirm the district court's vacatur of the May 2021 Violation Letter as arbitrary and capricious.

Respectfully submitted,

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1. This brief complies with the type-volume limitation of 7th Circuit Rule 28.1 because, according to the "word count" function of Microsoft Word 2016, it contains 13,520 words, excluding the parts of the brief exempted from the word count by Federal Rule of Appellate Procedure 32(f).

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July 25, 2022

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I hereby certify that on July 25, 2022, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

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