Nos. 21-3168, 21-3380

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.,

Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENERAL COUNSEL; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HEALTH RESOURCES SERVICES ADMINISTRATION; ADMINISTRATOR OF THE HEALTH RESOURCES SERVICES ADMINISTRATION,

Appellees.

On Appeal from the United States District Court for the District of New Jersey, No. 3:21-cv-00806, Hon. Freda L. Wolfson, U.S. District Judge

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COMBINED REPLY AND RESPONSE BRIEF OF APPELLANTS NOVO NORDISK INC. AND NOVO NORDISK PHARMA, INC.

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June 8, 2022

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes, Rules, and Regulations

Other Authorities

REPLY IN SUPPORT OF OPENING BRIEF

INTRODUCTION AND SUMMARY OF ARGUMENT

The government's position is extraordinary. It seeks to impose a new multi-billion-dollar obligation on manufacturers — to transfer their drugs to an unlimited number of commercial contract pharmacies — that would transform the 340B program from a charitable program designed by Congress to benefit poor and uninsured patients into a massive transfer scheme, with for-profit commercial pharmacies capturing billions of dollars in profit at manufacturers' expense. The government contends that imposing this obligation is required by the 340B statute, even though (1) the statute is indisputably silent on the question of contract pharmacies (as every district court to consider the issue has recognized), (2) the 340B program operated for decades on the shared understanding that covered entities were not entitled to use unlimited contract pharmacies, and (3) the government repeatedly told manufacturers that it had no authority to require manufacturers to transfer their drugs to contract pharmacies.

In light of the government's new position — and its concession that Congress has not granted the agency general rulemaking powers — one would have expected the government to ground its arguments in the statute's plain text. But it has almost nothing to say about the statute's language, and it offers almost no response to the careful arguments about text, structure, and traditional principles of statutory

construction set forth in Novo's opening brief. Instead, the government focuses its fire on extra-textual arguments, urging the Court to read into the statute substantive obligations that Congress did not impose.

Those arguments are meritless. A long line of precedent, from both this Court and the Supreme Court, rejects attempts to rewrite statutory language based on disputed snippets of legislative history, generalizations about Congress's supposed purposes, and other extra-textual policy considerations. Neither government agencies nor reviewing courts have authority to interline into statutes substantive obligations that Congress has chosen not to impose. Moreover, the government cannot reconcile its position with basic principles of statutory construction; the basic truth that offering to sell a product at a specified price does not encompass a separate obligation to deliver the product to whomever and wherever the purchaser demands; and the basic commonsense conclusion that a property owner retains its common law rights to control the distribution of its own products unless and until those rights are restricted by plain statutory language. Nor can the government overcome the essential administrative law principle that a court may uphold agency action only on the grounds articulated by the agency itself in its decision under review, and not based on post hoc rationalizations by counsel.

The government fails to engage with Novo's arguments because its superficial legal analysis is at odds with bedrock requirements of administrative law. Because

Congress did not grant HHS any general rulemaking authority, the government should not be permitted to rewrite the 340B statute to impose a multi-billion-dollar obligation on manufacturers that the statute does not address. The decision below should be reversed, and the government's unlawful actions should be struck down and vacated.

ARGUMENT

I. The 340B Statute Imposes No Obligation on Manufacturers to Transfer Their Drugs to Commercial Pharmacies.

The government concedes that Congress has not granted HHS general rulemaking authority to impose new substantive obligations on manufacturers. *See* HHS Br. 47. The government does not seek deference for its interpretation; nor does it identify any statutory language that it contends is ambiguous. *See* HHS Br. 31 (admitting that "HHS does not claim and is not entitled to *Chevron* deference"). The government can therefore prevail only if it can show that the "statute alone" requires manufacturers to transfer their drugs at discounted prices to commercial contract pharmacies. *See* HHS Br. 49, 50. It has not met that burden.

A. The Government Has No Textual Support for Its Position.

The government's brief includes no analysis of the statute's text. It has nothing to say because it cannot meaningfully dispute — as every court has concluded — that the 340B statute is "silent" on contract pharmacies. *See* Novo Br. 28. As Novo's opening brief explains, that should be the end of this case. If the

statute does not address contract pharmacies, it cannot be read to authorize them to participate in the 340B program or to impose an obligation on manufacturers to transfer drugs to them. It is a "fundamental principle of statutory interpretation that absent provision[s] cannot be supplied by the courts," because doing so "is not a construction of a statute, but, in effect, an enlargement of it by the court." *Rotkiske v. Klemm*, 140 S. Ct. 355, 360-61 (2019) (quotation marks omitted); *see also Angino v. Wells Fargo, N.A.*, 666 F. App'x 204, 207 (3d Cir. 2016) (holding that a court may not read into a contract's "silence an additional legal obligation").

The government's only textual argument is its suggestion that when a statute speaks in "broad terms," courts should not allow "tacit" exceptions or added "provisos." HHS Br. 33-35. But no one is carving out exceptions to the 340B statute and its requirement that manufacturers "offer" their drugs to covered entities for "purchase" at discounted prices. *See* 42 U.S.C. § 256b. Novo complies fully with that mandate. It is undisputed that every covered entity is able to purchase Novo's drugs at the discounted 340B price in whatever quantities each covered entity demands. Moreover, if a covered entity lacks an in-house pharmacy, Novo will ensure that the covered entity is able to purchase the drugs at the discounted price by shipping to a single contract pharmacy of its choosing. *See* VLTR 7754-7758 (JA__).

No matter how broad the government asserts the obligation should be for a manufacturer to "offer" its drugs to covered entities for "purchase" at discounted prices, that obligation does not encompass the separate obligation for manufacturers to deliver their drugs to whomever and wherever the covered entity demands. As Novo's brief explains, there is a fundamental difference between, on one hand, a requirement contract's "price" term and, on the other, the place and manner of delivery. *See* Novo Br. 30. The government does not dispute that point. Nor does it cite any authority even suggesting that the right to purchase a product at a specified price implicitly includes a right to demand delivery to others at whatever unlimited number of third-party locations the purchaser might demand.

With no response, the government is left with its indefensible suggestion that manufacturers cannot impose any conditions on the distribution of their own drugs because the statute does not authorize them to do so. *See* Novo Br. 31 (refuting this argument). But that "backward[]" view is contrary to essential principles of statutory construction, not to mention our system of limited, constitutional government. *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). As the Supreme Court has held, neither courts nor agencies may infer from statutory silence an "implicit[]" prohibition on otherwise lawful practices. *Id*. at 582. Private parties do not need statutory authorization to control their own property, and Congress must "speak directly" when it intends to interfere with common law rights. *United States*

v. Texas, 507 U.S. 529, 534 (1993). Nor can private parties be subject to severe monetary penalties, as they are under the 340B statute, "unless the words of the statute plainly impose" an obligation to which those parties must comply. *Commissioner v. Acker*, 361 U.S. 87, 91 (1959) (quoting *Keppel v. Tiffin Sav. Bank*, 197 U.S. 356, 362 (1905)).

The government has nothing to say about these essential points. It does not mention *Christensen* or address the other Supreme Court cases cited in Novo's brief. The government cannot cure the flaws in its position by ignoring contrary authority. Manufacturers retain the right to control their own drugs, and covered entities have no rights over those drugs, except as provided by the 340B statute. Because the statute says nothing about contract pharmacies — and does not explicitly or implicitly grant covered entities any rights to demand distribution to whomever and wherever they desire — it cannot be read to impose a multi-billion-dollar obligation on manufacturers to transfer their discounted drugs to an unlimited number of commercial pharmacies at a covered entity's request.

B. The Government Has No Response to Novo's Textual Arguments.

Besides having no textual support for its position, the government has little response to the many textual arguments advanced in Novo's brief. The statute's provisions establish that Congress carefully limited which entities would be permitted to participate in the 340B program and profit from the sale of

manufacturers' drugs. Congress designed the 340B program to allow certain covered entities — and only those entities — to gain access to deeply discounted drugs for the benefit of the poor and uninsured patients that visit and receive treatment at their facilities. There is no evidence that Congress intended the program to be used for the benefit of for-profit commercial pharmacies.

Novo recognizes that, in recent years, covered entities have come to expect revenue generated through the 340B program, which they may use to provide care to needy patients. But that does not mean that the government and covered entities are entitled to insist on an unbridled, extra-statutory expansion of the obligations imposed on manufacturers just because rewriting the statute increases generated revenues (while enriching private retail pharmacies). To the contrary, the 340B statute contains numerous provisions indicating that Congress carefully limited the statute's scope to prevent other entities from participating in and profiting from the 340B program, while limiting manufacturers' obligations to offer the drugs at discounted prices to only an enumerated list of covered entities.

The government does not dispute that the statute expressly restricts which entities are permitted to participate in the 340B program, and that contract pharmacies are not included. *See* Novo Br. 34 (citing 42 U.S.C. § 256b(a)(4)). It does not deny that the 340B statute specifies when agency-like relationships are permitted. *See id*. (citing 42 U.S.C. § 256b(d)(3)(B)(vi) (referring separately to

"associations or organizations representing the interests of [] covered entities")). And it does not dispute that Congress elsewhere addressed when contractual arrangements are permitted under the 340B program. *See* Novo Br. 35 (citing Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603(a)(1), 106 Stat. 4943, 4974 (codified at 38 U.S.C. § 8126(h)(3)(A)). It makes no sense for Congress to have been so careful in defining which entities are entitled to participate in the 340B program, and then to allow the government and covered entities to carve into the program nearly 30,000 contract pharmacies, which are reaping billions in profits from the sale of manufacturers' drugs. *See* Adam J. Fein, PhD, *340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021) (noting that roughly half of the pharmacy industry participates in the 340B program); Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy*, AJMC.com (May 4, 2022) (noting that five contract pharmacies "earn about $3.2 billion in gross profits from 340B").

The government does not deny that, in recent years, commercial pharmacies have extracted billions of dollars from manufacturers through contract pharmacy arrangements.[1] It instead tries to sidestep the issue, implying that contract

[1] Certain amici suggest that contract pharmacy fees are "modest" and generally equal "between $6 and $15 per prescription." AHA Br. 6 n.14, 22. In fact, the same GAO report to which they cite puts the range of flat hospital fees paid to contract pharmacies at $15 to $1,750 per prescription (and more for branded and specialty drugs). *See* R.40-9 at 26-27, GAO, GAO-18-480, Drug Discount Program: Federal

pharmacies are an essential, longstanding part of the 340B program. *See* HHS Br. 7 (suggesting that covered entities relied on contract pharmacies since the 340B program's "inception"). But that is wrong, and it is telling that the government has not been more forthright about the program's history.

The government cites no evidence that any covered entity relied on contract pharmacies when Congress enacted the 340B statute or at any other time before the 1996 guidance. The record establishes that, from 1996 until 2010, the government prohibited covered entities from using contract pharmacies unless they lacked an in-house pharmacy and, even then, they could use only one. *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). And until December 2020, the government had never before interpreted the statute to impose an obligation on manufacturers to transfer their drugs to an unlimited number of contract pharmacies. *See* Novo Br. 37 (reciting numerous times the government said that, while covered entities were permitted to use contract pharmacies, manufacturers owed no obligation to transfer their drugs to them). Indeed, HHS's non-binding guidance documents are all premised on the understanding that covered entities have no statutory right to use contract pharmacies.

Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 26-27 (2018) (JA__). Many also include additional fees based on a percentage of the revenue generated by each prescription. *See id*. (JA__)

If the government's new position were correct, the 340B program would have been operating illegally for at least the first half of its existence. The 1996 guidance — which governed the program for more than 14 years and reflected HHS's interpretation shortly after Congress enacted the 340B statute in 1992 — stated that the government would allow each covered entity to use a *single* contract pharmacy but *only if* it lacked an in-house pharmacy. *See* 61 Fed. Reg. at 43,550. Precisely because guidance documents by definition lack the force of law, agencies may issue them to clarify how they intend to enforce a statute; they cannot be used to change statutory requirements or to impose new substantive obligations on regulated parties. *See Limerick Ecology Action, Inc. v. U.S. Nuclear Reg. Comm'n*, 869 F.2d 719, 735 (3d Cir. 1989) (policy statements, "*by definition*, can have no binding effect"). The 1996 guidance thus makes sense only as a description of how the agency intended to exercise its enforcement discretion, allowing *covered entities* to do something the statute might otherwise prohibit. *See* 61 Fed. Reg. at 43,553 (explaining that safeguards were necessary to ensure "compliance with … the 340B prohibition against drug diversion"). In particular, the 1996 guidance provided public notice that HHS would allow covered entities to use a single outside pharmacy without treating that arrangement as a violation of the statute. *See* AstraZeneca Amicus Br. 11-13 (explaining how the replenishment model used by contract pharmacies necessarily results in diversion because covered entities do not take title to the

drugs). The guidance would have been both unlawful and entirely unnecessary if, as the government now contends, the 340B statute has always mandated that manufacturers deliver their drugs to an unlimited number of contract pharmacies.

The government does not address any of this inconvenient history. It does not attempt to reconcile its position with the 1996 guidance, let alone explain why the agency would issue guidance that is premised on conclusions about the statutory requirements that are flatly contrary to what it now contends to be the statute's clear mandate. It also does not explain why Novo's approach was permissible before and during the 14 years under the 1996 guidance but should now be deemed to violate the statute's plain terms. Nor does it address the bedrock principle that Congress should not be assumed to impose multi-billion-dollar statutory obligations in vague terms, much less hide them in congressional silence. *See* Novo Br. 38 (citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001)). Indeed, accepting the government's position requires embracing the implausible conclusion that the 340B statute has always mandated that manufacturers transfer their drugs to an unlimited number of contract pharmacies, but no one noticed until December 2020. *Cf. Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 510 (7th Cir. 2007) (implausible that an entire industry operated illegally "for a long time" without anyone noticing).

The government is similarly non-responsive to the serious constitutional concerns raised by reading into the statute new substantive obligations. The

government does not defend the doctrinal errors in the district court's takings analysis. *See* Novo Br. 52-54. Instead, the government asserts that there is no taking because HHS does not "acquire title" to Novo's drugs, "obtain them for a third party, or compel Novo to surrender them." HHS Br. 45 (quoting R.69 at 102 (JA__)). But that is obviously wrong. The government is trying to compel Novo to transfer its drugs at deeply discounted prices to contract pharmacies, which are making billions in profits by selling the drugs at non-discounted prices. *See* Novo Br. 14-15, 53. That is a classic example of a forced A-to-B transfer, where the government is physically appropriating property for its own policy reasons and for the benefit of preferred third parties. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021) (when government "physically appropriates property" by "whatever means," it is engaged in a *per se* taking); *see also Horne v. Dep't of Agric.*, 576 U.S. 350, 361 (2015).

The government also contends that Novo "voluntarily joined" the 340B program "with full knowledge of the discount [drug] scheme" it effected. HHS Br. 45 (quoting R.69 at 105 (JA__)). But that is also both wrong and non-responsive. When Novo joined the 340B program, there was no alleged requirement that it transfer its drugs to contract pharmacies. The government did not seek to impose that obligation until December 2020, and it has only been in the last few years that the 340B program exploded through the abuse of contract pharmacies. *See* Novo

Br. 11-14 (citing government reports and other authorities discussing recent explosion in the number of contract pharmacies and in the size and expense of the 340B program).

More fundamentally, the government ignores the essential point that a government program may require property owners to cede their rights as a condition of participation *only if* the condition bears an "essential nexus" and "rough proportionality" to a legitimate government interest. *See* Novo Br. 40 (citing *Cedar Point*, 141 S. Ct. at 2079). The 340B program allows covered entities to have access to discounted drugs for the benefit of patients that receive medical services at their facilities, based on the understanding that covered entities provide services to a disproportionate share of vulnerable or uninsured patients. Allowing for-profit pharmacies to profit from the sale of manufacturers' drugs has no "essential nexus" to the 340B program's justification. Nor does that massive expansion share any rough proportionality to the program that Congress created.

There is no evidence that allowing contract pharmacies to profit from the 340B program benefits the vulnerable and uninsured patients who visit the covered entities' facilities and who can easily obtain medications from the covered entities when they obtain services, as the program successfully operated from its inception in 1992 through 2010. Instead, forcing manufacturers to transfer their drugs to an unlimited number of contract pharmacies or else risk expulsion from federal

healthcare programs is precisely the type of "out-and-out plan of extortion" that is not permitted. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987). The government's non-response to this essential point, like its non-response to so many other points, is best viewed as an admission that it has nothing to say in its defense.

C. The Government Has No Defense for Its Failure to Engage in Reasoned Decision-making.

Even if the 340B statute could be rewritten to impose an obligation on manufacturers to transfer their drugs to contract pharmacies, the government still could not prevail. For the Court to uphold the government's May letter, the government not only must prove that the statute's plain text supports its substantive position, it also must show that it complied with the Administrative Procedure Act's *procedural* requirements when it reversed position and threatened enforcement and civil penalties against Novo and other manufacturers. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016); *Motor Vehicle Mfrs. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). It has not carried that burden.

The government offers no response to many of Novo's arguments and objections. As Novo's opening brief explains, HHS failed to adequately explain its position in its two-page May letter. *See Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 506 (D.C. Cir. 2016) (an agency's decision must be "reasonable and reasonably explained" (quoting *Communities for a Better Env't v. EPA*, 748 F.3d 333, 335 (D.C. Cir. 2014)). It did not "display awareness" that it was changing its position —

interpreting the statute in a manner that is flatly inconsistent with its 1996 guidance and correspondence with manufacturers. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2022 WL 484587, at *7 (D. Del. Feb. 16, 2022), *appeal docketed*, No. 22-1676 (3d Cir. Apr. 15, 2022) (providing a table showing that the agency's interpretation has changed over time without reasoned explanation). Nor did the government's May letter respond meaningfully to serious objections or provide adequate reasons for its decision. *See Dep't of State v. Coombs*, 482 F.3d 577, 581 (D.C. Cir. 2007).

The government's May letter also fails to address the widespread problems caused by allowing an unlimited number of contract pharmacies to participate in the program. *See* Eric Percher et al., Nephron Rsch. LLC, The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption 31, fig. 43 (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone). As some of the government's amici correctly recognize, "Congress assigned the 340B [p]rogram's savings and revenue benefits *solely* to covered entities." State AG Br. 4 (emphasis added). Allowing for-profit commercial pharmacies to capture billions in profit from the 340B program each year is contrary to the statute that Congress designed. Yet the government's May letter responds to none of these concerns.

The May letter's failures and omissions confirm that the government's actions cannot be sustained. Not only has the government violated the statute's plain text, its enforcement decision is inconsistent with the requirements of reasoned decision-making.

II. The Government's Extratextual Arguments Cannot Justify Its Request to Rewrite the Statute.

With no statutory text to support its position, the government effectively urges the Court to rewrite the statute to achieve its preferred policy objectives. *But see United States v. Jabateh*, 974 F.3d 281, 297 (3d Cir. 2020) (emphasizing that it is not this Court's role to "reimagine" a statute's "words as we think appropriate"). The government's extra-textual arguments are meritless and, in any event, should not be considered by the Court. Because the statute is silent on contract pharmacies — and does not require manufacturers to transfer their drugs to them — the statute's plain text is "conclusive." *Lawrence v. City of Philadelphia*, 527 F.3d 299, 317 (3d Cir. 2008). Moreover, because the government's arguments are not articulated in its May letter, they are post hoc rationalizations of counsel that cannot be relied on by this Court. *See* Novo Br. 44 (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)).

A. Disputed Legislative History Does Not Support the Government's Statutory Rewrite.

It is well established that when "statutory language is unambiguous," a "court should not consider statutory purpose or legislative history." *In re Phila.*

Newspapers, LLC, 599 F.3d 298, 304 (3d Cir. 2010), *as amended* (May 7, 2010); *see also In re Mehta*, 310 F.3d 308, 311 (3d Cir. 2002) (courts "look to legislative history only if the text is ambiguous"). As the Supreme Court has explained, "legislative history can never defeat unambiguous statutory text." *Bostock v. Clayton County*, 140 S. Ct. 1731, 1750 (2020). That principle should be dispositive here. The government has never identified any *ambiguous* statutory language that legislative history could illuminate; in fact, it insists that the 340B statute is *not* ambiguous.

Even though legislative history should not be consulted, the government puts almost all of its interpretive weight on a single, disputed snippet of legislative history. *See* HHS Br. 1, 7, 36; *but see ExxonMobil Gas Mktg. Co v. FERC*, 297 F.3d 1071, 1088 (D.C. Cir. 2002) ("snippets of legislative history do not a law make"). According to the government, because Congress considered a bill that in one of its versions would have limited 340B discounts to drugs purchased through an in-house pharmacy, the Court should read into the 340B statute an unwritten obligation that manufacturers must ship their drugs to an unlimited number of contract pharmacies. *But see S.H. ex rel. Durrell v. Lower Merion Sch. Dist.*, 729 F.3d 248, 259 (3d Cir. 2013) (legislative history "has never been permitted to override the plain meaning of a statute"). The government's attempt to use legislative history in this fashion is at odds with accepted principles of statutory interpretation. As this Court has

explained, a statute "should be enforced as written" and "'[o]nly the most extraordinary showing of contrary intentions in the legislative history'" can "'justify a departure from that language.'" *In re Phila. Newspapers*, 599 F.3d at 314 (quoting *United States v. Albertini*, 472 U.S. 675, 680 (1985)); *see also In re Trump Ent. Resorts*, 810 F.3d 161, 168 (3d Cir. 2016) (legislative history should be consulted only "as a last resort").

The government has made no showing — much less an "extraordinary" one — that could justify rewriting the 340B statute to impose an obligation on manufacturers that the statute does not itself impose. The government's "scant history" depends on drawing speculative inferences from Congress's decision not to enact particular statutory language included in a bill that Congress rejected. *Milner v. Dep't of Navy*, 562 U.S. 562, 572 (2011). But a "failed legislative proposal[]" is a "'particularly dangerous ground on which to rest an interpretation of a … statute.'" *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994) (quoting *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990)). As Novo's brief explains, Congress's unexplained removal of words from draft legislation is the type of "'mute intermediate legislative maneuver[]'" that is "not [a] reliable indicator[] of congressional intent." *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (quoting *Trailmobile Co. v. Whirls*, 331 U.S. 40, 61 (1947)). Congress "may change language in drafts for any number of reasons, but the law is

only what Congress enacts." *Sault Ste. Marie Tribe of Chippewa Indians v. Haaland*, 25 F.4th 12, 24 (D.C. Cir. 2022). As a result, disputed snippets of legislative history cannot be used to rework a statute to add requirements that Congress did not impose. *See Milner*, 562 U.S. at 572 (noting that unclear legislative history may not be used to "muddy clear statutory language").

More importantly, and as other courts have recognized, when the legislative history is considered in context, it undermines the government's position. *See AstraZeneca,* 2022 WL 484587, at *6. In particular, the legislative history "cuts against the government's position because Congress specifically did not enact statutory language referring to contract pharmacies." *Id.* at *2; *see also Novartis Pharms. Corp. v. Espinosa,* Nos. 21-cv-1479, -1686, 2021 WL 5161783, at *8 n.7 (D.D.C. Nov. 5, 2021), *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021) (holding that there is "insufficient evidence" to support HHS's legislative history argument). It is far more plausible — and the only reading of the legislative history that matches the statute's text — that Congress chose not to enact the language the government highlights because it allowed manufacturers to retain the right to decide if and when to accept requests by covered entities to transfer drugs to any third parties, including contract pharmacies. *See* 42 U.S.C. § 256b(a)(5)(B).

B. Assumptions About Congress's Purposes Do Not Justify the Government's Statutory Rewrite.

The government contends that its interpretation of the statute is required because "[a] contrary conclusion" would "'defeat Congress'[s] stated objective' of ensuring that covered entities could … obtain drugs at a discounted price." HHS Br. 38. The government argues that reading an implied obligation into the 340B statute is necessary to avoid rendering the statute a "dead letter" that is "devoid of reason and effect." HHS Br. 35-36.

It is unclear what interpretive principle the government is invoking. The government refers to the "presumption against ineffectiveness," but that canon applies only when a statute's language is ambiguous and the court must choose between two "textually permissible" readings. Antonin Scalia and Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 63-65 (2012) (discussing why it was "backward" to force a schoolhouse to be removed under a statute requiring that "no drinking saloon may exist within a mile of any schoolhouse"). Here, as noted above, the government does not argue that the statute is susceptible to different meanings, and it has failed to identify any textually permissible reading of the statute that supports its position.

Contrary to the government's suggestions, the 340B statute is not rendered ineffective by interpreting it according to its plain language. To the contrary, that is how the 340B program successfully operated for decades, consistent with the

necessary premise of the government's own 1996 guidance — that covered entities do not enjoy any statutory right to use an unlimited number of contract pharmacies and manufacturers do not have any obligation to transfer drugs to anyone other than the covered entity itself. The fact that the 340B program operated effectively for the first 18 years of its existence without bringing unlimited contract pharmacies into the program belies any argument that they are essential to the program's functioning.

The government points to the district court's observation that many covered entities lacked in-house pharmacies when Congress enacted the 340B statute in 1992 and, therefore, would not have been able to purchase drugs unless they could use contract pharmacies. *See* HHS Br. 24 (citing R.69 at 83-84 (JA__)). As AstraZeneca explains in its amicus brief, however, Congress was focused on rising out-of-pocket prices and, as a result, it was concerned only about those covered entities with in-house pharmacies — because those were the entities that were paying out of pocket for drugs at higher prices. *See* AstraZeneca Amicus Br. 16-17. In any event, even today, only about one third of all covered entities use contract pharmacies, and some that have registered contract pharmacies with HHS do not even use those pharmacies to dispense 340B drugs. R.40-9 at 16-17, GAO, GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 16-17 (2018) ("2018 GAO Report") (JA__); *see also* HHS Br. 13 (acknowledging that, as of 2017, only one third of covered entities in the program

used contract pharmacies). Because approximately two thirds of covered entities operate effectively without using any contract pharmacies, declining to impose an extra-statutory obligation on manufacturers to transfer their drugs to an unlimited number of contract pharmacies at covered entities' request cannot possibly be essential to avoid rendering the 340B statute a "dead letter."

The government's unstated position that its assumptions about Congress's purpose should override the statute's plain text is both dangerous and contrary to precedent. As courts have long held, it is never a court's "role … to 'correct' the text" of a statute to "better serve[]" its supposed general purpose. *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996); *see also Hozier v. Midwest Fasteners, Inc.*, 908 F.2d 1155, 1169-70 (3d Cir. 1990). If the interpretation dictated by the text demonstrates a need for a change in the law, "it is Congress — not the Judiciary — that must act." *Encompass Ins. Co. v. Stone Mansion Rest. Inc.,* 902 F.3d 147, 154 (3d Cir. 2018). Moreover, because "no legislation pursues its purposes at all costs," it "frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam).

In urging the Court to read into the statute a new obligation, the government is asking the Court to undertake a form of judicial surgery that is permitted only in very "rare" circumstances when a literal reading would be "demonstrably at odds

with the intentions of its drafters." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 242 (1989) (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982)). As the Supreme Court has explained, a court may depart from the letter of a statute to avoid an absurd outcome only when the absurdity is "so gross as to shock the general moral or common sense." *Crooks v. Harrelson*, 282 U.S. 55, 60 (1930). The burden is incredibly high: the outcome must be "so bizarre," "illogical," or "glaringly unjust" that "Congress could not plausibly have intended" such a result. *Stovic*, 826 F.3d at 505 (describing Supreme Court precedent).

The government has not come close to satisfying that heavy burden. There is nothing absurd about concluding that when Congress created the 340B program, it expected manufacturers to provide their deeply discounted drugs *only* to the covered entities themselves to be used in conjunction with providing services to the indigent or uninsured patients that visit their facilities (and not to for-profit commercial pharmacies who sell manufacturers' drugs to customers at non-discounted prices and keep a portion of the difference for their private financial gain). 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 grant them a right to require shipment to whomever and wherever they demand. Nor is it absurd to think that Congress may have expected covered entities to obtain their own pharmacies if they desired to participate in the program or, at least, to be limited to a single contract

pharmacy that serves as the functional equivalent of an in-house pharmacy — as Novo's policy provides and as the 340B program operated for most of its existence under the government's own 1996 guidance.[2]

The government suggests that if manufacturers are allowed to reject demands that they transfer their drugs to unlimited numbers of commercial contract pharmacies, there are no constraints on what a manufacturer could do. *See* HHS Br. 37 (suggesting that manufacturers could offer drugs at the discounted price "only if the covered entity agreed to purchase the manufacturer's drugs whenever possible, and never a competitor's"). But that argument is so implausible that it only underscores how far the government has exceeded its lawful authority. The types of conditions that the government discusses in its brief might arguably violate the 340B statute because they would render the "offer" illusory and prevent the covered entity *itself* from obtaining the drugs at the discounted price. *See M & G Polymers USA, LLC v. Tackett*, 574 U.S. 427, 440 (2015) (describing the "illusory promises doctrine [which] instructs courts to avoid constructions of contracts that would render promises illusory."). In contrast, Novo is not imposing any conditions on its "offers" to covered entities. They can purchase as much of Novo's drugs at the discounted

[2] Novo's policy applies only to hospital covered entity types and does not restrict contract pharmacy use of grantee covered entity types. For this reason, the policy arguments raised by the government's amici, which focus almost exclusively on exempt Federally Qualified Heath Centers ("FQHCs"), are generally inapposite.

price as they desire. Novo is simply refusing to go beyond the statutory requirements and declining requests to transfer its drugs to unlimited numbers of commercial contract pharmacies. Unlike covered entities, contract pharmacies have no right to access manufacturers' drugs and no right to participate in the 340B program.

The government also alleges that manufacturers' policies harm patients and deny them access to medications. *See* HHS Br. 16-18, 44. That falsehood has no support. Medications will be carried and made available to all patients regardless of whether the pharmacy is a contract pharmacy. As a result, most 340B patients seeking to fill a script at their neighborhood pharmacy will neither notice nor care if that pharmacy has signed a contract with a 340B hospital covered entity. The patients will be able to obtain their scripts, make their co-payments, authorize payment by their insurance carriers, and go on about their days none the wiser about the back-channel machinations of covered entities or contract pharmacies.

There is no evidence (other than self-interested anecdotal accounts from covered entities) that preventing commercial pharmacies from becoming lucrative contract pharmacies prevents patients from accessing their mediations. Importantly, no such evidence was identified or presented in the government's May letter. *See* Novo. Br. 44 (citing *Garland v. Ming Dai*, 141 S. Ct. 1669, 1679 (2021) (courts may not rely on counsel's *ex post* rationales)). Moreover, hospital covered entities are under no legal requirement to share 340B discounts with patients, even indigent or

uninsured patients, and in practice, they rarely volunteer to do so. The GAO has found that only 25% of hospitals pass on some portion of their 340B discount at all contract pharmacies, and then only to low-income, uninsured patients. *See* 2018 GAO Report at 31 (JA__). There is no evidence that hospital covered entities share any part of the 340B discounts with non-indigent, commercially insured patients. In fact, the evidence shows that while the use of contract pharmacies has exploded, the amount of charitable care has flatlined. *See* Novo Br. 14-15 (citing studies).

By falsely conflating covered entities' ability to force manufacturers to transfer drugs to contract pharmacies, on one hand, with patients' ability to access medications, on the other, the government attempts to create a public policy justification for contract pharmacies that simply does not exist.[3] Indeed, 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 imposed — without exercising lawful rulemaking authority and based only on a cursory two-page letter — there is no limit to what the government can read into the statute, based on nothing more than bare assertions about Congress's supposed purposes. But it is Congress's

[3] The government asserts that manufacturers' policies caused a significant decline in total sales. *See* HHS Br. 18. But the decline only confirms the abuses that are undermining the 340B program's integrity. As Novo's brief explains, 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. *See* Novo Br. 11-12.

prerogative to make those policy judgments. This Court should not impose new obligations that are not imposed by the statute itself.

C. The Statute's Dispute Resolution Procedures Do Not Justify the Government's Statutory Rewrite.

Although it fails to cite the most relevant Supreme Court precedent, the government correctly notes that, under the statute, covered entities are limited to the remedies provided by the statute and the alternative dispute process Congress directed HHS to establish. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011). The government is also correct to recognize that the federal 340B statute is exclusive and preempts attempts by states or covered entities to add to or change the federal requirements. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 379 (2000). But that does not mean that manufacturers lose all control over their drugs and must do whatever the government or covered entities demand. Congress's decision to impose only certain requirements on manufacturers — and not others — is entitled to judicial respect.

Contrary to the government's assertions, the ADR process under the 340B statute does not apply to this dispute. Those procedures apply only when a covered entity has been "overcharged" for drugs, or when a manufacturer asserts that a covered entity has engaged in "diversion" or impermissibly triggered a duplicate discount. *See* 42 U.S.C. § 256b(a)(5). When a manufacturer declines to transfer its drugs to contract pharmacies, the covered entity has not been charged at all. There

is no "overcharge" because the *covered entity* can still purchase unlimited quantities of the manufacturer's drugs at the discounted 340B price.

Moreover, while a manufacturer is entitled to bring an action against a covered entity for violating the statute's diversion or duplicate discount prohibitions, that does not mean that those are its only remedies. Congress has specifically granted parties, including manufacturers, the right to address agency overreach by bringing litigation under the Administrative Procedure Act. The problem here is that the government has tried to impose a new, extra-statutory obligation on manufacturers through its May letter — threatening enforcement and civil monetary penalties — that is contrary to the statute's plain text, and it has done so without complying with the requirements of reasoned decision-making. Nothing in the 340B statute's dispute resolution provisions displaces manufacturers' rights under the Administrative Procedure Act.

More fundamentally, the government's position forgets that the drugs belong to manufacturers. The government's right to control the drugs, and the covered entities' right to purchase them, is limited to the terms of the 340B statute. Manufacturers are free to control the distribution of their own drugs unless and until a duly enacted statutory provision restricts those rights. Accordingly, because the statute imposes no obligation on manufacturers to transfer their drugs to contract pharmacies, manufacturers can impose reasonable conditions when responding to

that extra-statutory request. And they can do so for any lawful reason, including because contract pharmacies are abusing the 340B program. In contrast, covered entities have no rights to access or control manufacturers' drugs, except on the terms set forth in the 340B statute (that is, to have the drugs offered to them at the discounted price), and the government has "no power to act" except and only to the extent that power has been granted by Congress. *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

That conclusion is hardly surprising. It is how our system of limited, constitutional government works. It is also how one would expect this type of government-run charitable program to operate. The program is supposed to benefit indigent and uninsured patients by granting covered entities the ability to access manufacturers' drugs at discounted prices. It would be incredibly surprising for Congress to have designed the 340B program as a multi-billion-dollar transfer scheme for the benefit of commercial pharmacies. To the contrary, as explained above, Congress carefully limited who could participate in the program, reflecting no intent that commercial pharmacies or other third parties would be able to profit from the sale of manufacturers' drugs at discounted prices. Consistent with Congress's express goals, the statute's dispute resolution procedures contemplate an audit process that depends on manufacturers being able to audit covered entities to protect against diversion and duplicate discounts. *See* 42 U.S.C. § 256b(a)(5)(C).

That process would be meaningless if the relevant data is kept in the hands of contract pharmacies and cannot be accessed by manufacturers. *See* Novo Br. 13-14.

In short, under the 340B program, the hospital covered entities have the right to have manufacturers' drugs offered to them at discounted prices for the benefit of the patients that visit their facilities for treatment. After covered entities receive that offer, they have no right to demand that manufacturers also transfer the discounted drugs to third parties (such as for-profit commercial pharmacies) for their own private financial gain.

III. The Court Should Vacate the Government's Unlawful Actions.

Novo's opening brief explains why the Court should strike down the government's December decision and also strike down and vacate the government's May letter. The government has no meaningful response.

A. The December Decision Should Be Declared Unlawful.

Although Novo's opening brief explains why the government's December decision should be declared unlawful, and why the district court's mootness ruling is legally wrong, the government does not address these issues. It does not defend the district court's decision or make any attempt to carry its "heavy burden" to show that its unlawful action is unlikely to recur. *See* Novo Br. 56 (citing *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)). Forfeiting any defense on the merits, the government merely suggests that the issue

is "academic" because the December decision has already been withdrawn. *See* HHS Br. 50.

That is wrong. A defendant's voluntary cessation of unlawful conduct does not moot a case when the unlawful conduct may reoccur. *See City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982) (challenge to a municipal ordinance was not moot because "the city's repeal of the objectionable language would not preclude it from reenacting precisely the same provision"). The government's decision to withdraw its December decision leaves no assurances to Novo or other manufacturers that it will not reissue the decision or base future enforcement actions on its discredited reasoning. No further evidence is needed on this point than the government's continued attempt to enforce the positions taken in its December decision through its defense of its May letter. *See* R.61-2 at 2, *AstraZeneca*, No. 21-cv-27 (D. Del. June 30, 2021), ECF No. 83 (JA__) (because the government "intend[s] to act in accordance with the withdrawn [decision], this litigation is not moot"); *Eli Lilly & Co. v. HHS*, No. 21-cv-81, 2021 WL 5039566, at *12 (S.D. Ind. Oct. 29, 2021) (holding that the December decision was not moot because "HHS's withdrawal does not include any indication that the agency has fully and for all time ... abandoned the position laid out in the December 2020 Advisory Opinion.").

B. The May Letter Should Be Declared Unlawful and Vacated.

The government concedes that Congress did not delegate rulemaking authority to HHS to impose obligations not contained in the 340B statute's plain text — denying the agency any power to expand the program's reach or to adjust the program in light of changed circumstances. *See* HHS Br. 2. All sides also agree that determining what number of commercial pharmacies should be allowed to participate in the 340B program is an exercise of legislative authority that can be accomplished only by the statute itself or through proper rulemaking procedures. *See SBC Inc. v. FCC*, 414 F.3d 486, 497 (3d Cir. 2005) ("Legislative rules are subject to the notice and comment requirements of the APA because they work substantive changes in prior regulations, or create new law, rights, or duties." (quotation marks omitted) (citation omitted)).

As courts have recognized, regulations that depend on a setting a "numerical component" — such as whether a covered entity should be able to demand that drugs be transferred to 0, 1, 2, or an unlimited number of contract pharmacies — generally require an exercise of a "legislative function" that cannot be accomplished through interpretive rules or non-binding guidance. *Hoctor v. U.S. Dep't of Agric*., 82 F.3d 165, 170-71 (7th Cir. 1996); *see also Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 495 (D.C. Cir. 2010). Because Congress has not granted HHS authority to impose new substantive obligations, any attempt by HHS to do so "is plainly

contrary to law and cannot stand." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (quoting *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001)).

This Court also does not have authority to rewrite the statute to accommodate HHS's policy preferences. The Court owes deference to the statute's plain text. Moreover, the government has never identified any words in the statute that it contends are ambiguous. Nor does its May letter rely on any suggestion that the statute is ambiguous. An agency cannot defend its position on the ground that an action is compelled by the statute and then, when that fails, prevail in court on the theory that the statute is ambiguous and its interpretation should be sustained at the expense of the common law property rights of private parties. *See Christensen*, 529 U.S. at 588; *Chenery*, 318 U.S. at 87; *see also Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985) ("[a]n agency decision cannot be sustained ... where it is based ... on an erroneous view of the law"). Such a position is especially bizarre where all parties concede that HHS does not have rulemaking authority and is due no *Chevron* deference.

Accordingly, because the May letter must rise or fall on the reasons provided by the agency itself, and not by the government's litigation counsel, the May letter is unlawful and should not be allowed to stand. "Vacatur 'is the normal remedy' when [courts] are faced with unsustainable agency action." *Bhd. of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 117 (D.C. Cir. 2020) (quoting

Allina Health Servs. v. Sebelius, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). This Court should vacate the May letter and leave it to Congress to make any policy changes to the 340B program.

CONCLUSION

The Court should reverse the district court, strike down and declare unlawful the December decision and May letter, and enjoin the government from taking enforcement action against Novo.

RESPONSE TO THE GOVERNMENT'S CROSS-APPEAL

The government's arguments in support of its cross-appeal appear on pages 45 through 48 of its brief. The government argues that the district court should not have remanded for HHS to address "how many contract pharmacies the 340B statute permits." HHS Br. 47 (quoting R.69 at 95 (JA__)). According to the government, remand was improper because Congress has not delegated HHS any general rulemaking authority. As a result, it lacks authority to make substantive rules regarding the 340B program. *See id*. It should be Congress, not the courts or HHS, that decides how many contract pharmacies are appropriate, if any. *See id.*

Novo agrees that the government lacks rulemaking authority, but that is just another reason to reject the government's attempt to read into the statute requirements that do not exist. Congress's decision not to grant HHS authority to fill in statutory gaps is further evidence that Congress intended the 340B program to be limited in scope and did not authorize the agency to impose new obligations on manufacturers not included in the statute itself. Indeed, HHS's concession that it lacks rulemaking authority confirms that HHS has exceed its authority. Its unlawful actions relying on an impermissible reading of the statute should be struck down and vacated in their entirety.

Contrary to the government's assertions, *see id.* at 48, the scope of HHS's authority to enforce the statute against covered entities is largely irrelevant to this

case. The only question is whether the 340B statute imposes an obligation on *manufacturers* to transfer their drugs to contract pharmacies. Because it does not, manufacturers retain the right to reject any request by covered entities that manufacturers make those transfers. A covered entity has a limited statutory right to purchase manufacturers' drugs at discounted prices — a right that they continue to exercise, unabated. They do not have any right to force manufacturers to transfer their drugs to wherever and whomever the covered entity demands.

The government's cross-appeal should be denied.

Respectfully submitted,

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June 8, 2022

CERTIFICATE OF COMPLIANCE

1. Pursuant to Local Rule 28.3(d), I hereby certify that the attorneys whose names appear on this brief are members of the bar of this court.

2. This brief complies with the type-volume requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8,420 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

3. The brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) and 3d Cir. L.A.R. 32.1(c) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 ProPlus in Times New Roman 14-point font.

4. Pursuant to Local Rule 31.1(c), I hereby certify that the text of the electronic brief is identical to the text in the paper copies, and that it has been scanned for viruses using McAfee Endpoint Security, Version 10.7.1, and no virus was detected.

Date: June 8, 2022

/s/ *Ashley C. Parrish*
Ashley C. Parrish

CERTIFICATE OF SERVICE

I hereby certify that on June 8, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ *Ashley C. Parrish*
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