IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1479 (DLF)

DEFENDANTS' COMBINED REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S CROSS-MOTION FOR SUMMARY JUDGMENT

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Novartis Pharmaceuticals Corporation has tried and failed to call into question the validity of the Health Resources and Services Administration's ("HRSA") determination that Novartis has violated its obligations under the 340B statute, 42 U.S.C. § 256b. In its cross-motion for summary judgment, Novartis offers no cogent response to the incontrovertible evidence demonstrating that it has unlawfully overcharged for 340B-eligible drugs and denied covered entities the ability to purchase discounted drugs to which they are statutorily entitled—clear-cut violations of § 256b(a)(1). Novartis instead chiefly disputes HRSA's interpretation of the 340B statute, arguing that Novartis has free rein under the 340B Program to impose burdensome restrictions on 340B purchases and that its statutory obligations do not require it to honor *any* such purchases made through a covered entity's contract-pharmacy arrangements. But Novartis's arguments on this score misconstrue the statutory text and ignore the congressional purpose and history of the 340B statute—the hallmarks of statutory meaning that collectively demonstrate the correctness of HRSA's interpretation. And Novartis's erroneous statutory theories further undermine its criticism that HRSA has acted arbitrarily and capriciously in finding Novartis in violation of its statutory obligations. None of Novartis's claims are based on a permissible reading of the 340B statute, nor do they reflect an accurate portrayal of the agency's historical guidance or find support in the administrative record.

The Court should therefore enter summary judgment in favor of Defendants on all of Plaintiff's claims, and deny Plaintiff's cross-motion for summary judgment.

ARGUMENT

I. NOVARTIS HAS NOT CARRIED ITS BURDEN TO DEMONSTRATE THAT HRSA'S ENFORCEMENT OF THE 340B STATUTE RESTS ON AN INCORRECT INTERPRETATION.

HRSA demonstrated in its opening brief, *see* HRSA Mot. at 20–30, that, read "as a whole," *United States v. Atl. Research Corp.*, 551 U.S. 128, 135 (2007), 42 U.S.C. § 256b(a)(1) plainly requires drug manufacturers to sell discounted drugs to covered entities at no more than the ceiling price—and that Novartis is flouting this obligation by charging covered entities far higher prices (and denying those purchases outright, in some instances) for all sales that fail to comply with Novartis's own arbitrary,

self-serving limitations. Rather than address the government's statutory argument head-on, Novartis's arguments continue to mischaracterize HRSA's interpretation and present a view of Novartis's obligation that ignores black-letter canons of statutory interpretation. Novartis's reading of the statute conflicts with the statutory text, undermines Congress's purpose, and must be rejected.

First, Novartis misframes HRSA's interpretation as imposing "***a Boundless Delivery Obligation***," and attacks the government's position as "argu[ing] that the statute's broad reference to a 'purchase' imposes a third statutory obligation on manufacturers: to ship 340B drugs to non-covered entities." Novartis Mot. 3–4. Not so. HRSA hasn't initiated enforcement action on the basis of a *delivery obligation*, but instead has found—after an extensive, months-long review and gathering voluminous evidence—that Novartis is *overcharging* covered entities by demanding payment far above the statutory ceiling price unless Novartis's extra-statutory demands are met.

Novartis's focus on *delivery* (rather than the price paid for 340B purchases) attempts to obscure its lack of compliance with its actual statutory obligation. As explained in the government's opening brief, the 340B statute requires Novartis to sell its drugs to covered entities at or below the ceiling price, and to treat covered entities' purchases as favorably as commercial purchases. HRSA has initiated enforcement action based on Novartis's refusal to comply with *those* obligations, not some new shipping obligation. Tellingly, despite all its protestations about covered entities' "unilateral demands on manufacturers … to ship drugs directly to … pharmacies," Novartis Mot. 4, *nowhere* does Novartis claim that it is not already shipping full-priced drugs to the very same pharmacies it now refuses to ship discounted drugs. Novartis willingly ships its drugs to pharmacies when full, commercial prices are paid—it just newly is refusing to ship those same drugs to those same locations when they are ordered and paid for by covered entities at statutory discounts (a change that evidence in the record demonstrates is likely calculated to most impact specialty drugs not available through local pharmacies, or patients who travel far from home to receive specialized hospital services such as oncology or organ transplantation, VLTR_3518; 6229–30). HRSA has not read into the statute any

"boundless delivery obligation,"[1] but instead has made clear that Novartis risks losing access to Medicaid and Medicare Part B if it continues to deny covered entities' purchases and/or to charge them inflated commercial prices. That determination is based on solid evidence that Novartis *is* overcharging covered entities. *See, e.g.*, VLTR_6396 (hospital paid more than $2 million above ceiling price for covered drugs of several manufacturers, including Novartis); *id.* 6410-12 (documenting Novartis overcharges including price of $5,677 per unit); *id.* 6229–30, 6243–44 (documenting hundreds of thousands of dollars in overcharges from several manufacturers and explaining that Novartis's 40-mile-radius limitation is calculated to deny purchases through specialty pharmacies used by patients "receiving medications for complex and specialized disease states").

Putting aside Novartis's inaccurate framing of HRSA's determination, Novartis's primary statutory argument rests on silence: Congress did not *expressly* prohibit the precise restrictions Novartis has imposed on covered entities' ability to access the 340B Program, so those restrictions must be fair game. *See, e.g.*, Novartis Mot. 2 ("[The 340B statute] is completely silent on shipments of covered outpatient drugs to non-covered entities"); *id.* 4 (admitting that the statute requires Novartis to honor covered entities' purchases but arguing "'Purchase' and 'offer' do not mean 'ship,' and Congress's silence on delivery location does not quietly signal a statutory mandate … to provide the 340B discount on drug products shipped to" pharmacies for dispensing to patients). This assertion is nonsensical; no interpretive doctrine requires Congress to spell out the minutiae of every facet of every transaction encompassed within a program created through novel legislation. Stated differently, Congress is permitted to (and often does) legislate through broad commands or prohibitions, and the use of more-general language does not permit a regulated entity to take actions that contravene a statute's purpose simply because those actions were not expressly prohibited by the plain text.[2] This intuitive principle

[1] Ironically, it is Novartis's preferred operation of the statute (where manufacturers are required only to ship 340B drugs *directly* to covered entities) that would result in new delivery obligations, since many covered entities do not operate a pharmacy and thus do not currently receive drug shipments.

[2] In suggesting otherwise, Novartis relies on "Justice Scalia['s] famous[] observ[ation] that Congress does not hide elephants in mouseholes." Novartis Mot. 1. But "the no-elephants-in-

is illustrated by the untenable results that would accrue should Novartis's interpretation be credited. Novartis hangs its hat on "Congress's silence on delivery location," *id.*, but if that "silence" indicated that manufacturers have *no* delivery or shipping obligations—as Novartis insists—then it would follow that Novartis could entirely refuse to deliver 340B-discounted drugs and require each covered entity across the nation to physically pick up their purchased drugs from Novartis's warehouses. Similarly, Novartis's capacious view of the meaning of Congressional silence would mean that, since the 340B statute is equally silent on payment method, Novartis could require covered entities to pay only in pennies. Congressional silence on drug quantities could similarly allow Novartis to require sky-high minimum order requirements that rendered it infeasible for resource-strapped safety-net providers to purchase Novartis drugs. None of these absurd results is permissible under the statute (nor is Novartis's wholly arbitrary 40-mile restriction) because Congress's intent in mandating maximum prices for covered entities is clear—and Congress was under no obligation to micromanage the details of those transactions in order to achieve its purpose of providing discounted drugs for certain safety-net providers. As the Supreme Court has made clear, there is no "such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Bostock*, 140 S. Ct. at 1747.[3]

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mouseholes canon … recognizes that Congress does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions," it does not require Congress to detail every aspect of a general statutory command. *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1753 (2020) (internal quotation marks and citation omitted) (explaining that "Title VII's prohibition of sex discrimination … is written in starkly broad terms" and "has repeatedly produced unexpected applications"). Precedent does not, as Novartis portrays, prevent Congress from writing in "starkly broad terms." *Id.*

[3] HRSA's reading of the statute certainly would not "give covered entities leeway to impose unilateral demands on manufacturers" to "deliver drug products via carrier pigeon, or package them in green boxes." Novartis Mot. 4. As HRSA explained back in 1994, the 340B statute requires manufacturers to make discounted drugs available to covered entities in the same manner as drugs are made available to commercial purchasers—*i.e.*, through wholesale arrangements, purchasing agents, and contracting pharmacies. *See* HRSA Mot. 24–25. Novartis does not deliver full-priced medications via carrier pigeons and thus is under no obligation to accede to such a demand from covered entities. But Novartis *does* ship full-priced drugs to pharmacies throughout the nation for dispensing to patients of non-covered entities and thus must permit covered entities to rely on these commonplace, real-world dispensing mechanisms as well.

Not only is Novartis's interpretation illogical, its "slimmed down" reading of the statute, Novartis Mot. 4, violates basic principles of statutory interpretation by asking this Court to consider the "purchase" and "offer" language in isolation from the statute's structure, additional text, and purpose. This Court "must (as usual) interpret the relevant words not in a vacuum, but with reference to the statutory context, structure, history, and purpose." *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted). "[I]t is a fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used." *Textron Lycoming Reciprocating Engine Div. v. Auto. Workers*, 523 U.S. 653, 657 (1998) (internal quotation marks and citation omitted); *see also Regions Hosp. v. Shalala*, 522 U.S. 448, 460 n.5 (1998) ("In expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." (citation omitted)).

Novartis's insistence that it complies with the statute while refusing covered entities' purchases and charging them far above the ceiling price simply because "'[p]urchase' and 'offer' do not mean 'ship,'" Novartis Mot. 4, ignores Congress's intent in carefully crafting a comprehensive scheme designed to allow safety-net providers and patients to *actually access* discounted medications. That type of hyper-technical reading does not comport with precedent; on the contrary, "[t]he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012). The most natural reading of the 340B statute plainly is not, as Novartis persists, one where manufacturers had no duty whatsoever to provide discounted drugs through covered entities' pre-existing dispensing mechanisms, thus rendering the program inaccessible in practice to 95% of covered entities *at time of enactment.* After all, one of the fundamental principles of statutory interpretation is "the presumption against ineffectiveness," *United States v. Castleman*, 572 U.S. 157, 178 (2014) (Scalia, J., concurring)—meaning "[a] textually permissible interpretation that furthers rather than obstructs [a statute's] purpose should be favored." *Tex. Workforce Comm'n v. U.S. Dep't of Educ.*, 973 F. 3d 383, 389 (5th Cir. 2020) (citation omitted); *see also United States v. Hayes,* 555 U.S. 415, 426–27 (2009) (rejecting a construction of a statute that "would

frustrate Congress' manifest purpose" and would have meant that the statute was "'a dead letter' in" many of its applications "from the very moment of its enactment"). Novartis's reading also ignores the separate statutory command not to discriminate against 340B purchases relative to commercial purchases (the non-discrimination provision added in 2010, *see* HRSA Mot. 23), which Novartis also is violating.

Equally unavailing is Novartis's insistence that HRSA's Violation Letter can only be upheld if "it can demonstrate that the statute *unambiguously* requires manufacturers to honor contract pharmacy arrangements." Novartis Mot. 3. As an initial matter, Novartis seeks to instill a sense of ambiguity on this issue by inviting the Court to interpret the statutory text in isolation, without "exhaust[ing] [all of] the traditional tools of statutory construction to determine whether a congressional act admits of plain meaning." *See Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000). But "[i]n determining whether a statute is ambiguous …, [a court] must employ all the tools of statutory interpretation, including 'text, structure, purpose, and legislative history.'" *Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (citation omitted). As already explained above, the text, structure, and purpose of the 340B statute collectively demonstrate that Congress required Novartis to honor the purchases it now is denying; there is no ambiguity simply because Congress did not expressly authorize outside-dispensing arrangements (upon which nearly all covered entities relied when Congress enacted the 340B statute). And with respect to the statute's legislative history, as discussed in HRSA's opening brief, *see* HRSA Mot. 25–26, Congress actually considered, but removed from the statute, language that would have restricted 340B drugs to those purchased and dispensed in-house or on-site by a covered entity. "[T]his Court may not narrow a provision's reach by inserting words Congress chose to omit." *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020). And it matters not that "HRSA never 'set out with a lawmaking pretense in mind'" in crafting the Violation Letter or earlier guidances, Novartis Mot. 6 (citation omitted), because both the Letter and guidances interpreted *the statute* and did not seek to impose new obligations. But even if the Court were to find that the 340B statute is susceptible to more than one plausible interpretation, HRSA's Violation Letter should still be upheld on the grounds that it relies on the *best* reading of the statute, for all of the reasons explained above. And contrary to Novartis's

assertions, HRSA has not "disavowed entitlement to deference" under *Skidmore*. *See* Novartis Mot. 5–6.

Novartis's remaining arguments are equally meritless. It continues (though half-heartedly) to assert that covered entities' decades-old reliance on outside pharmacies is "arguably prohibited" by the statute. Novartis Mot. 4–5. HRSA's opening brief explained the proper meaning of the prohibition on transfer or diversion of covered drugs, *see* HRSA Mot. 26–28, and Novartis offers no cogent argument to support its tautological assertion that allowing covered entities to continue serving patients through outside pharmacies *as they did at the program's inception* is "an escape hatch permitting covered entities to force manufacturers" to violate those provisions, Novartis Mot. 5. Any doubt on that score is settled by the fact that Congress acted to increase manufacturers' obligations in 2010 (by adding the non-discrimination requirement and allowing covered entities to bring claims for overcharging before an administrative-dispute resolution system, 42 U.S.C. § 256b(a)(1), (d)(3)(A)), but in no way restricted covered entities' reliance on outside pharmacies.

Elsewhere Novartis makes much of the fact that HRSA's guidances have varied with respect to how *covered entities* may use contract-pharmacy arrangements while ensuring compliance with the prohibitions on diversion and duplicate discounting. *See* Novartis Mot. 7 (charging HRSA with having "been consistently inconsistent over the years in its interpretation of what the 340B statute 'requires'"); *id.* 8-10 (arguing that "over time, HRSA's position shifted"). This gets Novartis nowhere; the statute plainly contains multiple requirements—including distinct prohibitions on manufacturers (not to overcharge or discriminate against discounted purchases) versus covered entities (not to transfer discounted drugs or claim duplicate discounts). That HRSA initially in 1996 restricted *covered entities* to reliance on one outside pharmacy (while making plain that it continued to evaluate such relationships and would later determine the feasibility of permitting "more than one site and contractor," Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Servs., 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996)), does not evince any change in HRSA's interpretation as to *manufacturers'* obligation. And for good reason: As HRSA has explained since 1994, the statute does not permit manufacturers to single out covered entities for restrictive conditions that would

undermine Congress's purpose. Final Notice Regarding 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). The fact that HRSA has expanded covered entities' ability to use outside pharmacies does not change the fact that HRSA's recognition of manufacturers' obligations has been consistent and unequivocal. *Contra* Novartis Mot. 8–9 (focusing exclusively on HRSA's guidance *to covered entities*). Nor does the fact that HRSA always has (correctly) recognized that guidance is non-binding undermine its current (and historic) position that *the statute* does not permit manufacturers to impose conditions on covered entities' access to discounted medications.

Finally, Novartis criticizes HRSA's brief for "repeatedly characteriz[ing] the obligation as a 'sale' rather than an 'offer'" despite the fact that "Congress could have used a term other than 'offer' if it wanted to." *Id.* 9 n. 3. This assertion is bizarre; even putting aside that the "offer" language was added in 2010—decades after Novartis's substantive obligation was enacted in 1992—Congress *did* use a term other than "offer," instructing manufacturers to comply with an agreement to ensure that "purchases by" covered entities do not exceed the ceiling price. 42 U.S.C. § 256b(a)(1). Unsurprisingly, Novartis provides no reason for this Court to interpret "purchases by" to mean anything other than a "sale."

Novartis's interpretation of the 340B statute is inconsistent with its text, undermines Congress's purpose, and should be rejected.

II. THE VIOLATION LETTER IS SUBSTANTIVELY COMPLIANT WITH THE APA.

A. The Violation Letter and the administrative record provide a reasoned basis for HRSA's conclusions.

HRSA's conclusion that Novartis's policy "resulted in overcharges" and is in "violation of the 340B statute" finds ample support in the administrative record. VLTR_5. Though Novartis argues that the Violation Letter is devoid of any basis for HRSA's conclusion, Novartis Mot. 11, the Violation Letter specifically refers to the agency's "analysis of the complaints HRSA has received from covered

entities" and its "review of [Novartis's] policy"[4] in support of its determination, VLTR_5, thus "suppl[ying] a roadmap by which 'the agency's path may be reasonably discerned,'" *see* Novartis Mot. 11 (quoting *Bowman Transp. Inc. v. Arkansas-Best Freight Sys.*, 419 U.S. 286, 281 (1974)).

Turning to the complaints HRSA received from covered entities, the complaints show that Novartis's policy has an outsize impact on specialty drugs and resulted in overcharges in violation of the statute. For example, the Arnot Ogden Medical Center stated that it was "unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity," VLTR_6230, and attached a spreadsheet listing specific Novartis drugs it was unable to purchase as well as the "estimated overcharge amount,"[5] VLTR_6243–45. The same complaint from Arnot highlighted the "financial[] damage[]" it will suffer as a result of Novartis's policy, and explained the impact on specialty pharmacies and drugs used to manage "complex and specialized disease states." VLTR_6230. Another covered entity, Nebraska Medicine, similarly complained that "specialty drugs" manufactured by Novartis were no longer being offered at the 340B ceiling price through contract pharmacies. VLTR_4454–57. These complaints support the conclusion that, however reasonable Novartis's policy may appear at first blush, it was designed to target these specialty drugs that are unavailable near many covered entities and accessed through nationwide specialty dispensers.

Novartis accuses HRSA of failing to "show that *Novartis's* policy violates the statute," Novartis Mot. 12, but it is difficult to imagine more direct evidence of violation than complaints from covered

[4] HRSA's Violation Letter states that Novartis's contract-pharmacy policy required covered entities to "provide claims data to a third-party platform." *See* VLTR_5. Although Novartis had initially informed covered entities that they would be required to provide claims data to purchase 340B-eligible drugs through contract-pharmacy arrangements, the drug manufacturer had later revised its policy and made its claims-data requirement voluntary. *See id.* 7747. The Violation Letter's misstatement in no way undermines HRSA's conclusion that Novartis's restrictions on the use of contract pharmacies contravene the 340B statute and have resulted in unlawful overcharges on covered outpatient drugs, because that conclusion is supported by sound statutory interpretation and ample evidence in the administrative record.

[5] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record, along with other figures that would allow a reader easily to calculate the ceiling price for any particular drug.

entities that they are unable to access Novartis's drugs at the statutorily mandated ceiling price. And while Novartis claims that HRSA's counsel is now improperly supplying "a reasoned basis for the agency's action that the agency itself has not given," Novartis Mot. 12 (quoting *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 648 (D.C. Cir. 2020)), HRSA, in fact, cited the covered-entity complaints referenced here and in HRSA's opening brief as a basis for its conclusions in the Violation Letter, *see* VLTR_5 (reaching conclusion "after … an analysis of the complaints HRSA has received from covered entities"). The APA imposes no requirement that every document in the administrative record be discussed at length in the agency's statement of decision. Indeed, "even when an agency explains its decision with less than ideal clarity, a reviewing court will not upset the decision on that account" alone. *Alaska Dep't of Envt'l Conservation v. EPA*, 540 U.S. 461, 497 (2004) (citation omitted). Here, however, the Violation Letter leaves no doubt as to the basis for HRSA's conclusion.

The self-proclaimed "generous geographic scope" of Novartis's policy does not excuse Novartis's violation of the 340B statute. Novartis Mot. 13. Novartis cites to evidence outside the record to support the proposition that most "contract pharmacies are located within a 40-mile radius of the covered entities they serve." *Id.* at 12. But, based on covered-entity complaints relied upon in the Violation Letter, as well as the extra-record evidence that Novartis cites, it is clear that many contract pharmacies fall outside of this geographic range and that Novartis's drugs are disproportionately dispensed through nationwide, specialty pharmacies. The UC Davis Medical Center, for example, serves more than 6 million residents over 33 counties and 65,000 square miles. VLTR_5622. Many of UC Davis's patients reasonably "rely on pharmacies closer to their homes" and UC Davis "has many contract pharmacies" that help their "patients to have access to medications." *Id.* Unsurprisingly, then, the Government Accountability Office concluded that almost half of disproportionate-share hospitals (hospitals serving a high number of low-income patients such as UC Davis) had at least one pharmacy that was more than 1000 miles away. GAO, Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 23 (June 2018), available at https://www.gao.gov/assets/gao-18- 480.pdf. It was thus reasonable for HRSA to determine that Novartis's policy resulted in overcharges to covered entities. HRSA's reference to

"neighborhood pharmacies" throughout its opening brief does not change this conclusion. Contrary to Novartis's understanding, neighborhood pharmacies exist in the covered entity's *patient's* neighborhood, regardless of how close that *patient* lives in proximity to the covered entity (and as already explained, many patients requiring specialty care may travel great distances to reach a safety-net provider). In any event, increased access of patients to pharmacies in their neighborhoods is only one benefit of contract-pharmacy arrangements—it in no way limits these arrangements, which are also intended to provide flexibility for covered entities, to those that Novartis unilaterally determines to be eligible. And even were it true that (as Novartis portrays) its 40-mile restriction impacted a relatively small number of patients, that would make no difference since partial compliance with a statutory obligation is not enough to avoid liability.

In addition to the specific complaints from covered entities referenced in the Violation Letter and highlighted above, HRSA also analyzed aggregate data of the effect of Novartis's policy before issuing the Violation Letter. *See* HRSA Mot. 18. And although Novartis attempts to write it off as merely an argument "in general terms," Novartis Mot. 12, there is no escaping the facts. The number of 340B-priced units of Novartis drugs sold through contract pharmacies shrank from 1.38 million to 1.20 million in November 2020, constituting $8.6 million in average lost savings by covered entities on Novartis products in that month alone. *See* VLTR_7937, 7940. The trend continued in the subsequent two months, constituting average lost savings on Novartis products of over $28 million each month. *See id.* Regardless of Novartis's arguments to the contrary, these statistics represent thousands of transactions in which Novartis's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices.

The Violation Letter also reasonably concluded that Novartis fails to "provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs." VLTR_5. Although Novartis claims that there is a "total lack of support" for this proposition, Novartis Mot. 14, it does not claim to impose any conditions on the purchase of drugs by non-covered entities. Novartis's argument that contract-pharmacy arrangements do not exist in the commercial world is irrelevant. Contract-pharmacy arrangements are not needed for full-priced transactions

because the contract at issue, between a covered entity and the dispensing pharmacy, is a creature of the 340B Program and functions to allow covered entities to access the discount program while ensuring compliance with the prohibitions on duplicate discounts and diversion. The relevant point is that Novartis imposes conditions on covered-entity purchases that it does not impose on commercial purchasers, and the fact that commercial purchasers need not utilize contracts similar to those relied upon by covered entities does not justify Novartis's covered-entity specific conditions.

Finally, although it pivots away from its unfounded claim that the withdrawn Advisory Opinion imposes an impermissible condition on manufacturers, *cf.* HRSA Mot. 33, Novartis still claims that the Advisory Opinion is relevant here, Novartis Mot. 11-12. The Advisory Opinion has been withdrawn, however, and the Violation Letter does not mention the opinion or purport to rely on the opinion. Nor would one expect it to, as HRSA's enforcement activities began before the Advisory Opinion was even issued, VLTR_7744 (referencing communications beginning in August 2020), and HRSA's process operated independently from the Advisory Opinion, as the withdrawal notice explicitly states. In any event, nothing in the Advisory Opinion undermines the record evidence relied upon by HRSA in issuing the Violation Letter, and Novartis points to nothing in the Advisory Opinion that undercuts HRSA's ultimate conclusions. The opinion thus has no bearing on this Court's determination on the reasonableness of the Violation Letter.

B. HRSA's Violation Letter reflects the agency's longstanding, consistent position regarding manufacturers' obligations under the 340B statute.

For nearly three decades, HRSA has made clear that a manufacturer participating in the 340B Program cannot unilaterally impose extra-statutory, restrictive conditions on 340B-eligible drug purchases by covered entities, as Novartis has done here. *See* HRSA Mot. 33–35 (surveying HRSA's relevant guidance documents). Novartis's cursory and selective review of HRSA's prior guidance documents identifies no inconsistencies on this point.

Start with the 1994 Guidance. There, HRSA stated in no uncertain terms that "[m]anufacturers must not place limitations on [340B] transactions … which would have the effect of discouraging entities from participating in the discount program," and "may not single out covered entities from

their other customers for restrictive conditions that would undermine the statutory objective." 59 Fed. Reg. at 25,113. And HRSA did not require one to "read[] between the lines," *see* Novartis Mot. 16, to understand that manufacturer-imposed "limitations" on the use of "contract pharmacies" in 340B transactions are among those prohibited restrictions that discourage covered-entity participation, 59 Fed. Reg. at 25,111. Therefore, Novartis cannot escape the conclusion that its contract-pharmacy policy imposes unlawful restrictions on 340B-eligible purchases by simply mislabeling these restrictions as "normal business policies" that it can address permissibly in an agreement with a covered entity. *See* Novartis Mot. 16. The 1994 Guidance permitted manufacturers to enter into contracts containing "provisions relating to normal business policies" and "other appropriate contract provisions," but understood those provisions to address matters akin to the gathering of "routine information necessary" for participants "to set up and maintain [a 340B] account." 59 Fed. Reg. at 25,112. HRSA thus drew a sharp contrast between permissible contract provisions that *facilitate* purchases of 340B drugs and manufacturer-imposed, extra-statutory conditions that unlawfully *restrict* purchases and discourage covered-entity participation. Novartis's arguments based on the 1994 Guidance efface this distinction.

Novartis also selectively reads HRSA's 1996 and 2010 Guidances, obscuring the agency's position regarding *manufacturers'* statutory obligations that was also reflected in HRSA's Violation Letter. In this respect, both guidance documents speak plainly: "[I]f a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs* the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Serv., 75 Fed. Reg. 10,272, 10,278 (Mar. 4, 2010) (emphasis added); *accord* 61 Fed. Reg. at 43,549. "If the entity directs the drug shipment to its contract pharmacy," the 1996 Guidance explained, there is "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance," as a contrary reading "would defeat the purpose of the 340B program" and would be "[in]consistent with the intent of the law." 61 Fed. Reg. at 43,549–50.

Rather than grapple with these points, Novartis gets tangled up in peripheral matters that are irrelevant to a *manufacturer's* obligations under the 340B statute. Namely, Novartis observes that (i) prior to 2010, HRSA had created non-binding limitations on the number of contract pharmacies a covered entity could utilize, and (ii) HRSA had suggested that covered entities address certain provisions in their contract-pharmacy arrangements. *See* Novartis Mot. 14–15. But the fact that *HRSA* (the agency authorized to administer the 340B Program) designed these guidelines for covered entities to facilitate their participation and compliance, *see* 61 Fed. Reg. at 43,555, in no way suggests that *manufacturers* are authorized under the 340B statute to take matters into their own hands by unilaterally imposing restrictions on contract-pharmacy arrangements as they see fit. Such a conclusion cannot be squared with the 340B statute or the agency's historical guidance.

C. HRSA's position is based on all relevant factors.

There can be no dispute that the 340B statute prohibits the "resell" or "transfer" of a 340B drug "to a person who is not a patient of the [covered] entity," informally known as "diversion." 42 U.S.C. § 256b(a)(5)(B). But an explicit finding that all contract-pharmacy arrangements, including those based on the replenishment model, are consistent with the statute's prohibition on diversion is beyond the scope of the Violation Letter, and is not relevant to HRSA's determination that Novartis has overcharged covered entities and otherwise violated its obligations under the statute. *See Confederated Tribes of Coos, Lower Umpqua & Siuslaw Indians v. Babbitt*, 116 F. Supp. 2d 155, 165 (D.D.C. 2000) ("[I]t was not arbitrary and capricious to not consider materials which, under the interpretation being employed, were irrelevant.").

The Violation Letter concludes that Novartis is violating its statutory obligations under Section 340B, and rejects Novartis's "rationale" for its policy by explaining that "the 340B statute provides a mechanism by which a manufacturer can address" diversion and duplicate discounts by conducting an audit and submitting a claim through the statutorily required ADR process. VLTR_5–6. The statute also provides a mechanism for HRSA to audit covered entities and to determine whether their contract-pharmacy arrangements constitute diversion, after which the covered entity may be liable to the manufacturer if it has violated the statute's prohibition on diversion. 42 U.S.C. § 256b(a)(5)(C).

The statute thus sets forth the process for determining whether the diversion provision has been violated, and this process operates separately from HRSA's authority to determine whether Novartis is in violation of its obligations under the statute.

Novartis would have HRSA sidestep this statutorily required process for determining whether covered entities are in compliance with the statute on a case-by-case basis to make an across-the-board determination about the propriety of contract-pharmacy arrangements that would be both inconsistent with Novartis's current policy and not supported by facts in the administrative record. Though Novartis highlights purported "serious diversion concerns surrounding the replenishment model" predominantly used in contract-pharmacy arrangements, it stops short of saying that replenishment models always constitute diversion. Novartis Mot. 19. This is not surprising, as Novartis's own policy allows for contract-pharmacy arrangements within a 40-mile radius of a covered entity. But Novartis offers no explanation for why replenishment models and contract-pharmacy arrangements supposedly do not constitute diversion in some geographic locations and supposedly do in locations not covered by Novartis's policy. And although Novartis itself acknowledges the "variety of contract pharmacy arrangements and data types," it expects HRSA to make a one size fits all determination about contract pharmacies unrelated the scope of Novartis's statutory violation. Novartis Mot. 19. Nothing of the sort is required by the APA.

In tacit acknowledgement of the weakness of its argument, Novartis tries to distance itself from the claim that HRSA acted arbitrarily and capriciously in not making an explicit finding of compliance with nonbinding guidance by attempting to read this guidance into the statute itself. HRSA's guidance identifies covered entities' maintenance of title to 340B drugs as an "element" to address in contract-pharmacy arrangements. 75 Fed. Reg. at 10,277. Notably, the statute itself says nothing about the "title" of drugs purchased by covered entities, and the guidance does not set forth the metes and bounds of when title may pass during a 340B transaction. The statute requires only that a covered entity may not "resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256(a)(5)(B). As explained in HRSA's opening brief, facts in the administrative record establish that the replenishment model does not violate this requirement. HRSA Mot. 37. And,

in any event, the record shows that covered entities generally retain title at least until the drugs reach a pharmacy's neutral inventory, a fact which is not disputed by Novartis. *Id.*

If Novartis has concerns about covered entities' compliance with the statute's prohibition on diversion, it should avail itself of the statutorily mandated audit and dispute resolution processes. Novartis should not be permitted, however, to use its so-far-unfounded concerns as a way to invalidate HRSA's sound judgment that Novartis itself is in violation of the statute.

CONCLUSION

Because each of Novartis's claims is meritless, the Court should grant summary judgment in favor of Defendants and deny Novartis's cross-motion for summary judgment.

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Respectfully submitted,

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