IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Civil Action No. 3:21-cv-806-FLW-LHG

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' NEW CLAIMS CONTAINED IN COUNTS I–IV; REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT; AND OPPOSITION TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

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As explained in HHS's dispositive motion, the present dispute arose when Novo and several other global drug makers upended the twenty-five year operation of the 340B Program by announcing they will no longer offer (or offer without manufacturer-imposed, extra-statutory restrictions) access to discounted drugs for certain statutorily defined providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies." By *denying* drug "purchases by" these safety-net providers, Novo has dramatically curtailed much-needed funding for these providers and forcing patients to pay more for medications or adjust their medication regimen. After a thorough review of Novo's new contract-pharmacy restrictions, the Health Resources and Services Administration ("HRSA") has determined that Novo is flouting its obligation under Section 340B by overcharging covered entities for its drugs and conditioning access to discounted drugs based on a covered entity's method of drug distribution. As shown herein, that conclusion is based on sound statutory interpretation and ample evidence; the Court should reject Novo's challenge to HRSA's violation finding and allow HRSA's enforcement of the statute to proceed.[1]

BACKGROUND

A comprehensive explanation of the 340B Program's statutory and regulatory background and the concerted actions by six drug manufacturers that led to the current litigation is set forth in HHS's brief supporting its dispositive motion. ECF No. 37-1, at 1–10 ("HHS Mot."). Included herein is information relevant to a new agency action, HRSA's 340B-violation letter, issued to Novo on May 17, 2021, and challenged in Novo's amended complaint, ECF No. 40 ("Compl.").

Four months before the AO was issued, and shortly after certain drug makers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA notified manufacturers that it was "considering whether [their new contract-pharmacy] polic[ies]" violate "section 340B and whether sanctions apply," including "civil monetary penalties [under] 42 U.S.C. § 256b(d)(1)(B)(vi)." Violation Letter Admin. Rec. ("VLTR") at 7627; *id.* 7658; ADVOP_1597.

[1] Since HHS filed its dispositive motion, the General Counsel has withdrawn the Advisory Opinion ("AO") that is challenged in this action. *See* ECF No. 52. The Court should therefore dismiss as moot Novo's claims challenging the AO.

HRSA also disavowed the manufacturers' assertion that restrictions on 340B discounts "did not give rise to an enforceable violation of the 340B statute," and warned that their new restrictions "would undermine the entire 340B Program and the Congressional intent" underpinning the statute, while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. VLTR_7627. HRSA explained that it "continues to examine" whether the manufacturers are "attempt[ing] to circumvent" their statutory obligation "by inappropriately restricting access." *Id.* And HRSA was clear that, "[e]ven for those covered entities with in-house pharmacies," manufacturers' new policies "to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions." *Id.* 7659. Unfazed, Novo and its cohort proceeded to implement their new contract-pharmacy restrictions.

HRSA's comprehensive review of Novo's policy culminated in a new agency action in the form of a 340B-violation letter issued by HRSA on May 17, 2021. VLTR_7 ("Violation Letter"). That letter informed Novo that HRSA "has determined that [Novo's] actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* It relies on statutory text to determine that the requirement that Novo honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA directs Novo to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that civil monetary penalties ("CMPs") may be imposed. *Id.* at 8. Although the letter instructs Novo to "provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on [Novo's] willingness to comply

with its obligations under section 340B(a)(1)." *Id.* HHS thus has not made any determination as to whether sanctions are warranted at all but, should Novo continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the Violation Letter does not rest upon or reference the AO (although the record demonstrates that HRSA considered the legal advice contained therein alongside other statutory interpretations, including the agency's previous guidances, VLTR_8048). The Violation Letter instead culminates the evaluative process drug manufacturers were apprised of in August 2020, months before the AO was issued.

The 8,000+-page administrative record demonstrates the thoroughness of HRSA's review and the voluminous evidence on which its conclusion is based. The record chiefly contains *thousands of pages* of complaints from covered entities. VLTR_110–6,806. This evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, but a few representative examples show the firm foundation of the Violation Letter. Strong Memorial Hospital alerted HRSA that Novo and other drug makers were refusing to offer 340B ceiling prices for covered outpatient drugs, resulting in overcharges of more than $2 million. *Id.* 6396. It documented specific transactions in which Novo denied the hospital the 340B ceiling price,[2] instead charging prices on medications of up to $1,291 per unit; these orders from Novo totaled several hundred thousand dollars in lost 340B savings. *Id.* 6417–36. These overcharges represented a fraction of "the lost opportunity and financial impact to the hospital," because the inability to purchase drugs at the ceiling price not only resulted in overcharges, but also deterred the hospital from purchasing drugs altogether. *Id.* 6396.

Several other hospitals documented specific transactions with Novo that resulted in thousands of dollars of overcharges for each covered entity. *Id.* 3140; 6250–55; 6296–303; 6339–40. Another covered entity notified HRSA that its hospitals were unable "to access 340B pricing for" a list of Novo products through "eligible 340B claims" through its contract pharmacies. *Id.* 3547–59. It explained that manufacturers were listing prices under the "'340B Price' in the Drug [Catalogs]" for its contract

[2] The 340B ceiling price is statutorily protected, 42 U.S.C. § 256b(d)(1)(B)(iii), and thus is redacted in the administrative record. But Novo cannot dispute that the ceiling price for medications referenced here are often a fraction of the wholesale acquisition cost ("WAC")—the highest commercial rate charged for medications.

pharmacies that were "consistently higher" than those "340B Prices" listed in catalogs for its in-house or inpatient pharmacy. *Id.* 3559. Two other covered entities reported that their inability to purchase certain Novo medications "at the 340B ceiling price for delivery to [their] contract pharmac[ies]" had been "impact[ing] patient care" by preventing them from accomplishing their "safety net mission" of "providing 340B pricing discounts directly to vulnerable patients in the communities where they live." *Id.* 5492, 5507. Countless other complaints against Novo echo these concerns.[3]

HRSA also relied on evidence of the importance of neighborhood pharmacies, even for covered entities that also operate an in-house pharmacy. A federally funded health center representing a sizeable, rural area and a "medically underserved population" submitted sworn testimony confirming that its in-house pharmacy can serve only 40% of its 25,000 patients. *Id.* 7255–56. That covered entity relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications … for as little as $4 to $7 a dose," or "no cost at all." *Id.* Six of its eleven health centers do not operate in-house pharmacies; those that do are open only weekdays 8AM to 5PM, making local pharmacies crucial because availability "during the traditional workday is a significant barrier for [its] patient population." *Id.* Aside from benefitting patients, the covered entity's contract pharmacies help it "generate additional revenue" through the spread between the 340B-discount price and the price paid by or on behalf of some patients (as Congress intended, *see* HHS. Mot. 2); the covered entity "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve vulnerable populations like "the homeless, migrant workers, people living in public housing, and low-income individuals and families." *Id.* Despite the critical importance of its contract-pharmacy network to both the provider and its patients, the covered entity documented that it "currently has no access

[3] *E.g.*, VLTR_384, 438, 468, 498, 520, 573, 587, 672–702 (listing numerous Novo drugs priced "above the ceiling price" for a covered entity's "contract pharmacy 340B accounts"), 975–82 (same), 1006–21 (same), 1037–67 (same), 1068–83 (same), 1090–1122 (same), 1130–37 (same), 1180–82 (same), 1153–55, 1163, 2592–94 (reporting overcharges by drug makers, including Novo, and the inability "to access 340B pricing" for several products when "plac[ing] orders to be shipped to contract pharmacy locations"), 4461 (documenting Novo "products no longer offered at the 340B ceiling price through contract pharmacies"), 4776, 4785, 5261–63, 5644, 5661, 5754.

to" certain "medications at 340B pricing to be dispensed through its contract pharmacies."[4] *Id.* 7257. Echoing these same concerns, another federally funded health center serving similar vulnerable populations explained that, without the assistance of contract-pharmacy services, many of its patients would have to travel "tremendous distance[s]" of up to 180 miles *each way* to fill prescriptions at in-house pharmacies, which would effectively prohibit "access [to] affordable medications." *Id.* 7303.

Copious sworn testimony further documents harms caused by drug makers' 340B restrictions. One safety-net provider serves a "*10,000-mile service area*" and thus relies greatly on retail pharmacies. *Id.* 7260–61. It "purchases 340B-priced drugs from the wholesaler and directs" the shipments to its pharmacy partners under contracts specifying that "[t]he health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible" patients. *Id.* It passes on 340B discounts "directly to eligible patients who meet federal poverty guidelines," and uses savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in certain rural areas (*e.g.*, addiction treatment; OB/GYN care). *Id.* 7261–62. The covered entity detailed the impossibility of serving patients through one pharmacy, along with the severe impacts on its services and budget caused by drug makers' restrictions. *Id.* 7262–63. Numerous other declarations detail similar harms to covered entities.[5]

HRSA also gathered relevant evidence by meeting with stakeholders impacted by drug makers' restrictions. For example, Avita Pharmacy explained that all of its 270 covered-entity clients (98% of whom lack their own pharmacies) were being denied 340B pricing and stand to lose millions of dollars in revenue. *Id.* 7891–92. It voiced concern that these changes "will lead to imminent harm to patients and possible site closures." *Id.* Through another pharmacy, HRSA learned that a covered entity "had

[4] This covered entity also rebuts manufacturers' portrayal of contract-pharmacy relationships as a boon for for-profit pharmacy chains, explaining that, although it pays a modest, predetermined fee to the pharmacy for its services, "[a]s required by HRSA, [it] does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount" and that a recent HRSA audit found no instances of non-compliance. VLTR_7257.

[5] *E.g.*, VLTR_7270–75, 7277–83 (all savings reinvested into patient care); 7295–98 (anticipating to lose three quarters of budget from 340B restrictions); 7300–06 (weighing services cuts because of lost revenue); 7309–14 (all savings go to patients); 7316–20; 7324–25 (restrictions placing "patients' access to care at risk" and may cause reduction or elimination of much-needed services); 7331–33; 7347–50.

14 patients denied insulin based on these practices," which had just gone into effect. *Id.* 7887. HRSA also gathered evidence from tribal leaders detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that "[p]atients are having to choose between buying food and buying medications" and "are ending up in the Emergency Room that costs a lot more money than medications cost." *Id.* 7894–97. Another tribe reported that its pharmacy bill has more than doubled, it is "not financially able to operate its own pharmacy," and it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898.

The record also contains the results of an annual survey of 340B hospitals, in which covered entities reported detailed information on how they use 340B savings to provide more-comprehensive services for medically underserved and low-income patients. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, most severely for "oncology and diabetes services." *Id.* 7957. One-third of covered-entity hospitals responding said that lost 340B savings could cause a hospital closure. *Id.* Rural hospitals are at even greater risk, since three-fourths of such "hospitals rely on 340B savings to keep the doors open" and program cuts are most likely to harm general patient care and diabetes services. *Id.* 7960–61. Importantly, respondents tied financial concerns to drug makers' contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—with most expecting to lose *more than fifteen percent* of annual 340B savings because of these restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962; *see also id.* 7957.

Novo's overcharges are also reflected in an analysis of aggregate statistics showing a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only 2.9 million in January 2021—an annualized reduction "of nearly 83" million. *Id.* 7936. Figure 1 shows that, in October 2020 when three manufacturers put in place their changes, 340B units sold nosedived from 9.4 million units to 5.1 million; WAC-priced units more than doubled that same month. *Id.* In January 2020, the number of 340B units sold plummeted to 2.9 million after Novo implemented its restrictions. *Id.* Figure 2 shows covered entities' monthly 340B savings falling from $357 million in

July 2020, before restrictions were put in place, to $92 million in January 2021—$3.2 billion in annualized lost savings. *Id.* Figure 3 shows covered entities losing an estimated $665 million from four months of restrictions, losing $234 million in January 2021 alone. *Id.* The analysis shows the impact of Novo's specific changes, which caused 340B sales to plummet *in one month* from 3.32 million units to only 1.19 million; that same month, WAC-priced units sold by Novo jumped from negligible to .41 million units. *Id.* 7937. Covered entities' monthly savings dropped from $144.6 million before Novo implemented its restrictions to about $47 million within one month. *Id.* 7939. Novo's restrictions represented an average lost savings to covered entities of $63 million monthly. *Id.* 7941.

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Novo's restrictions and its real-world impact on the 340B Program. After evaluating this evidence, alongside Novo's communications to covered entities and to the agency explaining its initiative, *e.g.*, VLTR_7756–58, HRSA concluded that Novo is violating the 340B statute and issued its May 17, 2021 letter to that effect.

ARGUMENT

I. THE COURT SHOULD ALLOW HRSA'S ENFORCEMENT OF THE 340B STATUTE TO PROCEED AGAINST NOVO.

A. HRSA correctly found that Novo is violating its statutory obligation.

HRSA's Violation Letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of [Novo's] policy that places restrictions on 340B pricing to covered entities," including "an analysis of the complaints HRSA has received from covered entities." VLTR_7. The determination that Novo's "actions have resulted in overcharges and are in direct violation of the statute," *id.*, is not only consistent with HRSA's interpretation since 1996, HHS Mot. 2-10, 16-22, but also relies directly on statutory text. VLTR_7 (citing 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Novo's adherence to the 340B statutory scheme that Novo opted into by executing a Pharmaceutical Pricing Agreement ("PPA") that requires manufacturers to ensure that "the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the statutory ceiling

price. 42 U.S.C. § 256b(a)(1). It also states that "such agreement shall require … that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As HRSA explained, that obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. HRSA also reminded Novo that compliance with its PPA requires Novo to "ensure that the 340B ceiling price is available to all covered entities." *Id.*

HRSA further explained that Novo's restrictions run afoul of its obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs" because Novo's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA cited existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). An "[i]nstance of overcharging" is also defined by regulation as "any order for a covered outpatient drug" "result[ing] in a covered entity paying more than the ceiling price" for that drug. 42 C.F.R. § 10.11(b). HRSA's analysis thus rests on the statute itself and regulations duly issued through an express grant of rulemaking authority. It does *not* rest on the now-withdrawn AO.

And HRSA plainly is correct in its statutory interpretation. In urging this Court to find that it can somehow fulfill its duty to honor "purchases by" covered entities while admitting that it now *denies* those safety-net providers' purchases based solely on the location specified for delivery, ECF No. 45-1 ("Novo Mot."), at 12, 2, Novo removes words from statutory context and asks the Court to consider them in a vacuum. The statute does not "require[] only that manufacturers 'offer' their drugs at discounted prices for 'purchase' by covered entities," *id.* 16, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access. Nor has HRSA required Novo "to transfer its discounted drugs to commercial contract pharmacies," and HRSA has not "allowed commercial pharmacies to become major participants in and beneficiaries of the 340B program," *id.* 9, 15.

Since 1992 the statute has conditioned Medicaid coverage on compliance with "an agreement with each manufacturer of covered drugs under which the amount required to be paid … to the manufacturer for covered drugs … purchased by a covered entity … does not exceed" the statutory ceiling price. Pub. L. No. 102-585, tit. VI, § 602(a), 106 Stat. 4943, 4967 (1992). And as discussed in detail, HHS Mot. 19-21, HRSA's 1996 and 2010 guidances were unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense those drugs (importantly, both guidances were issued *before* Congress amended the statute to include the language on which Novo relies). *E.g.,* ADVOP_370. Read "as a whole," *United States v. Atl. Rsch. Corp.*, 551 U.S. 128, 135 (2007), § 256b(a)(1) plainly requires manufacturers to *sell* discounted drugs *to covered entities*.

Additional historic evidence demonstrates that HRSA always has understood the statute (and, as evidenced by their past conduct, so have manufacturers) to prohibit drug makers from placing restrictive conditions on covered entities' access to 340B discounts. Nearly thirty years ago, HRSA issued "final program guidelines," after notice and comment, confirming that manufacturers *may not* place conditions, even those which purport only to "require [covered] entity compliance" with the statute, before fulfilling 340B orders. 59 Fed. Reg. 25,110-01, 25,112-14 (May 13, 1994). In 1994 HRSA demonstrated the distinction between manufacturer requirements that *facilitate* access versus those that *restrict* access, explaining that manufacturers could "require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account)." *Id.* at 25,112. But although the task of collecting "standard information" such as that needed to set up an account is permissible, HRSA made clear that manufacturers could not deny 340B purchases by covered entities unless non-statutory demands are met: "Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor can they "place limitations on the transactions … hav[ing] the effect of discouraging entities from participating in the discount program." *Id.* "A manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and drug makers are prohibited from conditioning 340B sales on covered entities "submitting information related to drug acquisition, purchase, and inventory systems." *Id.*

25,113-14. HRSA may not have conceived in 1994 of the *precise* restrictions Novo now seeks to impose by denying sales based on the delivery and commonplace dispensing mechanisms used by the covered entity, but HRSA made plain that manufacturers cannot impose their own conditions generally on whether, and when, they will fulfill orders placed by covered entities—not even "require[ments] to sign agreements assuring manufacturers of their compliance with section 340B provisions." *Id.*

The "offer" language in § 256b(a)(1) on which Novo relies, added in 2010, codified an additional requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases. *See* ADVOP_394. That amendment in no way changed the substance of Novo's preexisting obligation. Crediting Novo's assertion that the "sum total of the statute's language regarding manufacturers' obligation" is that they simply "offer each covered entity covered outpatient drugs," Novo Mot. 17, would lead to the unsupportable conclusion that, from 1992 until 2010, manufacturers sold deeply discounted drugs to covered entities on a purely voluntary basis (since the "offer" language did not exist). This is false; from the statute's enactment, drug makers wishing to receive drug coverage through certain federal health-insurance programs have been required by statute and their PPAs to ensure that drugs "purchased by a covered entity" do not exceed the ceiling price. That obligation did not arise from the 2010 amendments and has not changed substantively (aside from the *additional* non-discrimination requirement) since the statute's enactment. Novo fails to accept that its restrictions *do* violate the "offer" provision's non-discrimination requirement by treating commercial purchases far more favorably than 340B purchases, as evidenced by it placing no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases.

Novo's claim that the letter "threatens to enforce the legal obligations first addressed in the [AO]," Novo Mot. 41, fails for multiple reasons. The Violation Letter does not "enforce" the AO, but relies on the statute itself and the fact that, since 1996, "HRSA has made plain … that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." VLTR_7. HRSA could not have begun a review of whether drug makers' actions violated *the statute* in August 2020, *id.* 7627, 7658, were there no basis for such a decision before the AO issued in December. HRSA's determination that Novo is overcharging covered entities rests on its own investigation and

did not derive from the same administrative process as the AO. Moreover, the AO now has been withdrawn, yet HRSA fully intends to proceed with enforcement of *the statute* against Novo.[6]

Legislative history forecloses Novo's reading of its statutory obligation, too: In 1992 Congress considered, but *removed from the statute*, a provision that mirrored Novo's interpretation of the program's proper operation. The draft of what would become § 256b(a)(1) proposed to restrict 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity). *See* S. Rep. No. 102-259, at 1-2 (1992) (emphasis added). In other words, the bill as originally drafted would have restricted covered entities' purchases of 340B drugs to only those dispensed *directly by* the covered entity or *on-site* at the same location. Rather than codify that restriction on covered entities' choice of dispensing mechanism—precisely the constraint Novo urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed by a covered entity.[7] Congress legislates against the backdrop of real-world facts and surely knew both that (1) covered outpatient drugs can only be dispensed by licensed pharmacies, not any healthcare provider entitled to prescribe them, and (2) in 1992 when the statute was enacted, only 5% of covered entities had an in-house pharmacy, and reliance on outside pharmacies was commonplace. 61 Fed. Reg. 43,529-01, 43,550 (Aug. 23, 1996). It

[6] HRSA has never suggested that it "had no authority to force manufacturers to honor contract pharmacy arrangements." Novo Mot. 24. Novo rips from context statements of a HRSA official acknowledging that the agency is limited to enforcing requirements that derive *from the statute* because Congress has not granted HRSA explicit authority to promulgate rules having the force and effect of law in some instances. This only confirms that *guidance* is unenforceable. That does not mean HRSA now is relying on the AO or guidance, rather than the statute and manufacturer PPAs, to determine that Novo is out of compliance. The record evidences that Novo's restrictions have forced some covered entities to pay inflated prices for Novo's drugs, while others are foregoing certain 340B purchases altogether. Both results are unlawful, when caused by Novo's restrictions.

[7] HHS respectfully submits that the district court's reading of the legislative history in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-27-LPS (D. Del.), ECF No. 78 ("*Astra* Opinion") was incorrect. The court relied on the omission of the above-described provision to conclude that Congress "did not *clearly* intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* at 21 (emphasis added). The court's statement should be read in context with its conclusion that the statute does not speak *clearly* on the issue one way or the other, not that the statute was intended to prohibit HHS's interpretation. Indeed, that Congress chose not to include that language indicates that it did not *clearly* adopt Novo's preferred reading of the statute either.

defies reason to suggest that Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients—but intentionally and implicitly structured it in such a way that only 5% of the providers statutorily eligible to participate would be able to access the program in practice. That Congress specifically chose to remove any restriction on how covered entities dispense medications forecloses Novo's attempt to read those restrictions back into the statutory scheme.

Novo's repeated claim that covered entities' decades-old, commonplace reliance on outside pharmacies to dispense the drugs they purchase violates the statutory prohibition on transfer of 340B drugs, Novo Mot. 2-4, 12, 17-19, is meritless. As explained, *see* HHS Mot. 28-29, the statute states that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), which means that covered entities may not provide discounted drugs for use by non-patients or non-covered providers for prescribing to their own patients. That straightforward limitation on use of 340B drugs cannot be stretched into an implicit prohibition on eligible patients physically attaining those drugs at neighborhood pharmacies where most Americans receive prescription drugs. Pharmacies only store and handle the medications on behalf of eligible patients of eligible covered entities; the drugs are not "transferred" for the pharmacy's own use.

The proper understanding of the prohibition on transfer of 340B drugs has been clear since 1994, when HRSA issued drug-diversion guidelines explaining that "[c]overed entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity" and that "[t]here are several common situations in which this might occur." 59 Fed. Reg. 25,112-13. That guidance went on to explain that covered entities must "develop and institute adequate safeguards" to ensure that discounted drugs are dispensed only to eligible patients, that covered entities must use 340B drugs only in outpatient settings, and that a provider containing both a covered entity and non-eligible entity must "maintain separate dispensing records for the eligible entity." *Id.* Each example involves the dispensing and use of 340B-discounted drugs for either ineligible patients, services, or settings—but they certainly would not entail instances where a licensed pharmacist dispenses outpatient drugs to an eligible patient on behalf of an eligible covered entity. As HRSA has long confirmed, "the use of contract services is only providing those covered

entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility." 61 Fed. Reg. 43,550. There is thus no "transfer [of] discounted drugs to commercial pharmacies at a covered entity's request," Novo Mot. 2-3, when a covered entity purchases drugs for dispensing at outside pharmacies, because pharmacies only are facilitating the exchange of tightly controlled *prescription drugs* on behalf of admittedly eligible patients of admittedly eligible prescribers.

Novo's claim that HRSA has "allowed commercial pharmacies to become major participants in and beneficiaries of the 340B program" is false. Novo Mot. 9. As explained above and demonstrated in the record, pharmacies do not participate in the program and do not purchase 340B-discounted drugs. On the contrary, drug makers must provide discounts to covered entities, although those providers rely on neighborhood pharmacies to store, handle, and dispense drugs to patients. Not only is Novo's portrayal ungrounded in evidence, it relies on extra-record materials that this Court should not credit. Judicial review must focus on "the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Novo points to a "study" performed by Aaron Vandervelde, a self-styled "expert on the 340B program" who has filed an *amicus curiae* brief in a related case pending before this Court. *Sanofi-Aventis v. HHS*, No. 3:21-cv-634-FLW (D.N.J.), ECF No. 69-2 at 1, 14-21.[8] In addition to Mr. Vandervelde's "study," Novo relies on a press release from its industry-trade association, a document produced by a nebulous research firm, and other such materials. Novo Mot. 9-10. These extra-record materials are particularly

[8] Mr. Vandervelde acquired his "expertise" serving as a consultant for PhRMA, the predominant drug-manufacturer trade organization. Vandervelde *curriculum vitae*, *available at* https://media.thinkbrg.com/wpcontent/uploads/2020/06/27145336/Vandervelde_Aaron_CV.pdf (last visited June 21, 2021). He prepared for PhRMA a lengthy publication on "abuse" of 340B by contract pharmacies, Aaron Vandervelde, et al., *For-Profit Pharmacy Participation in the 340B Program* (October 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacy Participation340B_2020.pdf (cited at Novo Mot. 9), and has developed and sold the very software platform that some manufacturers now are using to impose contract-pharmacy restrictions. *See* Email from J. Garner to K. Talmor (May 7, 2021), attached here as Exhibit 1. Further, Mr. Vandervelde has a *financial* stake in manufacturers' ability to continue their contract-pharmacy restrictions (and a client relationship with PhRMA), rendering his views a particularly inappropriate basis for Novo's assertions.

inappropriate bases for review because each come from biased sources and are used by Novo to present a warped view of the so-called "replenishment model" on which some covered entities rely. *Id.* 10-11. Though Mr. Vandervelde attacks the replenishment model, even he admits that orders under the model are made "on behalf" of the covered entity. *Id.* at 14. Under the replenishment model drug makers still sell drugs to covered entities, not pharmacies, and thus must do so at the discounted 340B price. *See* Decl. of Krista M. Pedley ("Pedley Decl.") ¶ 10, attached here as Exhibit 2 (explaining that, under the replenishment model, "the covered entity is the legal purchaser and authorizes the order").[9]

Generally speaking, under the replenishment model, a covered-entity patient who is 340B eligible fills a prescription at a neighborhood pharmacy and, after the pharmacy dispenses the prescription out of its general inventory, its inventory is "replenished" with a drug that the covered entity has purchased at the 340B price. *Id.* ¶ 3; *e.g.*, VLTR_7323, 7257. The model works in three main steps. First, a contract pharmacy dispenses a drug to a patient, and 340B-tailored software programs determine whether the patient was eligible for 340B product. Pedley Decl. ¶¶ 5-6. The covered entity oversees operation of the software, and HRSA audits the process by taking a sample of drugs dispensed and requiring the covered entity to show "each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient." *Id.* ¶ 6. Second, the software will notify the covered entity that it may place a replenishment order for drugs when enough dispenses have accumulated to reach a pre-set package size. *Id.* ¶¶ 7-8; *e.g.*, VLTR_7317. The replenishment order is placed on a covered entity's 340B account and *the covered entity* is billed for that order. Pedley Decl. ¶ 9. If any dispute (including non-payment) about the invoice arises, it is the covered entity that is responsible—not the contract pharmacy—which merely serves as the "ship to" address on the invoice. *Id.* During this process, "the covered entity is the legal purchaser and authorized the order."[10] *Id.* ¶ 10; *e.g.* VLTR_7296 (covered entity explaining that it purchases "drugs at 340B pricing," directing shipments "to our contract

[9] While Novo's challenge to HRSA's letter should be decided on the basis of the administrative record, RADM Pedley submits her declaration in response to the Vandervelde materials and Novo's extra-record assertions in its motion, in the event the Court considers those materials. Pedley Decl. ¶ 2.

[10] Novo asserts, absent any citation or support, that "[t]he covered entity never takes title to … the 340B discounted drug." Novo Mot. 11; *accord id.* 22. While HRSA does not necessarily agree that the vesting of "title" to the drugs is the relevant inquiry, Novo is nonetheless wrong. *E.g.*, VLTR_7296.

pharmacies on a replenishment basis," and "maintains title to the drugs"); VLTR_7279 (same). The covered entity should be aware of all replenishment orders and "the order is often approved by the covered entity prior to submission to the wholesale/distributor to ensure accuracy." Pedley Decl. ¶ 10. Finally, the "replenished" drug is shipped to the contract pharmacy, where it becomes neutral inventory "and may be dispensed to any subsequent patient." *Id.* ¶ 11.

At no point during this process is the pharmacy *purchasing* 340B drugs (nor do they "drive the transactions," Novo Mot. 22; drugs simply are delivered to pharmacies after being purchased by covered entities to replenish drugs distributed to 340B-eligible patients. This model is not (as Novo asserts) "inconsistent with Congress' intent that only covered entities should participate in the 340B program," *id.*, because the manufacturer still is charging the covered entity the price of the 340B-eligible drug and those purchases are tracked and tied to dispenses to eligible patients of the covered entity. In fact, it is Novo's policy that violates the will of Congress because, when Novo refuses to honor purchase requests placed by a covered entity based solely on the "ship to" location specified on an invoice, it forces the covered entity either to pay commercial pricing or forego the needed medication altogether. 75 Fed. Reg. 57,233-01, 57234 (Sept. 20, 2010); 59 Fed. Reg. at 25,113.

Novo most glaringly distorts HRSA's interpretation by claiming that it forces "manufacturers to allow commercial pharmacies to … profit off of the 340B program," Novo Mot. 2. As Novo points out, only the statutorily enumerated covered entities are entitled to participate in the program, but the list need not "be expanded," *id.* 18, for covered entities to continue their decades-old reliance on neighborhood pharmacies. HRSA has never permitted contract pharmacies to purchase Novo's discounted drugs or act as "beneficiaries" of the program. Novo's misframing of the program's current operation and HRSA's interpretation obscures the fact that Novo is *denying* 340B sales to covered entities, forcing them to pay WAC rates, based solely on how they dispense medications to patients, even though safety-net providers relied on outside pharmacies before the 340B statute was enacted.

Novo downplays the real-world impact of its restrictions, claiming that it still "offers" 340B discounts while simply declining the "more burdensome obligation to deliver" drugs to whichever contract-pharmacy "locations the covered entities demand." *Id.* 2. Novo's assertion that delivery to a

neighborhood pharmacy is "more burdensome" than delivery to the provider is illogical; there is no basis to believe that one domestic delivery point is substantially more burdensome than another (particularly since pharmacies presumably receive many more shipments of prescription drugs and that such deliveries can take advantage of existing infrastructure and economies of scale).

More importantly, Novo's assertion ignores that refusal to deliver its 340B drugs to pharmacies capable of dispensing them renders its "offer" to sell drugs meaningless in many instances. These are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Congress did not need to expressly impose a "third-party delivery obligation on manufacturers," *id.* 17, because Congress knew that prescription drugs *cannot* be delivered to any location. Just because a healthcare facility employs doctors able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, staff pharmacists, appropriate storage to keep and safeguard medications, software to bill insurers, etc., that would allow it to take delivery of, and dispense, pharmaceuticals. As already explained, the majority of covered entities do not operate a licensed pharmacy or employ a pharmacist and thus are not entitled to handle their own dispensing or even to *take delivery* of Novo's medications. And for those that do, *see* Background, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients to fill their prescriptions each month on-site or in just one location.[11] *E.g.*, VLTR_7260-61. Were it as simple as Novo portrays for covered entities to accept its "offer" through direct, in-house dispensing, 340B sales would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra* pp. 9-10.

These practical realities demonstrate that Novo's offer to ship its drugs to each provider's physical location often is meaningless in practice. If Novo were correct that it only had to "offer" drugs to covered entities, not to also "deliver the discounted drugs" to a location where the covered entity can accept and use the drugs for its patients, Novo Mot. 1-2, then by the same logic it could refuse to deliver drugs at all and force covered entities to physically pick up prescriptions from Novo's

[11] The record, *see supra* pp. 3–7, belies Novo's assertion that "[t]here is no evidence" growth in 340B access "benefits patients." Novo Mot. 22.

warehouses. Clearly, in mandating that manufacturers provide discounted drugs to covered entities, Congress intended manufacturers to honor real-world, preexisting supply chains (including sales made through wholesale channels for delivery to pharmacies, which Novo now refuses), not to force safety-net providers to restructure their businesses to allow for in-house drug dispensing *or* to require their patients all to obtain their monthly refills at one designated location. Novo's restrictions thwart the intent of Congress by erecting barriers to covered entities' ability to access the program in practice. Nowhere does the statute grant Novo the discretion to deny any discounted-drug orders by any covered entities, regardless where the covered entity specifies that its purchase should be shipped.[12]

HRSA agrees with Novo that the statute does not allow contract pharmacies to participate in or become beneficiaries of the 340B Program, and that Novo has no obligation to sell discounted drugs to *any* pharmacies. But to "prevail in this case," HHS need not "show that the statute unambiguously imposes an affirmative obligation on manufacturers to transfer their drugs to for-profit commercial pharmacies." *Id.* 16. The statute conditions Medicaid and Medicare Part B access on Novo's agreement to sell its discounted drugs to covered entities, and does not authorize Novo to place barriers that make those purchases inaccessible in practice. HRSA's review of the evidence has demonstrated that Novo is denying sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies. Novo remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to flout its statutory obligation.

B. The *Astra* Opinion does not compel a different conclusion.

The district court's recent decision in *AstraZeneca Pharmaceuticals LP v. Becerra* does not answer the statutory question before this Court—whether HRSA correctly found that Novo is overcharging covered entities—because the Violation Letter was not even before that court. Besides, the letter is

[12] Novo cites the Uniform Commercial Code, arguing that "the price of a product" and "requirements for delivering it are separate and distinct" under contract law. Novo Mot. 20; *id.* 2. Basic contract-law principles have no bearing on this dispute or 340B sales; there is no evidence of contracts between Novo and safety-net providers, and providers enjoy a *statutory right* to buy Novo's drugs at substantial savings. Even the PPA Novo signed with the Secretary is not a bargained-for contract. *Astra*, 563 U.S. at 113. Manufacturers have long known they cannot "place limitations on the transactions" that "discourag[e] entities from participating in the discount program." 59 Fed. Reg. 25,113.

based on the best reading of the statute and HRSA's interpretation is entitled to deference. Far from deciding that the General Counsel's interpretation of the 340B statute was contrary to law, the court stated: "HHS's current interpretation of the statute is permissible." *Astra* Op. at 19. But the court found the *AO* "legally flawed" because, in the court's view, "there is more than one permissible interpretation of the 340B statute" and the AO claimed its conclusion was "mandate[d]" by "purportedly unambiguous statutory language." *Id.* at 17. Though HHS disagrees that the statute is ambiguous, the HRSA letter does not purport to rest on unambiguous language, and HHS has demonstrated its reading of the statute is best, *see supra* § I.A, even if this Court agrees with the *Astra* Opinion's finding of ambiguity. While Novo claims that HHS can only prevail "if it proves that its position reflects the only permissible reading of what the statute requires," Novo's theory is not based on the reasoning underlying the *Astra* Opinion. Novo Mot. 1. Instead, Novo's argument is based on the theory that the Violation Letter is a legislative rule subject to notice-and-comment procedures, *see id.* (citing *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92 (2015)), which as explained *infra* § I.E, is incorrect.

To the extent this Court finds ambiguity in the 340B statute, it should afford a high level of deference to HRSA's interpretation of the statute under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The Third Circuit conceptualizes the *Skidmore* framework "as a sliding-scale test in which the level of weight afforded to an interpretation" varies based on several considered factors that militate in favor of deference to HRSA's Violation Letter here. *Hagans v. Comm'n of Soc. Sec.*, 694 F.3d 287, 304 (3d. Cir. 2012). HRSA's statutory interpretation is consistent "with its prior positions," *id.* at 304, was explained in the exercise of the "agency's specialized experience overseeing the complex" 340B program, *Hayes v. Harvey*, 903 F.3d 32, 47 (3d. 2018), and is "reasonable given the language and purpose" of the statute, *Sec'y U.S. Dep't of Labor v. Am. Future Systs., Inc.*, 873 F.3d 420, 428 (3d. Cir. 2017). Because the *Astra* Opinion was limited to the narrow ground of finding that the AO erred in concluding its interpretation was compelled by unambiguous statutory text, and the court explicitly left open the possibility of the agency legally applying its statutory interpretation, *Astra* Op. 22, as it has done in the Violation Letter, the *Astra* Opinion does not undermine HRSA's determination that Novo is violating the statute.

C. HRSA's Violation Letter raises no constitutional concerns.

Novo argues that the Violation Letter is based on a constitutionally problematic reading of the 340B statute, such that the Court should apply the canon of constitutional avoidance and reject the agency's statutory interpretation. Novo Mot. 29. But because the 340B statute offers but "one plausible construction," *see Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018)—that drug makers must sell 340B-discounted drugs to covered entities irrespective of their method of distribution, *see supra* § I.A "the canon of constitutional avoidance has no role to play here," *see Warger v. Shauers*, 574 U.S. 40, 50 (2014). Were the Court to disagree, Novo's contention would still fail, because it has identified no "serious constitutional problems" with HHS's interpretation. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988). As explained in HHS's motion, Novo's takings claims are doctrinally barren and do not articulate a viable theory under the Takings Clause.

1. To begin, Novo challenges the Violation Letter as effecting a private regulatory taking. Apart from "two relatively narrow categories" of *per se* regulatory takings not applicable here, "regulatory takings challenges are governed by the standards set forth in *Penn Central Transportation Co. v. N.Y. City*, 438 U.S. 104 (1978)." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538–40 (2005). But Novo makes no mention of *Penn Central* or the factors it applied to determine whether regulatory action amounts to a taking. By ignoring this governing legal framework "for resolving regulatory takings claims," *id.*, Novo's private-regulatory-takings claim (as well as its derivative unconstitutional-conditions claim, *see Singer v. City of N.Y.* 417 F. Supp. 3d 297, 327 (S.D.N.Y. 2019) ("Absent the pleading of facts sufficient to demonstrate a 'taking,' an unconstitutional conditions doctrine claim fails.")) cannot succeed.[13]

That should resolve Novo's constitutional complaints. But even assuming that Novo addressed the *Penn Central* factors and that they weighed in its favor (they do not, *see* HHS Mot. 37 n.8), Novo cannot demonstrate a taking based on an obligation arising under the 340B Program in which it voluntarily participates. *See Ruckelshaus v. Monsanto Co.* (*Monsanto*), 467 U.S. 986, 1007 (1984); *Westinghouse Elec. Corp. v. U.S. Nuclear Regul. Comm'n*, 555 F.2d 82, 95 (3d Cir. 1977); *see also* HHS Mot.

[13] HHS moved to dismiss Novo's takings claims on the grounds that Novo cannot satisfy the factors identified in *Penn Central*. *See* HHS Mot. 37 n.8. By failing to address HHS's arguments, Novo has abandoned this claim. *See, e.g.*, *Yucis v. Sears Outlet Stores, LLC*, No. CV 18-15842, 2019 WL 2511536, at *4 n.4 (D.N.J. June 18, 2019).

31 (collecting cases from eight other federal courts of appeals). Novo apparently concedes this point by offering no response to this substantial, unified body of precedent.

Instead, the only argument Novo musters is to claim that it "never 'voluntarily' participated" in the 340B Program with the understanding that it was statutorily required to sell discounted drugs to covered entities with contract-pharmacy arrangements. But Novo cannot escape the record. Drug manufacturers participating in the 340B Program have been aware for decades that the 340B "statute directs [a] manufacturer to sell [a covered outpatient] drug at the discounted price" to "a covered entity using contract pharmacy services." 61 Fed. Reg. at 43,549; 75 Fed. Reg. at 10,278. Notwithstanding this statutory obligation, Novo chose to participate in the 340B Program, *see* Compl. ¶ 32, in exchange for the substantial economic benefits available under Medicaid and Medicare Part B. Indeed, Novo *continues* to participate (and thus *continues* to generate substantial revenue from those federal health insurance programs) even though it is free to walk away from the program at any time and to thus free itself from any regulatory burdens it finds objectionable. An obligation imposed under such a voluntary government program "can hardly be called a taking." *See Monsanto*, 467 U.S. at 1007.

2. Assuming for argument's sake the Violation Letter does effect a taking of Novo's property, such a taking would easily satisfy the Fifth Amendment's deferential "public use" requirement because it is "rationally related to a conceivable public purpose." *See Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 241 (1984); *see also Monsanto*, 467 U.S. at 1014 ("The role of the courts in" determining "what constitutes a public use is extremely narrow."). As already explained, *see* HHS Mot. 38–39, Congress created the 340B Program to help both uninsured and under-insured patients "afford costly medications" and covered entities serving those patients to "use the discounts [on drugs] to stretch scarce federal resources and serve a greater number of uninsured and under-insured patients." *See Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.*, No. 4:20-cv-8806-YGR, 2021 WL 616323, at *1 (N.D. Cal. Feb. 17, 2021). And Congress sought to achieve these public benefits by requiring drug makers, in exchange for the benefits available under Medicaid and Medicare Part B, to sell discounted drugs to covered entities, regardless of how those drugs are dispensed. That legislative determination cannot be said to be "palpably without reasonable foundation," *Carole Media LLC v. N.J. Transit Corp.*, 550

F.3d 302, 309 (3d Cir. 2008) (citation omitted), particularly in light of evidence that this statutory requirement is achieving its objectives, *e.g.*, VLTR_1571, 7257, 7262; *but see Nat'l R.R. Passenger Corp. v. Bos. & Me. Corp.*, 503 U.S. 407, 422–23 (1992) (a taking need not "accomplish its objectives" to satisfy the public-use requirement). It is thus "not for [this Court] to reappraise" Congress's decision, *Berman v. Parker*, 348 U.S. 26, 33 (1954), *even if* the Court finds that it was not the "perfect" plan or "the best possible scheme," *Keystone Bituminous Coal Ass'n v. Duncan*, 771 F.2d 707, 719 (3d Cir. 1985).

Novo offers no arguments addressing the standard (outlined above) by which public-purpose determinations are properly evaluated under the Fifth Amendment, choosing instead to craft new, alternative standards that have no doctrinal basis in the Public Use Clause.

Novo contends that the Violation Letter effects a "*purely* private taking" of the drug maker's property because selling 340B drugs to covered entities with contract-pharmacy arrangements benefits private parties—*i.e.*, contract pharmacies. Novo Mot. 31. But "the fact that a taking creates incidental benefits for individual private parties 'does not condemn that taking as having *only* a private purpose.'" *Carole Media*, 550 F.3d at 309 (emphasis added) (quoting *Midkiff*, 467 U.S. at 243–44). In fact, the Supreme Court has "foreclose[d] this objection" because "government's pursuit of a public purpose will often benefit individual private parties," and "[a]ny number of cases illustrate that the achievement of a public good often coincides with the immediate benefitting of private parties," *Kelo v. City of New London*, 545 U.S. 469, 485 & n.14 (2005); *e.g.*, *Berman*, 348 U.S. at 32–34 (affirming the public purpose of a taking that would transfer property to private parties whose private interests would directly benefit from the taking); *accord Midkiff*, 467 U.S. at 243–45; *Monsanto*, 467 U.S. at 1014–16.[14]

Novo also maintains that the Violation Letter cannot satisfy the public-use requirement because it does not "abate some public nuisance." Novo Mot. 31. But no public nuisance was abated by the alleged taking of trade secrets in *Monsanto*, 467 U.S. at 1014–16; nor by the taking of interest from IOLTA funds in *Brown v. Legal Foundation of Washington*, 538 U.S. 216, 231–33 (2003); nor by the

[14] Novo misapprehends *Kelo* and *Midkiff,* which held that the Public Use Clause forbids the government from taking property "when executed *for no reason other than* to confer private benefit on a particular private party … [or] a particular class of identifiable individuals." *Midkiff*, 467 U.S. at 245; *accord Kelo*, 545 U.S. at 477–78. No such argument can be made here.

taking of rail track in *National Railroad Passenger Corp.*, 503 U.S. at 422—and the list could continue, *see Kelo*, 545 U.S. at 486 n.16 (rejecting the "novel theory that the government may only take property and transfer it to private parties when the initial taking eliminates some 'harmful property use'"). Yet, in each case, the Court found the taking of property was justified by an underlying public purpose.

3. In challenging the Violation Letter under the unconstitutional-conditions doctrine, Novo relies on the Supreme Court's decisions in *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), *Dolan v. City of Tigard*, 512 U.S. 374 (1994), and *Koontz v. St. Johns River Water Management Dist.*, 570 U.S. 595, 612 (2013), *see* Novo Mot. 32–33, without acknowledging that the Supreme Court has doctrinally delimited the applicability of these three decisions to "the special context of exactions" in land-use permitting decisions, *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702–03 (1999); *accord Koontz*, 570 U.S. at 604. But even assuming this idiosyncratic line of cases could be generalized to apply beyond the land-use permitting context, Novo fails to mention, let alone apply, the nexus-and-rough-proportionality test the Supreme Court has distilled from *Nollan* and *Dolan* to evaluate the constitutional propriety of an exaction conditioning the provision of a land-use permit. *See Koontz*, 570 U.S. at 604–05. Novo instead suggests that *all* conditions on government benefits that affect constitutionally protected interests are *per se* invalid, a position rejected by the very authorities on which Novo relies, *see, e.g.*, *id.*, and others, *see Burgess v. Lowery*, 201 F.3d 942, 947 (7th Cir. 2000).

Novo also suggests that the Constitution forbids the government from "using financial inducements" to encourage private parties to relinquish property in exchange for a government benefit. *See* Novo Mot. 33 (quoting *Nat'l Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519 (2012)). But Novo's reliance on *NFIB* is misplaced, as that case concerned the coercion of state governments to implement a federal program, which is not at issue here. Nor can Novo square its argument with the Supreme Court's decision in *Monsanto*, which rejected an unconstitutional-conditions challenge to a condition on a valuable government benefit (*i.e.*, a license to sell a product) *for the very reason* that the plaintiff received "the economic advantages of" the license "in exchange" for relinquishing its property. 467 U.S. at 1007. Lower courts are in accord, finding regulatory conditions affecting property constitutionally permissible under the Takings Clause "[d]espite the strong financial inducement" the

government used to encourage compliance. *See, e.g.*, *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *see also* HHS Mot. 35–36 (collecting cases).

D. HRSA's Violation Letter is neither arbitrary nor capricious.

Novo has identified no sound basis in the APA to set aside the Violation Letter. *See FCC v. Prometheus Radio Proj.*, 141 S. Ct. 1150, 1158 (2021).

1. Novo argues that HHS has not adequately "explained how its position can be reconciled with its earlier pronouncements about what the statute requires." Novo Mot. 38. But as explained, *see* HHS Mot. 4-6, the agency has long understood the 340B statute to direct drug makers to sell discounted drugs to *covered entities* regardless whether they use contract pharmacies for distributing those drugs. Novo thus fails to identify a change in policy needing to be "reconcile[d]" in the Violation Letter.

2. Novo argues that HRSA failed to consider concerns about the use of contract pharmacies and growth of the 340B program. Novo Mot. 38. But HRSA was not required to consider these concerns because they were not relevant to the question before it—whether Novo's specific policy violated the 340B statute. *See NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d 182, 190 (3d Cir. 2006). Similarly irrelevant was HHS's prior decision to close the reimbursement gap for 340B hospitals. Novo Mot. 38. As explained in *American Hospital Association v. Azar*, 967 F.3d 818, 821-22 (D.C. Cir. 2020), HHS lowered the reimbursement rate for 340B hospitals to compensate for the gap created when 340B hospitals were able to obtain drugs from manufacturers at the discounted price mandated by statute, but were being reimbursed by Medicare at a higher rate, leading to a loss to Medicare. Because that decision was entirely unrelated to the existence of contract-pharmacy arrangements or manufacturers' 340B obligations, it has no bearing on HRSA's decision that Novo's policy violates the 340B statute, and failure to consider it does not render HRSA's decision unreasonable. *See NVE*, 436 F.3d at 190.

Still, HRSA *did* consider Novo's concerns about contract-pharmacy arrangements, including diversion and duplicate discounts. The Violation Letter explained that the 340B statute provides drug makers "a mechanism" to "address these concerns," whereby the drug maker "(1) conduct[s] an audit and (2) submit[s] a claim through the [ADR] process." VLTR_8. Although Novo suggests that HRSA

improperly placed "the burden on manufacturers," it is *Congress* who required manufacturers to audit covered entities before availing themselves of the ADR process. 42 U.S.C. § 256b(d)(3)(b)(iv). It cannot be arbitrary and capricious for HRSA to simply require manufacturers to follow statutorily mandated procedures to address their concerns regarding diversion and duplicate discounting.

While Novo purports to be concerned with "program integrity," the record underlying the Violation Letter tells a different story. *See* Novo Mot. 38. One covered entity, for example, has explained that it is "highly dependent" on the 340B program "to support its mission of providing care to underserved populations" and that 340B savings allow it to "open new locations to improve access for low-income patients, expand services for patients …, and increase pharmacy services for uninsured and under-insured patients." VLTR_1571. Novo dismisses these important benefits, repeating its assertion that contract-pharmacy arrangements enrich others "at the expense of patients." *Id.* 1578. And as shown above, *see supra* pp. 6–7, aggregate statistics contained in the record provide even further evidence that Novo's actions negatively impact covered entities and their patients, in contrast to congressional intent, and in contrast to Novo's grievances with the 340B program. These statistics represent thousands of transactions in which Novo's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices, which substantially impact covered entities' savings. Thus, contrary to Novo's claim that HRSA failed to "reconcile" with the "abuses" in the 340B program, HRSA relied on clear evidence of the harm to covered entities in issuing the Violation Letter.

3. Novo claims that the Violation Letter did not comply "with the requirements of HHS's 'good guidance rule.'" Compl. ¶ 140. But the Violation Letter does not constitute a "guidance document" under the rule and is exempt from the rule's requirements. 45 C.F.R. § 1.1. A "guidance document" is defined as a "statement of general applicability," and does not include communications "that interpret or apply the law to a specific set of facts," such as "pre-enforcement rulings" and "notices of noncompliance." *Id.* § 1.2(a). Because the Violation Letter interprets the law as applied to the facts of Novo's policy, it is not a statement of general applicability subject to the good guidance rule.

4. Novo alleges that the Violation Letter is unlawful because HRSA has "threate[ed] to enforce statutory requirements that are subject to pending litigation under an agreed-upon briefing schedule."

Compl. ¶ 141. In the absence of preliminary injunctive relief, which Novo did not seek, an agency need not agree to a self-imposed restriction on its enforcement efforts. For the same reason, Novo's claim that HRSA's decision is unlawful because agencies may not "threaten a litigant with [CMPs] if it does not immediately accede to the government's position and give up its legal rights" is meritless. *Id.* An agency may always exercise its enforcement authority consistent with the law.

E. HRSA's Violation Letter is exempt from notice-and-comment rulemaking.

Novo claims that HRSA's Violation Letter should be set aside because it "enforce[s]" the AO, which (Novo contends) HHS issued in violation of 5 U.S.C. § 553(b)(3)(A)' s notice-and-comment procedures. Compl. ¶ 128. Novo's procedural challenge to the Violation Letter, which is derivative of its procedural challenge to the AO, fails because the Violation Letter does not "enforce" the AO—it enforces a pre-existing obligation sounding in the 340B statute itself. *See supra* § I.A. Novo's procedural objections are thus also built on the mistaken assertion that the Violation Letter imposes a "new obligation" on the drug maker, turning the letter into a legislative rule that can only be issued by notice-and-comment rulemaking. *See* Novo Mot. 36. But as with the AO, *see* HHS Mot. 24, the Violation Letter imposes no "new burden" on Novo, *see Catawba Cty. v. EPA*, 571 F.3d 20, 34 (D.C. Cir. 2009), but simply alerts the drug maker that it is acting in contravention of "what existing law [already] requires"—that Novo sell 340B-discounted drugs to covered entities regardless of how those drugs will be dispensed to patients, *see Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994). It is thus *Congress* that has spoken "with the force of law" to "bind" Novo to this statutory requirement, not HHS. *See* Novo Mot. 35 (citations omitted). And as Novo appears to concede, Novo Mot. 3, 35–36, an agency letter merely informing a regulated entity that it has violated a statutory requirement is not subject to notice-and-comment procedures, *e.g.*, *Bimini Superfast Ops. LLC v. Winkowski*, 994 F. Supp. 2d 106, 122–25 (D.D.C. 2014); *Ass'n for Regulatory Reform v. Pierce*, 849 F.2d 649, 650, 654–55 (D.C. Cir. 1988).

CONCLUSION

Because each of Novo's claims is meritless, the Court should dismiss each count or, in the alternative, grant summary judgment for HHS.

Dated: June 22, 2021

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jody D. Lowenstein
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Attorneys for Defendants

Exhibit 1

From: Jekka Garner
To: Talmor, Kate (CIV)
Subject: Re: [EXT] RE: Consent to File Amicus
Date: Friday, May 07, 2021 12:07:47 PM

Hi Kate,

Mr. Vandervelde provided the below information:

- For clarification, we do have a client relationship with Sanofi as they license BRG's 340B ESP platform technology. I have made this clear in the amicus brief.
- With regards to Pharmaceutical Research and Manufacturers of America, BRG does policy analysis work for PhRMA but is not engaged with PhRMA related to any active litigation.

Please let me know if any further information is required. Thank you.

Best,
Jekka

Jekka Garner | Associate General Counsel

BRG
1800 M Street NW Second Floor | Washington, DC 20036
O 202.480.2700 | M 910.770.0317
JGarner@thinkbrg.com | thinkbrg.com

From: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Sent: Friday, May 7, 2021 11:26 AM
To: Jekka Garner <JGarner@thinkbrg.com>
Subject: RE: [EXT] RE: Consent to File Amicus

Hi Jekka, Thank you for the information. Your email below mentions that Mr. Vandervelde does not have a client relationship with respect to either Eli Lilly or Sanofi; can you please advise as to whether Mr. Vandervelde has a client relationship with the Pharmaceutical Research and Manufacturers of America?

Thank you,

Kate Talmor

From: Jekka Garner <JGarner@thinkbrg.com>
Sent: Wednesday, May 5, 2021 4:56 PM
To: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Subject: Re: [EXT] RE: Consent to File Amicus

Hi Kate,

Thank you for the prompt response. Mr. Vandervelde would like to file next Monday.

Best,
Jekka

Jekka Garner | Associate General Counsel

BRG
1800 M Street NW Second Floor | Washington, DC 20036
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From: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Sent: Wednesday, May 5, 2021 2:12 PM
To: Jekka Garner <JGarner@thinkbrg.com>
Subject: [EXT] RE: Consent to File Amicus

Ms. Garner,

When do you propose to file your amicus brief?

Kate

From: Jekka Garner <JGarner@thinkbrg.com>
Sent: Wednesday, May 5, 2021 2:10 PM
To: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>
Subject: Consent to File Amicus

Dear Ms. Talmor,

My name is Jekka Garner, Associate General Counsel at Berkeley Research Group (BRG), and I am writing to seek your consent to file an amicus brief in the cases set forth below. Aaron Vandervelde, a managing director at BRG and nationally recognized expert on the 340B program, has authored the

brief with the goal of providing background information to the court on how contract pharmacy operations work and the downstream operational challenges that arise through these arrangements. Mr. Vandervelde has no client relationship with respect to either litigation matter and the parties listed have consented to the filings in the respective cases.

- Eli Lilly and Company and Lilly USA, LLC, Civil Action No. 1:21-cv-81 in the Southern District of Indiana
- Sanofi-Aventis U.S. LLC, Civil Action No. 3:21-cv-634 in New Jersey District Court

Please let me know if I should reach out to a different attorney to seek this consent. Thank you for your assistance and I look forward to your response.

Best,
Jekka

Jekka Garner | Associate General Counsel

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Exhibit 2

DECLARATION OF KRISTA M. PEDLEY

I, Krista M. Pedley, declare as follows pursuant to 28 U.S.C. § 1746:

1. I currently serve as Director of the Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), United States Department of Health and Human Services (HHS). OPA is the component within HRSA with primary responsibility for the day-to-day administration of the 340B Program. I have worked at OPA since 2007 and served as Director since 2010. In my role at OPA, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies.

2. I submit this Declaration to respond to certain factual representations that I understand have been made by drug manufacturers and a consultant for the pharmaceutical industry, Aaron Vandervelde, in litigation involving the issue of contract-pharmacy use. Specifically, Mr. Vandervelde has submitted amicus briefs in various cases that describes the "replenishment model" used in some contract-pharmacy arrangements. *See* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party, *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind. May 12, 2021), Dkt. 92-1 at 13-14; *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del. Apr. 16, 2021), Dkt. 46; *Sanofi-Aventis U.S., LLC v. HHS et al.*, 21-cv-634 (D.N.J. May 13, 2021), Dkt. 71-2. The drug manufacturers, in reliance on Mr. Vandervelde's brief, have also made assertions about how contract-pharmacy arrangements work. *See* Tr. of May 27, 2021 Hrg., *AstraZeneca Pharmaceuticals LP v. Becerra et al.*, 21-cv-27 (D. Del.), 10:6-14:6; Tr. of May 27, 2021 Hrg., *Eli Lilly and Company et al. v. HHS et al.*, 21-cv-81 (S.D. Ind.), 20:9-15, 22:21-25, 67:8-14.

3. The following paragraphs describe my understanding of how, in general, contract-pharmacy arrangements work under the replenishment model. Of course, contract-pharmacy arrangements vary, and I cannot speak to the exact details of every existing relationship between a covered entity and contract pharmacy. But at its most basic level, under the replenishment model, to the extent that

an individual is determined to have been a 340B patient of the covered entity, the contract pharmacy's drug inventory is "replenished" with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed.

4. As an initial matter, for all contract-pharmacy arrangements (replenishment or otherwise), a covered entity may establish a relationship directly with a pharmacy, or it may elect to employ a third-party vendor or administrator (TPA) to facilitate data-capture and reporting in the administration of a covered entity's contract-pharmacy program. In the former situation, the covered entity sends data feeds about its patients' 340B eligibility directly to the contract pharmacy; in the latter, it sends that data to the TPA.

5. The replenishment model proceeds in three steps. First, a contract pharmacy dispenses a certain drug in a certain amount—say, 90 tablets of Amoxicillin—to a patient (the dispense). That patient may present a prescription to the pharmacy, or the dispense may result from "e-prescribing," whereby the covered entity directly transmits the prescription to the pharmacy. Either way, the dispensed drug comes from the contract pharmacy's own inventory.

6. Various 340B-tailored software programs exist to evaluate each dispense. That software compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product. The software operates under the oversight of the covered entity, in that each 340B-eligible dispense is recorded and reported to the covered entity. And HRSA audits this process: we obtain a random sample of the drugs dispensed, and the covered entity has to provide auditable records that show each dispense that was deemed 340B-eligible is actually tied to a 340B-eligible patient. Each year, HRSA audits approximately 200 covered entities, along with any of the covered entities' contract-pharmacy arrangements.

7. Second, the 340B software notifies the covered entity that it may place a replenishment order for the drug in question—90 tablets of Amoxicillin—under the covered entity's 340B account with the relevant wholesaler. The replenishment order has to be an exact 11-digit match under the National Drug Code (NDC) system for the product that was identified by the software. (The NDC for a product identifies (1) the product's labeler, *i.e.* manufacturer or distributor; (2) the identity of the product, *i.e.* strength, dosage form, and formulation of the drug; and (3) the product's package size and type.)

8. The trigger for a replacement order will not usually be a single dispense. Rather, the TPA and/or contract pharmacy will "accumulate" 340B-eligible dispenses of a specific 11-digit NDC product towards a pre-set package size. So, for example, a package may be 270 tablets of Amoxicillin, which means that it would take 3 dispenses of the 90-tablet bottles to accumulate one package and lead to submission of a replenishment order. Covered entities are provided accumulation reports where they can track each accumulation to a specific patient/dispense.

9. As noted, the replenishment order will be placed on a covered entity's 340B account with the relevant wholesaler. The 340B account is in the covered entity's name and reflects its financial payment information. That 340B account reflects a "bill to" address and "ship to" address. The covered entity is reflected as the "bill to" party; the contract pharmacy (or sometimes, its warehouse) is reflected as the "ship to" address. The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. And so, the covered entity pays for and purchases the drug at the 340B discount price from the wholesaler. If the wholesaler's invoice is not paid, it will seek to collect payment from the covered entity directly—not the contract pharmacy.

10. While it is true that the logistics of placing the replenishment order can vary—for example, sometimes the covered entity places the order, sometimes the contract pharmacy orders it as a purchasing agent of the covered entity, sometimes the order is submitted by the TPA—HRSA

understands that the covered entity is the legal purchaser and authorizes the order. If the replenishment order is sent on behalf of the covered entity, the entity should be aware of the replenishment order; indeed, the order is often approved by the covered entity prior to submission to the wholesaler/distributor to ensure accuracy.

11. Third and finally, the drug in question—90 tablets of Amoxicillin—is shipped to the contract pharmacy, where it is placed on the shelf, becomes "neutral inventory," and may be dispensed to any subsequent patient.

12. When utilizing a replenishment model, covered entities must ensure that appropriate safeguards are in place at the contract pharmacy to ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients. The covered entity must have systems in place to be able to demonstrate that the covered entity is properly accounting for 340B purchases in a replenishment system. HRSA ensures that is the case through the audits mentioned above (¶ 6).

13. OPA maintains the 340B Office of Pharmacy Affairs Information System (OPAIS), a database that assists in the functioning of the 340B Program. When registering on OPAIS, a covered entity must list its contract pharmacy(ies), and that listing must reflect a bill-to/ship-to arrangement. Thus, OPAIS clearly shows that the covered entity, as the bill-to party, is the party that purchases the 340B drugs.

Executed on June 16, 2021, in Frederick, MD.

Krista M. Pedley -S

Digitally signed by Krista M. Pedley -S
Date: 2021.06.16 12:41:17 -04'00'

Krista M. Pedley, PharmD, MS
RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health and Human Services