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

SANOFI-AVENTIS U.S., LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 3:21-CV-634

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S NEW COUNTS X-XII; REPLY IN SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT; AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitution

Statutes

Legislative Materials

Rules

Regulations

Other Authorities

As explained in HHS's pending dispositive motion, the present dispute arose in mid-2020 when Sanofi and several other large, global drug makers abruptly upended the twenty-five year operation of the 340B Program by restricting access to discounted drugs by safety-net healthcare providers that rely on neighborhood pharmacies. Specifically, the manufacturers announced that no longer will they offer (or offer without manufacturer-imposed, extra-statutory restrictions) access to discounted drugs for certain statutorily defined healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside "contract pharmacies." Sanofi's specific policy demands that healthcare providers turn over HIPAA-protected information not required by the statute to a for-profit, third-party consultant's software platform, and *denies* "purchases by" these safety-net providers should they refuse Sanofi's demands. This policy has increased Sanofi's profits while dramatically curtailing much-needed funding for safety-net providers and forcing patients to pay more for medications or adjust their medication regimen.

After a thorough, months-long review of Sanofi's newly imposed contract-pharmacy restrictions, including assessment of thousands of complaints from safety-net providers, detailed analysis of real-world changes to Sanofi's discounted-sales volumes, review of correspondence from Sanofi and other manufacturers, and meetings with numerous stakeholders, the Health Resources and Services Administration has determined that Sanofi is flouting its obligation under Section 340B by overcharging covered entities for its drugs and conditioning access to discounted drugs on onerous demands for data to which Sanofi is not entitled. As shown herein, that conclusion is based on sound statutory interpretation and voluminous evidence; this Court should reject Sanofi's challenge to HRSA's violation finding and allow HRSA's enforcement of the statute to proceed. This Court should also decline to review the HHS General Counsel's Advisory Opinion (which is not reviewable final agency action and now has been superseded by HRSA's finding) and grant summary judgment to HHS on Sanofi's challenge to the new ADR Rule.

BACKGROUND

A comprehensive explanation of the 340B Program's statutory and regulatory background, and the concerted actions by six pharmaceutical manufacturers that led to the current litigation, are

set forth in HHS's Motion to Dismiss or, in the Alternative, for Summary Judgment at 3-12 ("HHS Mot."), ECF No. 62-1. Included herein is information relevant to the new agency action, the Health Resources and Services Administration (HRSA's) May 17, 2021 violation letter issued to Sanofi and challenged in Sanofi's second amended complaint (hereinafter "Compl."), ECF No. 78.

Four months before the Advisory Opinion ("AO") challenged in this action was issued, and shortly after Sanofi and its peers began announcing their novel restrictions on covered entities' access to 340B-discounted drugs, HRSA explicitly put manufacturers on notice that the agency was "considering whether [manufacturers' new contract-pharmacy] polic[ies] constitute[] a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *See* Violation Letter Administrative Record ("VLTR")[1] at 7627, Adm. Pedley Letter to D. Asay, Aug. 26, 2020; *see also e.g.*, *id.* 7658. 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 the newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* HRSA transparently explained that it "continues to examine" whether the manufacturers' restrictions "amount to attempts 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, Sanofi and its cohort proceeded to implement their new contract-pharmacy restrictions.

[1] Due to the large file size for the record of HRSA's violation letter, Defendants were unable to file it on the docket and instead produced electronic copies to this Court's chambers, to the clerk's office, and to counsel for Sanofi. *See* ECF No. 86 (granting request to manually file administrative record). The administrative records for the Advisory Opinion and ADR Rule already have been filed on the docket. *See* ECF No. 61.

HRSA's comprehensive review of Sanofi's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. *See* VLTR_9, D. Espinosa Letter to G. Gleeson ("Violation Letter"). That letter informed Sanofi that HRSA "has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 1. It relies on statutory text to determine that the requirement that Sanofi 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 Sanofi 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.* 2. Although the letter instructs Sanofi to "provide an update on its plan to restart selling, without restriction, 340B 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 Sanofi'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 Sanofi 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 even reference—the General Counsel's December 2020 legal advice (although the administrative record demonstrates that the agency considered that advice alongside other statutory interpretations, including the agency's previous guidances, VLTR_8048). Instead, the Violation Letter culminates the evaluative process pharmaceutical 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. Alongside the statute and its legislative

history, the agency's previous notices and guidances interpreting and administering the program, and several hundred pages of correspondence from manufacturers, covered entities, lawmakers, and other stakeholders, HRSA also gathered proof of the real-world implications of Sanofi's changes and the substantial harm to covered entities its restrictions have wrought.

The record contains *over six thousand pages* of complaints from covered entities. VLTR_110-6,806. Although that multitudinous evidence of manufacturers' overcharges cannot adequately be summarized within the limitations of this brief, a few representative examples demonstrate the firm foundation of HRSA's violation letter. Beverly Hospital's complaint alerted HRSA to the fact that "manufacturer(s) [are] deliberately refusing [the] 340B Price" and explained that the restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] contract pharmacy" orders—the highest commercial rate.[2] *Id.* 1460-61. That complaint included a spreadsheet showing specific transactions where the 340B ceiling price[3] was denied and the hospital instead was subject to wholesale acquisition cost on Sanofi's medications of up to $1,516 per unit; that hospital's orders from October 2020 alone totaled $126,508 in lost 340B savings. *Id.* 1463.

Another covered entity included a screenshot from its ordering system showing that, when it tried to reorder Lantus Solostar, one of Sanofi's drugs, all formulations of that medication were marked as "Ineligible" for purchase on its 340B account. *Id.* 1589. That community health center told HRSA that it "is forced to pay WAC for these products if purchased for a contract pharmacy" to handle dispensing to patients, and included another screenshot showing the non-340B pricing to which it was subject. *Id.* 1593, 1595.

Similarly, a county health service wrote to Sanofi requesting a refund after it "identified a 340B overcharge by Sanofi" and, "[a]fter a review of all 340B purchases," determined "a total of 8 packages

[2] A different complaint from covered entities shows that the wholesale acquisition cost for one of Sanofi's medications, Dupixent, was more than $3,000 per unit—significantly higher than the 340B ceiling price. *See* VLTR_6993.

[3] 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. Sanofi cannot dispute, however, that the ceiling price for medications referenced in this discussion are only a tiny fraction of the WAC price.

were overcharged on 340B" for a total of "$3087.61 [in] overcharged products on 340B." *Id.* 3158-59. When Sanofi refused to refund the county, it documented the overcharge to HRSA. *Id.* 3157-59.

Blue Ridge Medical Center complained specifically that "Sanofi is blocking 340B prices for their drugs ordered by [the medical center] that are shipped to my contract pharmacies. *I am forced to pay WAC* [wholesale acquisition cost] for these products for my contract pharmacies." *Id.* 1603 (emphasis added). Lancaster Health Center notified the agency that Sanofi is "refusing to fulfill orders (for any of their manufactured products) placed by [the] covered entity and shipped to my contract pharmacies at 340B prices. *I am forced to pay WAC* for these products." *Id.* 3303 (emphasis added). Lancaster specified three separate drug formulations it had tried to order at 340B prices, but found that Sanofi was "refusing to ship my orders to my contract pharmacies." *Id.* 3302-03. The Chief Executive Officer of Windrose Health Network reported to HRSA in March 2021 that "Sanofi is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. *I am forced to pay WAC* for these products." *Id.* 6650 (emphasis added). That covered entity also included the drug formulations for which Sanofi had overcharged it by charging full price. *Id.* 6649. Countless complaints echo these concerns. *E.g.*, *id.* 139-40; 150-51; 282-83; 301-02; 321; 405-11 (attaching lengthy list of Sanofi drugs hospital was blocked from purchasing at 340B rate); 443-49 (same); 473-79 (same); 848-54 (same); 1525-26; 1669-70 (confirming covered entity "forced to pay WAC" for Sanofi's products to have drugs shipped to contract pharmacies); 1674-75 (same); 3243 (same); 3263.

HRSA also relied on evidence regarding the importance of outside, neighborhood pharmacies, even for covered entities that may also operate an in-house pharmacy. For instance, one federally funded health center in Georgia, which represents 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. VLTR_7255-56. That health center relies on 340B savings through its contract-pharmacy network to "provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all." *Id.* The covered entity also explained that six of its eleven health centers do not operate an in-house pharmacy, and those that do are only open

weekdays 8AM to 5PM, so neighborhood pharmacies are crucial because "available time during the traditional workday is a significant barrier for our patient population." *Id.* Aside from the benefit to patients, the covered entity explains that its contract pharmacies enable it to "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,[4] and that it "reinvest[s] all 340B savings and revenue in services that expand access" for patients and serve "vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families."[5] *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 to … Sanofi medications at 340B pricing to be dispensed through its contract pharmacies." *Id.* 7257.

Copious sworn testimony further documents the harms caused by drug makers' unlawful 340B restrictions. A safety-net provider in Michigan evidenced its reliance on the 340B program; it serves a "*10,000-mile service area*" and thus relies extensively on retail pharmacies. VLTR_7260-61. Through its contractual arrangements, it "purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped 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," while using savings earned from other dispenses to pay for "essential health care services to its underserved rural community," including those not readily available in the

[4] As explained in HHS's opening brief (3), Congress designed the program to allow covered entities to generate revenue "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (conf. report). Much of this revenue is generated through payments by private insurance. Uninsured patients often receive medications for free but also may be charged a small amount on a sliding-income scale, relative to their financial ability. As explained herein, this enables covered entities to reinvest in patient care and services.

[5] This covered entity also thoroughly rebutted 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, "as 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 it recently "underwent a 340B HRSA Audit where there were no [non-compliance] findings." VLTR_7257.

rural Upper Peninsula, such as addiction treatment and OB/GYN care. *Id.* 7261-62. The covered entity detailed the impossibility of serving patients through just one pharmacy, along with the severe impacts on its services and budget that Sanofi and its peers' restrictions have caused. *Id.* 7262-63. The administrative record contains numerous similar declarations detailing harms to covered entities. *E.g.*, *id.* 7270-75; 7277-83 (federally funded health center explaining that it does not operate an in-house pharmacy and instead pays for drugs to be shipped to a contract pharmacy where provider "maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services"; savings generated are "100%" reinvested into patient care, including addiction treatment); 7295-98 (safety-net provider with high-poverty population expects to lose $6 million from its $8 million budget due to 340B restrictions, and is preparing to lay off 35 employees as a result); 7300-06 (federally funded provider in Arizona documenting that patients would have to travel up to 180 miles *each way* to fill prescriptions at in-house pharmacies and that, as a result of lost revenue, entity is weighing services cuts); 7309-14 (confirming that "[u]ninsured patients get 100% of the savings at our partner (contract) pharmacies" and that, for other patients, "[a]ny net revenue we derive from the 340B Program also goes directly to our patients"; further documenting significant harm to patients, *id.* 7312); 7316-20; 7324-25 (explaining that covered entity "decided not to enroll" in Sanofi's data-sharing platform because of its "burdensome reporting" requirements and that manufacturers' restrictions are "put[ting] our patients' access to care at risk" and may cause reduction or elimination of much-needed services); 7331-33; 7347-50.

The record also evidences Sanofi's denial of 340B pricing even where a covered entity *was* relying on an in-house pharmacy—in direct contravention of the supposed "exceptions" to its contract-pharmacy restrictions. Cassopolis Family Clinic Network, a federally funded provider in Michigan, filed a complaint with HRSA after finding it was "unable to purchase Sanofi Aventis products at the 340B ceiling price" for its "2 clinics *with outpatient pharmacies*." VLTR_3288 (emphasis added). That clinic reported that it instead was charged $410.42 for one of Sanofi's drugs—far above the applicable 340B price. *Id.* 3291. Although it is unclear whether Sanofi's denial of 340B pricing for

an on-site pharmacy was inadvertent, it further underscores the havoc wrought by Sanofi's abrupt, marketplace-shifting restrictions.

During its evaluation HRSA also gathered relevant evidence through meetings with stakeholders impacted by Sanofi and its cohort's restrictions. For example, HRSA officials met with representatives of Avita Pharmacy, a national chain that almost exclusively contracts with and dispenses for covered entities, including community health centers and AIDS clinics. VLTR_7891-92. Avita relayed that, of its 270 covered-entity clients—98% of whom do not operate their own pharmacies—all were being denied 340B pricing and stand to lose millions of dollars in lost revenue. *Id.* Avita expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.* The very next day, HRSA officials learned in another meeting that one pharmacy in West Virginia that dispenses on behalf of a covered entity "has already had 14 patients denied insulin based on these practices," which had only just gone into effect. *Id.* 7887. In another listening session that same month, HRSA gathered evidence from tribal leaders in multiple states detailing the harms befalling income-disadvantaged tribal members and underfunded rural health clinics as a result of manufacturers' restrictions, including that, for one tribe in California, "[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, that it is "not financially feasible for the tribe to operate its own pharmacy" and that it had been forced to pay more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." *Id.* 7894, 7898. Yet another tribal leader implored HRSA "to take immediate action," pointing out that drug makers are "experiencing record-breaking profit" so it was "unacceptable for them to gauge [sic] small entities." *Id.*

The administrative record also contains the result of an annual survey of 340B hospitals completed by 340B Health, a nonprofit trade organization for certain covered entities. VLTR_7957-63. In the survey virtually all covered entities reported "feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies" while reporting

that "cuts are likely" should these actions continue. *Id.* 7957. Respondents provided detailed information on how they use 340B savings to provide more-comprehensive serves for medically underserved and low-income patients, such as addiction treatment, oncology treatment, medication management, and outpatient behavioral health for children. *Id.* 7958. Continued funding cuts caused by lost 340B savings were shown to "threaten a range of services for" hospitals, with the "most impact [to] oncology and diabetes services." *Id.* 7959. Fully 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 fully 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. Of particular note, survey respondents expressly tied financial concerns to six manufacturers' (including Sanofi's) contract-pharmacy restrictions, which are impacting the resources of 97% of 340B hospitals—most of which expect to lose *more than fifteen percent* of their annual 340B savings as a result of contract-pharmacy restrictions—and "[n]early all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread." *Id.* 7962.

Sanofi's overcharges are also reflected in aggregate statistics compiled at HRSA's request in an "attempt[] to quantify the loss of units sold and savings." VLTR_7936-47. That analysis showed a decrease in 340B units sold *monthly* from 10.5 million prior to manufacturers' restrictions down to only 2.9 million in January 2021. *Id.* 7936. "Annualized this equates to a reduction in 340B units sold of nearly 83 [million]." *Id.* The statistics include graphs showing the stark, immediate impacts of Sanofi and its peers' refusal to honor 340B pricing. Figure one shows that, in October 2020 when Sanofi and two other manufacturers put in place their changes, 340B units sold took a nosedive from 9.4 million units to 5.1 million in just one month; WAC-priced units more than doubled at the same time.[6] *Id.* Figure two shows that covered entities' monthly 340B savings fell from $357 million in July 2020, just

[6] As the analysis explains, VLTR_7936, WAC-priced units do not fully reflect the loss of 340B-priced sales and thus underrepresent the impact of manufacturers' changes. This is because some sales will be lost entirely and because covered entities' third-party administrators will shift 340B-priced sales to other purchasing accounts rather than pay the highly marked-up WAC price. For this reason, lost 340B sales is a better indicator of impact than increased WAC sales.

before restrictions were put in place, to $92 million in January 2021—representing annualized lost savings of $3.2 billion. *Id.* Figure three shows that, in January 2021, covered entities lost an estimated $234 million in that month *alone* and had lost an estimated $665 million in roughly four months of restrictions. *Id.* That analysis also shows the impact of Sanofi's specific changes, separated from other manufacturers; what it terms its "integrity initiative" caused 340B sales to plummet *in one month* from 2.04 million units to only .28 million units—that same month, WAC-priced units sold by Sanofi skyrocketed from negligible to .37 million units. *Id.* 7937. Stated plainly, in a one-month period the graph shows millions of units of Sanofi's drugs sold at above-ceiling prices to covered entities. The analysis also quantifies the fiscal impact of Sanofi's changes. Monthly savings to covered entities dropped from $54.2 million just before its "integrity initiative" to only about $5 million within two months. *Id.* 7939. By January 2021, Sanofi's restrictions represented an average lost savings to covered entities of $43.4 million monthly. *Id.* 7941.

HRSA also gathered evidence that Sanofi's data-collection demands are infeasible for covered entities (in addition to being unauthorized by statute). For example, covered entities report that the so-called "integrity initiative" could increase the risk of unauthorized access to patients' health information and thereby expose covered entities to significant liability under various federal and state privacy laws, including HIPAA. VTLR_1545-46. The initiative may also contravene the terms of the covered entities' contract-pharmacy agreements. *Id.* 1547. Putting those legal concerns aside, Sanofi's initiative imposes undue administrative burden on covered entities: Sanofi demands bi-weekly submission of data, which in some instances may require the submitter to organize or reformat the data they otherwise collect to prepare such a submission. *Id.* 1548. And even without undue burden, Sanofi is attempting to co-opt covered entities' resources to support data collection that could be used by private insurance to facilitate the reduction of reimbursement on claims involving 340B drugs, against the interests of covered entities and their patients. *Id.* 1544-45.[7] *See also id.* 7324-25 (informing

[7] In this litigation, undersigned counsel also have learned that the software platform used by Sanofi to collect covered entities' data was designed and is administered by a third-party consultant who has been employed by a pharmaceutical-industry trade group to undermine the 340B program—and who

HRSA of covered entity's decision not to enroll in Sanofi's data-collection system due, in part, to burden of producing data).

As even this truncated overview demonstrates, HRSA spent many months gathering a legion of evidence with which to analyze the legality of Sanofi's "integrity initiative" and its real-world impact on the 340B Program. After evaluating this evidence, alongside Sanofi's communications to covered entities and to the agency explaining its initiative, *e.g.*, VLTR_7617, HRSA concluded that Sanofi is violating the 340B statute and issued its May 17, 2021 letter to that effect.

ARGUMENT

HRSA's 340B-violation letter is a new agency action that must be challenged and considered independently from previous agency decisions. Although Sanofi amended its complaint to challenge the violation letter after this Court ordered it to do so, ECF No. 83, it continues inaccurately to allege that the violation letter "enforced against Sanofi the Advisory Opinion's new rule." Compl. ¶ 173. Not so: HRSA's Violation Letter is the culmination of a separate process begun *months* before the AO was issued and based directly on the statute itself—not the General Counsel's legal advice—along with copious evidence gathered through HRSA's investigative process. It also embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Sanofi is overcharging covered entities and may face sanctions or expulsion from government-insurance programs. More importantly, whereas the AO opined generally and consistently with previous agency guidances on what the 340B statute requires, without purporting to analyze the legality of Sanofi's "integrity initiative," HRSA's violation letter concludes directly and for the first time that Sanofi's specific policy violates the statute. The actual dispute between the parties—whether that conclusion is correct—is squarely presented in the 340B violation letter, demonstrating

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also has submitted a purported *amicus curiae* brief to this Court. *See infra* § I.B.1. This further raises concerns about covered entities being forced to divulge patient and prescribing information to a third party.

why the ultimate dispute must (notwithstanding Sanofi's inapposite framing) be decided on the basis of HRSA's reasoning in the violation letter and the administrative record supporting it. [8]

This distinction is elucidated by the fact that, *even if* this Court were to agree with Sanofi that the AO is reviewable *and* that it should be set aside, that would not resolve the merits of HRSA's determination that Sanofi is overcharging covered entities. Indeed, Sanofi continues to seek declaratory relief that so fundamentally misportrays the agency's interpretation that granting it would have no bearing on HRSA's ongoing enforcement. Sanofi asks this Court to declare that the statute "does not require drug manufacturers to provide discounted covered outpatient drugs *to contract pharmacies*" and "does not prohibit drug manufacturers from imposing conditions on the provision of discounted covered outpatient drugs *to contract pharmacies*." Compl., Prayer for Relief ¶¶ 4-5 (emphasis added). As explained in HHS's opening brief, neither the General Counsel nor HRSA have *ever* interpreted the statute to allow contract pharmacies to purchase 340B-discounted drugs, receive 340B discounts, or otherwise participate in the program (as opposed to covered entities), so Sanofi's requested declaration is meaningless. *See* HHS Mot. 14-15 (explaining that Sanofi relies on artful drafting to misframe the General Counsel's conclusion). Neither HHS nor HRSA require Sanofi to sell any drugs to any pharmacies at any price.

But in its violation letter HRSA made the specific determination that Sanofi's policy violates the 340B statute, 42 U.S.C. § 256b(a)(1), and may warrant sanctions, including expulsion from Medicaid and Medicare Part B, because Sanofi is overcharging and refusing statutorily mandated discounts *to covered entities* using outside-dispensing channels. As demonstrated below, that conclusion is based on voluminous evidence and a correct interpretation of the statute (and would remain in place, unaffected, should the AO be set aside). This Court should grant summary judgment in favor

[8] In its order denying Sanofi's request for an emergency stay, this Court wrote that, "[a]ccording to Defendants, the Advisory Opinion prohibits Plaintiff's integrity initiative." *See* ECF No. 83 ¶ 3. HHS respectfully wishes to clarify that the AO neither addressed nor specifically prohibited Sanofi's new policy; instead it contained a general interpretation of *the 340B statute's* requirements. As explained in HHS's opening brief, 16-19, the AO does not itself impose any obligation on manufacturers and thus does not even constitute reviewable final agency action. It also is time-barred because it repeated a decades-old interpretation.

of the agency on Sanofi's challenge to the violation letter and allow HRSA's enforcement action to proceed. The Court should also dismiss or grant summary judgment for HHS on Sanofi's numerous (but meritless) challenges to the ADR Rule and Advisory Opinion.

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

A. HRSA Correctly Found That Sanofi Is Violating Its Statutory Obligation

HRSA's 340B violation letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of Sanofi's policy," including "an analysis of the complaints HRSA has received from covered entities." Violation Letter 1. The determination "that Sanofi'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, *see* HHS Mot. 3-6, 19-23, but also relies directly on statutory text. *See* Violation Letter 1 (citing "Section 340B(a)(1) of the Public Health Service (PHS) Act," 42 U.S.C. § 256b(a)(1)). The statute conditions Medicaid and Medicare Part B access on Sanofi's adherence to the 340B statutory scheme that Sanofi 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 specifies that "[e]ach 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 straightforward 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 Sanofi that compliance with its PPA requires Sanofi to "ensure that the 340B ceiling price is available to all covered entities." *Id.*

HRSA further explained that Sanofi'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 Sanofi'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)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." *Id.* (citing 42 C.F.R. § 10.11(b)(2)). In short, HRSA's analysis rests on the statute itself and duly promulgated regulations issued through an express grant of rulemaking authority.

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 millions of dollars in purchases every month unless certain conditions are met, Compl. ¶ 177, Sanofi rips particular words from context and asks the Court to consider them in a vacuum. The statute does not, as Sanofi insists, "only require[] [] manufacturers" to "offer discounted drugs to covered entities," Sanofi Mot. 29, ECF No. 68-1, regardless whether the terms of its "offer" pose practical barriers restricting covered entities' access.

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, *infra* § III.B, HRSA's early guidances issued in 1994 and 1996 were unequivocal that the statute requires manufacturers to honor purchases by covered entities regardless how they dispense those drugs (as did the 2010 guidance, which also was issued *before* Congress amended the statute to include the language on which Sanofi relies). *E.g.,* ADVOP_370 (interpreting statute to *prohibit* manufacturers from denying purchases where the covered entity "directs the drug shipment to its contract pharmacy"). Read "as a whole," *United States v. Atlantic Research Corporation*, 551 U.S. 128, 135 (2007), as this Court must, 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to sell discounted drugs to covered entities.

The "offer" language on which Sanofi relies, added in 2010, codified an additional requirement that manufacturers cannot discriminate by prioritizing full-priced purchases over 340B purchases. *See* ADVOP_394, Clarification of Non-Discrimination Policy, May 23, 2012. That amendment in no way changed the substance of Sanofi's preexisting obligation. Crediting Sanofi's assertion that the statute's requirement that drugs "purchased by a covered entity" not exceed the ceiling price "*imposes no obligation on manufacturers*," Sanofi Mot. 30 (emphasis added), would lead to the bizarre and unsupportable conclusion that, from 1992 until 2010, manufacturers sold deeply discounted drugs to covered entities on a purely voluntary basis. That assertion is false and illogical; from the statute's enactment, pharmaceutical companies wishing to receive drug coverage through certain government health-insurance programs have been required by both the 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.

Sanofi's claim that "HRSA enforced against Sanofi the Advisory Opinion's new rule that drug manufacturers must provide 340B-priced drugs to contract pharmacies" and thus "is contrary to law and in excess of statutory authority," Compl. ¶¶ 165, 167, fails for multiple reasons. The violation letter does not "enforce[]" the AO. Instead, the letter relies on the statute itself and the fact that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." Violation Letter 1. HRSA could not have begun a review of whether various manufacturers' actions violated *the statute* back in August 2020, VLTR_7627, 7658, were there no basis for such a determination before the General Counsel opined in December. HRSA's determination that Sanofi is overcharging covered entities rests on its own investigation and did not even derive from the same administrative process as the AO.

Sanofi again distorts the agency's interpretation as requiring it to allow for-profit pharmacies "to acquire 340B-priced drugs." Compl. ¶ 10; *see also* Sanofi Mot. 19 (claiming that HHS interprets statute to "legally obligate[] drug manufacturers to provide 340B-priced drugs to contract

pharmacies"). Once again, the violation letter does not require Sanofi to provide discounts to *any* pharmacies whatsoever—only to resume selling 340B-priced drugs to eligible covered entities, regardless how they dispense medications to needy patients.

Legislative history forecloses Sanofi's reading, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Sanofi's interpretation. *See* S. Rep. No. 102-259, at 1-2 (1992) (proposing 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) (emphasis added). Rather than codify that plain requirement that a covered entity *itself* dispense the drugs, either in-house or on-site—indeed, precisely the constraint Sanofi 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. 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. 43,550. It 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. The fact that Congress specifically chose to remove any restriction on how covered entities dispense medications forecloses Sanofi's attempt to read those restrictions back into the statutory scheme.

Sanofi's attempt to sanitize its restrictions by downplaying their real-world impact is unavailing. Sanofi claims that, under its "integrity initiative, covered entities have no obligation to provide the requested claims data" because, if they decline, "Sanofi continues to offer its drugs at 340B prices *for shipment to the covered entity's own facilities*; the entity simply may not order discounted drugs *for shipment to contract pharmacies*." Compl. ¶ 48 (emphasis added). This assertion ignores the fact that these are prescription drugs, some of which are controlled substances—not everyday commodities that can be shipped to any address. Just because a healthcare facility employs doctors

able to prescribe medications does not mean it has the infrastructure, including state licensing, DEA registration, employees legally able to dispense drugs, appropriate storage space to keep and safeguard medications, software to bill insurers, etc., that would allow them to take delivery of, and dispense, pharmaceuticals. As has been explained in this litigation, 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 Sanofi's medications. And even for those that do, as explained *supra*, Background, covered entities often serve vulnerable populations over huge geographic areas with transportation and timing difficulties, making it impossible for all patients (tens of thousands per provider, in some cases) to fill their prescriptions each month on-site. Were it as simple as Sanofi portrays for covered entities to access the program through direct, in-house dispensing, sales of discounted medications would not have taken the nosedive evidenced in the analysis prepared for HRSA. *See supra* 9-10. While these practical realities demonstrate that Sanofi's offer to ship its drugs to each provider's physical location often is meaningless in practice, the critical point is that nowhere does the statute authorize Sanofi to make 340B-discounted drug sales contingent on a provider operating a pharmacy and accepting drugs on-site. Nor does the statute permit Sanofi to deny any discounted-drug orders by any covered entities, regardless whether the covered entity specifies that its purchase should be shipped to an outside dispenser (and certainly not based on a refusal to turn over voluminous patient and prescribing data to which Sanofi has *no* statutory entitlement).

Sanofi's interpretation is equally incompatible with the Supreme Court's depiction of the pharmaceutical pricing agreements manufacturers sign as "uniform agreements that recite the responsibilities § 340B imposes," including "impos[ing] ceilings on prices drug manufacturers *may charge for medications sold to specified health-care facilities*." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (emphasis added); *id.* at 115 ("manufacturers agree to charge covered entities no more than predetermined ceiling prices"). The Court's straightforward pronouncements mirror the agency's interpretation and foreclose Sanofi's policy—under which, as Sanofi admits, a covered entity is denied 340B discounts (and must pay full price) when the covered entity directs discounted drugs be *shipped to* outside dispensers.

Nor has HRSA ever suggested that it lacked authority to enforce the 340B statute's requirements against manufacturers, *contra* Sanofi Mot. 46. Sanofi rips from context statements in which an individual HRSA official acknowledged that the agency is limited to enforcing requirements that derive *from the statute* because Congress has not granted the agency explicit authority to promulgate rules having the force and effect of law in some instances. HRSA's statements only confirm (accurately) that *guidance* is unenforceable. But that does not mean HRSA now is relying on the AO or guidance, rather than the statute and manufacturer PPAs (which are enforceable), to determine that Sanofi's is out of compliance.

In its complaint and motion Sanofi insists, without evidentiary support, that under its policy "when [Sanofi] declines to provide a 340B discount (and instead charges standard commercial prices) for drugs shipped to a contract pharmacy, a covered entity is not 'overcharged'—indeed, it typically is not charged at all." Compl. ¶ 177. This wishful thinking is flatly belied by the administrative record. As detailed *supra* 3-10, it is covered entities that place and *are charged for* orders of Sanofi's drugs that are shipped to, and dispensed by, neighborhood pharmacies. Whether or not some covered entities are foregoing certain 340B purchases altogether (a result that also is unlawful, when caused by Sanofi's refusal of discounts), Sanofi is simply incorrect that its restrictions result in only pharmacies paying commercial pricing; the administrative record is replete with examples of covered entities being subject to commercial rates due to Sanofi's denial of 340B pricing.

Sanofi ignores additional historic evidence to maintain that HHS has had "a longstanding position that manufacturers *are* permitted to impose certain conditions, such as reasonable data-collection requests," on their provision of discounted drugs. Sanofi Mot. 45 (citing 59 Fed. Reg. 25,112, 25,114). Precisely the opposite is true. Nearly thirty years ago—and not long after the statute's enactment—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 (1994). In arguing otherwise, Sanofi points to a single response confirming that a manufacturer may "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 and account) if this is a usual business practice of the manufacturers." *Id.* But permitting a manufacturer to perform the ministerial task of collecting "standard information" such as that needed "to set up … an account" is a far cry from blessing policies by which manufacturers, like Sanofi, *deny purchases by covered entities* unless non-statutory data demands are met. Indeed, the 1994 guidance prohibits such moves: "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 (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* 25,113. Indeed, "[a] manufacturer may not [even] condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," and—most pertinent here—drug companies 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 yet have conceived in 1994 of the *precise* data demands Sanofi now seeks to impose through its so-called "integrity initiative," but the agency 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.* There is no support for Sanofi's position that HHS previously has approved of manufacturer-imposed conditions.[9]

Moreover, Sanofi's assertion that, even if the statute permits covered entities to use multiple contract pharmacies (it does), that Sanofi's data-collection demands "are designed to aid compliance with the statute's other provisions and are reasonable," Compl. ¶ 11, is unavailing. As discussed above, nothing in the statute allows a manufacturer to place conditions on its fulfillment of its statutory obligation, HRSA long ago interpreted the statute to forbid it, and Sanofi's policy has the effect of *denying* sales to covered entities, so it matters not whether Sanofi thinks its conditions are "reasonable."

[9] Sanofi's focus on "conditions" on sales is a distraction; HRSA now has found that Sanofi's contract-pharmacy restrictions are *overcharging* covered entities by denying discounted purchases and forcing safety-net providers to pay commercial rates.

But even were that the proper inquiry, Sanofi's demands are not as reasonable as it portrays. The federal government long has made efforts to *reduce* the burden on participants in federal programs, including from data-collection demands, and Sanofi's restrictions would contravene that attempt by requiring covered entities to collect data, in cooperation with their contract pharmacy, reformat it, and submit it on a biweekly basis to an as-yet untested system (with unknown privacy protections). This burden to provide claims-level data would fall on the safety-net community that provides care for the most vulnerable patient populations on already-thin margins. And the provision of information to *commercial* payors, to which Sanofi repeatedly analogizes, arises from contracts between covered entities and those payors to facilitate reimbursement—unlike Sanofi's program, which requires additional effort and time by the provider's staff. Plus, since other drug manufacturers do not require covered entities to expend the labor to format and submit detailed prescribing data every other week in order to realize their right to discounted medications, allowing Sanofi to do so would disincentivize providers from relying on Sanofi's drugs, thus improperly shifting discounted sales from its drugs to those of other companies. Regardless, Sanofi cannot prevail on its challenge by portraying its restrictions as reasonable because, as evidenced throughout the administrative record, Sanofi *is overcharging* them by forcing providers to pay WAC prices unless they accede to Sanofi's demands.

HRSA agrees with Sanofi that the statute does not allow contract pharmacies to participate in the 340B Program, and that Sanofi has no obligation to sell discounted drugs to pharmacies. But HRSA's review of the evidence has demonstrated that Sanofi is denying sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies (forcing those providers to either forego needed medications for their patients or pay commercial prices). Sanofi also is making extra-statutory demands that covered entities disgorge data to which Sanofi has no entitlement, that burdens covered entities, and that could place covered entities at risk of significant liability under privacy laws should a data breach occur. Sanofi remains vulnerable to monetary sanctions and expulsion from Medicaid and Medicare Part B for each day it continues to flout its statutory obligation.

B. HRSA'S VIOLATION LETTER IS A REASONABLE INTERPRETATION OF THE 340B STATUTE, AND IS BOTH SUBSTANTIVELY AND PROCEDURALLY COMPLIANT WITH THE APA.

1. HRSA's determination that Sanofi is flouting its statutory obligation is neither arbitrary nor capricious.

HRSA reasonably explained its conclusion that Sanofi is violating its statutory obligation in the Violation Letter, and properly grounded its determination in the text of Section 340B. Agency action is not arbitrary and capricious under § 706(2)(A) of the APA if the agency "has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Judicial review is "deferential, and a court may not substitute its own policy judgment for that of the agency." *Id.* (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U. S. 29, 43 (1983)). And a court "should 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). Here, Sanofi makes a number of attempts to pick apart HRSA's reasoning—none of which are persuasive—and the Court should reject Sanofi's effort to undermine HRSA's enforcement of the 340B statute.

Running throughout all of Sanofi's allegations is the mischaracterization that HRSA is requiring drug manufacturers to "provide 340B-priced drugs to contract pharmacies." Compl. ¶ 173, *see also e.g., id.* ¶ 175 (alleging that HRSA determined that "contract pharmacies" are "entitled to 340B-priced drugs"). In reality, drug manufactures must provide discounted drugs to covered entities, though covered entities are permitted to use contract pharmacies to distribute drugs to their patients. While unsupported by the allegations of Sanofi's complaint, Sanofi's theory appears to rely on assertions made in the *amicus curiae* brief of Aaron Vandervelde, a self-styled "nationally recognized expert on the 340B program." ECF No. 69-2 at 1, 14-21.[10] Though Mr. Vandervelde attacks the

[10] Mr. Vandervelde acquired his purported "expertise" by serving as an industry consultant for PhRMA, the same trade organization to which Sanofi belongs (and which brought the 1996 litigation acknowledging HHS's longstanding interpretation of Section 340B, explained *infra* Sec. III.B.). Vandervelde *curriculum vitae*, *available at* https://media.thinkbrg.com/wpcontent/uploads/2020/06/27145336/Vandervelde_Aaron_CV.pdf (last visited June 15, 2021). Mr. Vandervelde 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-ForProfitPharmacyParticipation340B_2020.pdf, and has even developed and sold the very software platform Sanofi is using to impose contract-pharmacy

predominant replenishment model, even he admits that orders under the replenishment model are made "on behalf" of the covered entity. *Id.* at 14. The fact is that, even under the replenishment model, manufacturers are still selling drugs to covered entities, 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").[11]

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; *see also e.g.*, VLTR_7323 (declaration of covered entity CEO explaining that "contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used"); VLTR_7257 (same). 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 software is operated under the oversight of the covered entity, 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; *see also e.g.*, VLTR_7317 (covered entity CEO explaining "virtual inventory" system where "each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed … [the covered entity] places an order via our 340B wholesaler to replenish the contract

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restrictions. *See* Email from J. Garner to K. Talmor (May 7, 2021 12:07:47 PM), attached here as Exhibit 1. Aside from constituting impermissible extra-record evidence, Mr. Vandervelde has a *financial* stake in Sanofi's ability to continue its data-collection demands (and a client relationship with PhRMA), thus rendering his views a particularly inappropriate basis for Sanofi's claims.

[11] While Sanofi's arbitrary-and-capricious claim should be decided on the basis of the administrative record, RADM Pedley submits her declaration in response to the Vandervelde amicus brief, to the extent Sanofi relies on any extra-record facts therein. Pedley Decl. ¶ 2.

pharmacies' stock"). Importantly, 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 instances of 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." *Id.* ¶ 10; *see also, e.g.* VLTR_7296 (declaration of covered entity CEO explaining that it purchases "drugs at 340B pricing … and direct[s] those drugs to be shipped to our contract pharmacies on a replenishment basis," during which time the covered entity "maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies"); VLTR_7279 (same). Indeed, 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." ¶ 11.

At no point during this process are the 340B drugs "purchased by" the contract pharmacy. The drugs are simply delivered to contract pharmacies after being purchased by covered entities to replenish the pharmacy's stock of drugs that were distributed to 340B-eligible patients. Thus, contrary to Sanofi's allegation, the replenishment model does not foreclose HRSA's determination that Sanofi's policy resulted in overcharges to covered entities. *See* Compl. ¶ 177. As explained above, the manufacturer or wholesaler is still *charging the covered entity* for the price of the 340B-eligible drug under the replenishment model. Since the commercial price charged often is much higher than the 340B ceiling price, *see infra* for examples, this provides a reasonable basis for HRSA's conclusion that Sanofi is overcharging covered entities in violation of the 340B statute. Moreover, even if Sanofi's contention that no covered entity was "charged" for 340B-eligible drugs was always true, Sanofi would still be overcharging covered entities by not allowing covered entities to reap the benefits of the 340B statute at all. *See* 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57234 (Sept. 20, 2010) (evidence of overcharge may include "cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program"); Final

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25, 110, 25,113 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Here, though, and contrary to Sanofi's allegation that HRSA failed to support its "determination that Sanofi's integrity initiative has resulted in overcharges" with any evidence, *see* Compl. ¶ 178, the administrative record is replete with evidence that covered entities were, in fact, forced to pay higher prices as a result of Sanofi's policy. Indeed there are numerous complaints by covered entities that explicitly state: "Sanofi is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. I am forced to pay [the wholesale acquisition cost] for these products for my contract pharmacies." *See, e.g.*, VLTR_151 (Adelante Healthcare); VLTR_283 (Alcona Citizens for Health); VLTR_1198 (Aspire Health Center); VLTR_1603 (Blue Ridge Medical Center); VLTR_1679 (Central FL Health Center); VLTR_1806 (Cherry Street Services); VLTR_1886 (Christ Community Health Services Augusta, Inc.); VLTR_1904 (Clinicas De Salud De Pueblo, Inc.); VLTR_2052 (Compass Health Inc.); VLTR_2263 (El Rio Health); VLTR_2333 (Family Medical Center of Michigan, Inc.); VLTR_2934 (HealthNet Inc.); VLTR_6595 (Maricopa County Special Health Care District DBA Valleywise Health); VLTR_4357 (MHC Health Care); VLTR_4702 (North Country HealthCare, Inc.); VLTR_4829 (Penobcot Community Health Care); VLTR_5037 (South Central Missouri Community Health Center); VLTR_5052 (Salina Health Education Foundation); VLTR_5127 (Santa Barbara County Health Care); VLTR_5312 (Tandem Health). Multiple complaints go even further, and identify screenshots or detail specific transactions in which a covered entity had to pay a wholesale acquisition price for Sanofi drugs that resulted in significant lost savings to the covered entity. *See e.g.*, VLTR_1468 (including multiple Sanofi drugs in monthly loss of over $70,000); VLTR_1595-99 (screenshot of drugs unavailable at 340B price).

While the administrative record clearly "identifies" a "covered entity that Sanofi has … overcharged" and "transaction[s]" in which Sanofi has done so, *see* Compl. ¶ 178, the record also reflects Sanofi's overcharges in aggregate statistics. In October 2020, for example, when Sanofi

stopped offering 340B pricing on drugs shipped to contract pharmacies, the number of 340B-priced units of Sanofi drugs sold through contract pharmacies plummeted from 2.04 million to .28 million and the number of WAC-priced units rose from under .01 million to .37 million. *See* VLTR_7937. This constituted $40.8 million in average lost savings by covered entities on Sanofi products in October 2020 alone. *See* VLTR_7940. The trends continued in the subsequent three months, constituting average lost savings on Sanofi products of over $40 million each month. *See id.* These statistics represent thousands of transactions in which Sanofi's initiative resulted in purchases by covered entities at prices significantly higher than the 340B ceiling prices, which further supports HRSA's determination that Sanofi has, in fact, overcharged covered entities.

In addition to Sanofi's new arguments with respect to the Violation Letter, Sanofi attempts to recast several of its other arguments as reasons to declare the Violation Letter arbitrary and capricious. These attempts are unpersuasive. For example, Sanofi argues that, because the AO is supposedly arbitrary and capricious, "HRSA's enforcement of the new rule announced in the Advisory Opinion against Sanofi in the HRSA Letter is also arbitrary and capricious." Compl. ¶ 174. But as explained *supra* § IV.A, the AO did not amount to a "new rule" and, in any event, is entirely separate from HRSA's Violation Letter that speaks to the legality of Sanofi's particular restrictions. *Id.* Thus the merits of the AO have no relevance to the Court's inquiry with respect to the Violation Letter.

Regardless, the Violation Letter is not "inconsistent" with the AO, as Sanofi claims. *See* Compl. ¶ 175. At the threshold, the AO did not conclude that "contract pharmacies are entitled to 340B-priced drugs because they act as agents of covered entities." *Id.* To the contrary, the AO specifically concluded that "*covered entities*," not *contract pharmacies*, "are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price." VLTR_8055. And, rather than requiring manufacturers to offer 340B discounts to contract pharmacies, the AO reiterated that the statute requires manufacturers to "offer" discounted drugs to covered entities, "even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* The AO's reference to an agency relationship was merely an example used to illustrate the reality that contract pharmacy arrangements do not constitute unlawful diversion. VLTR_ 8053. In any case, the Violation Letter is

consistent with the AO's conclusions. The Violation Letter explicitly states that the 340B statute does not "grant[]" Sanofi "the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities," and that the statute does not permit the imposition of any conditions, such as "the production of claims data," independent of "how the covered entity chooses to distribute" the drugs. VLTR_9. Thus, the gravamen of both the AO and the Violation Letter is that manufacturers, including Sanofi, have a statutory obligation to provide discounted drugs even if covered entities use contract pharmacies to aid in distribution, and that Sanofi's attempts to undermine this statutory reality are inconsistent with the law.

Finally, Sanofi also incorrectly characterizes prior HRSA guidance related to the 340B program in reiterating its argument that the Violation Letter is "inconsistent … with prior guidance permitting manufacturers to impose certain conditions … such as agreement to the manufacturer's normal business policies and the collection of standard information." *See* Compl. ¶ 176. As explained above, the agency long ago forbid manufacturers from conditioning discounted-drug sales on manufacturer-imposed conditions. *See supra* § I.A.

The Violation Letter represents HRSA's reasonable consideration of the relevant issues and provides a reasonable explanation of the agency's decision. Accordingly, the Court should reject Sanofi's claims that it is arbitrary and capricious.

2. The APA's notice-and-comment requirement is inapplicable to HRSA's 340B violation letter.

Sanofi claims that HRSA's 340B-violation letter should be set aside under 5 U.S.C. § 706(2)(D) because it "enforce[s] … the Advisory Opinion," which (Sanofi contends) HHS issued in violation of the notice-and-comment procedures set forth in 5 U.S.C. § 553(b)(3)(A). Compl. ¶¶ 181–83. This procedural challenge to the violation letter, which is wholly derivative of Sanofi's procedural challenge to the AO, fails because the violation letter does not "enforce" the AO—it enforces the 340B statute itself. *See supra* § I.B.1. And as Sanofi appears to concede, a letter merely informing a regulated entity that it has violated a statute administered by the agency is not subject to the APA's notice-and-comment requirement. *See, e.g.*, *Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 122–

25 (D.D.C. 2014) (holding that an agency letter informing a regulated entity that its business practices violated a federal immigration statute, that these practices must cease, and providing the entity time to come into compliance with the statute, was not subject to APA notice-and-comment procedures). But even if the Court were to conclude that the letter "enforces" the AO (which it does not, *see supra* § I.B.1), Sanofi's claim would still fail because, as explained below, *infra* § IV.A, the AO is at most an interpretive rule that is exempt from the APA's notice-and-comment requirement and is thus procedurally sound. *See also* HHS Mot. 24–26.

II. THE ADMINISTRATIVE-DISPUTE RESOLUTION MECHANISM MANDATED BY CONGRESS WAS LAWFULLY ESTABLISHED

A. ADR BOARD MEMBERS ARE LAWFULLY APPOINTED INFERIOR OFFICERS

Sanofi's Article II challenge to the ADR Rule collapses under the briefest scrutiny. The Appointments Clause, U.S. Constitution art. II, § 2, cl. 2, concerns the *appointment* of federal officers—not the interim *assignments* on which those officers are tasked to work. Sanofi tacitly admits that ADR *Board* members receive a constitutionally proper appointment under the Rule by asking this Court instead to focus on ADR *panelists*. *See* Sanofi Mot. 60-68 (focusing exclusively on whether "ADR panelists are principal officers"). But that shift in focus is unavailing: Just as Article III is concerned with the manner in which federal judges are appointed and removed (through Senate confirmation and impeachment)—not their selection or deselection from particular cases or appellate panels during their judicial tenure—so, too, the Article II analysis turns on the manner in which ADR *Board* members, as officers, are appointed and can be removed—not the individual panel assignments for which they later are selected. Indeed, were Sanofi correct that "ADR *panelists* are principal officers who must be appointed by the President and confirmed by the Senate," *id.* 60 (emphasis added), the U.S. President and Senate would need to act to select panelists from the Board each time a 340B ADR petition is filed. That clearly is not the law. *See* HHS Mot. 32-39.

And even putting aside Sanofi's incorrect focus on ADR panelists, Sanofi's arguments fail even as applied correctly to the ADR Board—*i.e.*, the body to which officers actually are appointed. Sanofi first argues, without support in the statute or Rule, that ADR panel decisions bind even "the

Secretary himself" and "cannot be reversed by the Secretary." Sanofi Mot. 62-63. That is incorrect as a matter of law. Neither the statute nor the Rule purport to prohibit the Secretary from overturning a panel decision with which he disagrees. And, "[a]s a general proposition of administrative law, the head of an administrative agency has the power to review and revise the acts of subordinates where … the powers in question are vested in the subordinate under the supervision and direction of the superior." *Morrow v. Clayton*, 326 F.2d 36, 45-46 (10th Cir. 1963); *accord Chevron Oil Co. v. Andrus*, 588 F.2d 1383, 1387-88 (5th Cir. 1979) (confirming officer who delegates authority does not divest himself of the power to exercise that authority to review and overrule subordinate absent express restriction in delegation).

But *even if* the Secretary were in some way constrained from reversing ADR decisions, Sanofi still is flatly incorrect that "[m]any courts, including the Supreme Court, have confirmed … that Executive Branch review is critical to inferior officer status." Sanofi Mot. 63. Controlling and persuasive authority establishes the opposite; as HHS explained in its opening brief, the Supreme Court has never ruled that an inferior officer's individual decisions must be subject to review by a higher executive official, and binding circuit precedent holds explicitly that the absence of direct review does not render an officer a "principal." HHS Mot. 32-36 (discussing, *inter alia*, *Pennsylvania v. HHS*, 80 F.3d 796, 798 (3rd Cir. 1996), which confirmed that the absence of direct review by the HHS Secretary did not render board members principal officers). Sanofi attempts to escape that controlling precedent by suggesting that the board members in *Pennsylvania*, who reviewed decisions of the Secretary himself, were more closely supervised because they did not set policy and exercised authority "strictly limited by the statute and implementing regulations." Sanofi Mot. 65 (citing *Pennsylvania*, 80 F.3d at 804). But those factors are present to a greater degree here, where ADR Board members decide only three types of claims delineated by Congress in statute, 42 U.S.C. § 256b(d)(3)(C), have no policy-setting role whatsoever, *contra* Sanofi Mot. 65, and must adhere to both the Rule and procedures established by the Secretary (and operate under his supervision). HHS Mot. 36-39 (discussing constraints and supervision applicable to Board members).

Sanofi's argument cannot prevail under *Pennsylvania*, but even were that not the case, the other authorities it cites are equally unhelpful. Sanofi's reliance, Mot. 63, on *Association of American Railroads v. Department of Transportation* is especially misplaced since that court twice explicitly has rejected the argument Sanofi portrays as settled law. 821 F.3d 19, 39 (D.C. Cir. 2016). The arbitrators in question there were not deemed principal officers solely because their decisions lacked secondary review before constituting final agency action. Rather, that "anomalous" statute permitted a *private arbitrator* to exercise regulatory authority, and "[n]owhere d[id] [the statute] suggest the arbitrator" was "directed and supervised by any federal entity." *Id.* at 39 (citation omitted). Indeed, the arbitrators lacked *any* supervision, whatsoever, and could operate wholly outside the government. *Id.* at 39. That level of independence is fundamentally different from the ADR Rule, which leaves Board members subject to supervision by the Secretary in numerous ways. Moreover, it is telling that Sanofi places heavy reliance on the D.C. Circuit's opinion in *Association of American Railroads* while misstating that circuit's holding in *Intercollegiate Broadcasting*; after severing a statutory removal restriction, the court was "confident" that the judges were inferior officers *despite* issuing decisions "final for the executive branch." *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1340 (D.C. Cir. 2012); *accord Fleming v. U.S. Dep't of Agric.*, 987 F.3d 1093, 1103 (D.C. Cir. 2021) (rejecting Sanofi's argument) (both cited at Sanofi Mot. 63-64).

Sanofi's remaining arguments misconstrue the Board's true functioning to obscure the fact that Board members are both supervised and freely removable by the Secretary. In arguing that ADR proceedings will be conducted without adequate supervision, Sanofi Mot. 64, Sanofi ignores all of the relevant tools for control that the Secretary may exercise to supervise the ADR Board and its proceedings, as explained in HHS's opening brief, HHS Mot. 36-37. Rather than address these factors, Sanofi suggests that the Secretary "*cannot* lawfully supervise ADR panelists" because Section 340B does not contain an express grant of *general* rulemaking authority, Sanofi Mot. 64. This is nonsensical; Congress not only authorized, but directed, the Secretary to exercise rulemaking authority *over the ADR process*, and the Secretary is free to revise or revoke the ADR Rule as he sees fit. Aside from rulemaking authority, Board members must follow the Secretary's rules of procedure and substantive policy; the

fact that members have "discretion" and "latitude" to conduct their day-to-day duties within the bounds set by their superior, *id.*, is neither constitutionally significant nor unusual, even for federal employees in many roles.

Finally, Sanofi's removal argument elucidates the reason for its insistent focus on ADR panelists, not Board members. Sanofi claims that "the government cites no authority for th[e] proposition" that removal from the Board, not a panel, is relevant for constitutional purposes. Sanofi Mot. 67. That is incorrect on its face; each and every Article II case cited in the government's opening brief, HHS Mot. 32-39, concerned the question whether an officer can be removed from an appointment, not when (or by whom) that officer can be re-assigned from any particular task during his tenure. That is unsurprising, since this dispute arises under the Appointments Clause, not an "assignments clause." Under the ADR Rule, a federal employee becomes an officer when s/he receives an *appointment* by the Secretary to the ADR Board, not when s/he is selected from that Board by the HRSA Administrator to hear any particular petition. Sanofi's argument that removal must be considered "in the only context in which ADR panelists exercise any authority—their service on ADR panels" is akin to arguing that federal appellate judges must be impeached by the Senate before being removed from a panel assignment, since judges enjoy constitutional removal protection yet they, too, exercise their authority in the context of particular disputes. Similarly, Sanofi's claim that the removal power "belongs to the individual that appointed the ADR panelists: the HRSA Administrator," Sanofi Mot. 67, is nonsensical because the HRSA Administrator only assigns Board members to particular disputes *after* they have been appointed as federal officers by the Secretary. Clearly it is removal from one's appointment—not one's interim assignment—that matters for constitutional purposes. And neither the Rule nor the statute contain any restraint on the Secretary's ability to remove ADR Board members, thus demonstrating that this "powerful tool for control," *Edmond v. United States*, 520 U.S. 651, 664 (1997), remains fully with the Secretary. Indeed, the Secretary's unfettered power of removal allows him to exercise much broader supervision than was the case in *Pennsylvania*, 80 F.3d at 803, where the Secretary *was* limited to removal "for cause or misconduct." The Secretary's partial

delegation of authority to the HRSA Administrator to share in this task, by re-assigning a panel member when cause is shown, is a sensible delegation without constitutional significance.[12]

Accepting Sanofi's argument that Article II is violated by an inferior officer's ability to render a final decision would upend modern administrative law. Throughout the federal bureaucracy, countless inferior officers have the "last word" by issuing final agency decisions through delegated authority. The fact that this challenge involves adjudicatory decision-making as opposed to administrative rulemaking does not change the constitutional calculus. Because Board members receive a proper appointment under the ADR Rule, Sanofi's Article II claim fails.[13]

B. CONGRESS PROPERLY VESTED ADJUDICATION OF STATUTORILY CREATED 340B RIGHTS BEFORE THE AGENCY

Sanofi's Article III challenge is equally wrong on the law. Sanofi spills significant ink insisting that the alleged remedial powers granted to the Board render it unconstitutional, Sanofi Mot. 68-72, while ignoring the caselaw and examples set forth in the government's brief demonstrating that, far from an infringement on the judiciary, the powers granted to the ADR Board are commonplace features of modern administrative law. HHS Mot. 39-41. HHS disagrees with Sanofi regarding the scope of the Board's remedial powers, but even if Sanofi is correct that panels may purport to issue injunctive relief (which, as explained in the government's opening brief, would resemble a cease-and-desist demand to comply with statutory requirements, not a judicial-style order backed by contempt power) or a damages calculation, that *still* would pose no Article III problem. *See id.* 41 (explaining that

[12] Even if the Court considered the circumstances for re-assignment of panel members, rather than removal from the Board (an approach not supported by caselaw), the Rule contains *no* constraint on the Secretary's ability to re-assign panels, *contra* Sanofi Mot. 66-67. On the contrary, the Rule merely authorizes the HRSA Administrator to re-assign panelists in more-limited circumstances where cause is shown.

[13] Sanofi further misportrays the government's position as arguing that "the Secretary could essentially revise the ADR Rule to cure its violation of Article II." Sanofi Mot. 68 (discussing HHS Mot. 35-36). There is no Article II violation for the Secretary to "cure." Rather, in its opening brief HHS explained that the Secretary can revise the ADR Rule to change the workings of the Board, supervise its conduct, or impose additional restrains if he sees fit; in other words, Congress gave the Secretary power to issue regulations establishing the Board, and he is free to modify those regulations over time.

many agencies have the power to order equitable relief and damages, including findings of violation, restitution, and fines, subject to judicial review under the APA, just like ADR panel rulings).

Sanofi's private-rights argument rests on inapposite caselaw and ineffective attempts to distinguish relevant authorities. Article III challenges arise in two distinct settings: challenges arising in *bankruptcy courts* typically concern the ability of those Article I bodies, serving as adjuncts of district courts, to adjudicate common-law counterclaims and similar matters that arise with some relationship to the bankrupt estate. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 56 (1989) ("fraudulent conveyance actions by bankruptcy trustees … are quintessentially suits at common law that … resemble state-law contract claims" and "therefore appear matters of private rather than public right"); *Stern v. Marshall*, 564 U.S. 462, 487 (2011) ("No 'public right' exception" permitted bankruptcy court to adjudicate "state common law counterclaim" for tortious interference); *N. Pipeline Const. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 71 (1982) (adjudication of "the right to recover contract damages" under state law "obviously is not" a public right and thus belongs in Article III court). In other words, Article III challenges to the jurisdiction of bankruptcy courts involve private rights because traditional, common-law *claims* (or those closely resembling them, and created by statute) are at stake. By contrast, Article III challenges arising before *administrative agencies* often involve the adjudication of entirely *new* rights, created by Congress through statute as part of a comprehensive regulatory scheme. *See Thomas v. Union Carbide Agric. Prod. Co.*, 473 U.S. 568, 593-94 (1985). In such cases, Congress need not even create a remedy in the courts at all, so it "may set the terms of adjudicating" that right, including by assigning adjudication in another branch of government. *Stern*, 564 U.S. at 489 (citation omitted). And it matters not that the dispute may arise between private parties, or affect some interest in money or property. It is the nature of the claim asserted that renders it capable of non-judicial adjudication. *See* HHS Mot. 41-46 (providing thorough analysis of public-rights caselaw and demonstrating that ADR Board adjudicates only statutory rights created by Congress).

Sanofi ignores the proper test for determining when *statutory* rights may be adjudicated outside Article III. Sanofi Mot. 72. For example, Sanofi emphasizes that "the claim at issue in *Granfinanciera* was created by federal statute but nevertheless involved a private right," Sanofi Mot. 76, and asserts

that this proves that "new rights" under a federal regulatory scheme still must be adjudicated in Article III courts. Not so: *Granfinanciera* involved a private right because the statutory cause of action effectively supplanted and resembled a pre-existing common-law action. 492 U.S. at 53-56 (analogizing statutory claim to state-law contract dispute). And the *Granfinanciera* Court emphasized that "[t]he crucial question" in determining whether public rights are at issue is whether it "involv[es] statutory rights that are integral parts of a public regulatory scheme and whose adjudication Congress has assigned to an administrative agency or specialized court of equity." *Id.* at 54, 55 n.10. That precisely describes the comprehensive 340B drug-discount program, and the novel claims for "overcharging," "diversion," and "duplicate discounting" that arise under it. *See also Stern*, 564 U.S. at 490-91 (public rights are "cases in which the *claim at issue* derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority") (emphasis added). Sanofi's dismissal of *Union Carbide*, 473 U.S. at 584, ignores the Supreme Court's discussion and approval of *various* agency adjudicative schemes which "determine liabilities of individuals" to one another yet are able, consistent with constitutional constraints, to adjudicate "claims between individuals." 473 U.S. at 587, 589. *Union Carbide* does not, as Sanofi posits, stand for the proposition that any pre-existing property rights must be extinguished by a statute before claims may fall within the public-rights exception. *Contra* Sanofi Mot. 75-76. [14]

Sanofi's continued insistence that the claims heard by ADR panels—that a manufacturer has charged a covered entity more than the ceiling price for pharmaceuticals, or that a covered entity unlawfully has diverted or claimed duplicate discounts for 340B drugs—would have been "tried by the courts at Westminster in 1789," is absurd, as there clearly is no historic precedent for these disputes. Sanofi Mot. 72 (quoting *Stern*, 564 U.S. at 484). Congress created these rights from whole

[14] The fact that patent "infringement cases today must be tried to a jury, as their predecessors were more than two centuries ago," *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996) (discussed at Sanofi Mot. 76), is irrelevant to the present dispute, since patent infringement rights are not integral to a federal regulatory scheme.

cloth, so it is no infringement on the traditional power of the judiciary for initial adjudication to be placed outside the third branch.[15]

Were Sanofi correct that the claims brought by covered entities against it are "the subject of a suit at the common law" that even *could* be heard, in the first instance, by Article III courts, *id.* 73 (citing *Den. ex dem. Murray v. Hoboken Land & Improvement Co.,* 59 U.S. (18 How.) 272, 284 (1855)), then the Supreme Court wrongly decided *Astra v. Santa Clara County*, 563 U.S. at 121-22 (holding covered entities may not litigate 340B claims for overcharging in federal court). Sanofi's contention that "covered entities' claims against manufacturers in ADR proceedings are effectively state-law contract claims," Sanofi Mot. 74, is precisely the theory rejected by the high court. *Astra*, 563 U.S. at 118 (rejecting attempt by covered entities to sue to enforce manufacturer PPAs because it would "render[] meaningless" "[t]he absence of a private right [of action] to enforce the statutory ceiling-price obligations"). Stated differently, were Sanofi correct that covered entities' claims of overcharging cannot be adjudicated before the agency, the result—in light of the Supreme Court's holding that those same claims cannot be heard in federal court—would be that claims for 340B violations cannot be heard in *any* forum, thus negating the will of Congress to create a remedy for claims of "overcharging." That untenable result should be rejected.

C. HHS Fully Complied With Notice And Comment In Promulgating The ADR Rule

All parties agree that "[t]he [APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures."

[15] Sanofi asserts, without any citation to authority, that the government "misunderstands the nature of the rights at issue" because, "[a]lthough Section 340B creates covered entities' entitlement to drug discounts, it is *Sanofi's* private rights that are at stake." Sanofi Mot. 75. Sanofi is wrong. As evidenced in the government's opening brief, 42-45, the private/public rights inquiry focuses on the *claim* being adjudicated and whether it is "an integral part of a public regulatory scheme, assigned to an administrative agency," *Beard v. Braunstein*, 914 F.2d 434, 441 (3rd Cir. 1990), not whether property changes hands through the disposition. ADR panels simply do not, as Sanofi claims, determine "Sanofi's underlying private rights to hold and alienate property on terms of its choosing," Sanofi Mot. 75. Besides, Sanofi absolutely has the "voluntary choice," *id.* 77, to opt out of participation in Medicaid and Medicare Part B and charge whatever it wants to whomever it wants for its drugs. But it may not continue to profit from these lucrative government programs while shirking its complementary statutory obligations.

See, e.g., *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978). Here, to follow the APA's procedures, the agency need only have published a notice of proposed rulemaking that included "either the terms or substance of the proposed rule or a description of the subjects and issues involved," 5 U.S.C. § 553(b)(3), and then "give[n] interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). HHS has complied with these requirements. Yet, while accusing HHS of "impos[ing] upon agencies specific procedural requirements that have no basis in the APA," Sanofi Mot. 59, Sanofi endorses the one opinion of a district court in another case that does just that. In *Eli Lilly & Co. v. Cochran*, No. 1:21-CV-81, 2021 WL 981350 (S.D. Ind. Mar. 16, 2021) the court essentially imposed a new (and highly subjective) procedural requirement on agencies not found in the APA—that agencies must publish a new NPRM and re-do the notice and comment process if the totality of the circumstances would lead a reasonable observer to view the original NPRM as withdrawn. In addition to creating a new rule that improperly inhibits an agency's statutorily delegated rulemaking authority, this "totality-of-the-circumstances" test, created in the first instance by the *Lilly* court, is incompatible with existing law setting forth the procedures for review of agency action under the APA.

As explained in HHS's opening brief, courts review the decision to terminate rulemaking as final agency action under the APA. *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 846 (D.C. Cir. 1983); *see also* HHS Mot. 47-48. Accordingly, the APA requires the agency to provide "an explanation [for terminating a rulemaking] that will enable the court to evaluate its rationale at the time of the decision." *Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor*, 358 F.3d 40, 44 (D.C. Cir. 2004). Because the need for a statement explaining the reasons for withdrawal stems from the APA itself, *see Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990) (characterizing 5 U.S.C. § 706(2)(A) as imposing "a general 'procedural' requirement of sorts by mandating that an agency take whatever steps it needs to provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision"), HHS's position does indeed have a "basis in the APA" and is far from "nonsensical," *see* Sanofi Mot. 59 n.22. Thus, it is no surprise that

not only have other courts reviewed the termination of rulemaking on the basis of a withdrawal notice published in the Federal Register, *see Int'l Union, United Mine Workers*, 358 F.3d at 42 (acknowledging withdrawal of proposed rule published in the Federal Register); *Ctr. for Auto Safety*, 710 F.2d at 844 (same); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016) (same), but HHS's usual practice is to publish a notice of withdrawal in the Federal Register. *See, e.g.*, 78 Fed. Reg. 12,702-01 (Feb. 25, 2013); 79 Fed. Reg. 19,848-01 (Apr. 10, 2014); 83 Fed. Reg. 60,804-01 (Nov. 27, 2018); 84 Fed. Reg. 37,821-01 (Aug. 2, 2019).

Even if this Court were to adopt the *Lilly* Court's newly-created and extra-statutory totality of the circumstances test (and it should not), the facts on which Sanofi relies, Sanofi Mot. 58, would not have led a reasonable observer to believe the ADR Rule had been withdrawn. First, listing or delisting of rulemaking on the Unified Agenda is not presumed to provide notice of a proposed rulemaking to regulated parties of agency action. Though the Unified Agenda exists to provide "uniform reporting of data on regulatory and deregulatory activities under development" in the Executive Branch, *About the Unified Agenda*, REGINFO.GOV,[16] listing a rulemaking on the Unified Agenda does not satisfy statutory requirements to provide notice of rulemaking, 5 U.S.C. § 553(b), or establish presumptive notice of regulation required for enforcement, *cf.* 44 U.S.C. § 1507. Accordingly, de-listing a rulemaking from the regulatory agenda is not sufficient to withdraw that rulemaking for the purposes of the APA. The Unified Agenda is simply an administrative tool to assist the Executive Branch in the organization and exercise of its regulatory authority. For the same reasons, the existence of a different RIN is legally insignificant. RINs are administrative tags created by the Office of Information and Regulatory Affairs, not the agency, and cannot properly be interpreted as a sign of the agency's intent with respect to rulemaking. *See* How to Use the Unified Agenda, Reginfo.gov.[17]

Second, the statements by an unnamed HRSA official in a news publication are far from a clear and direct statement of withdrawal that the public would expect if a rulemaking were terminated.

[16] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_About.myjsp (last visited June 15, 2021).
[17] https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/UA_HowTo.myjsp#rin (last visited June, 15, 2021).

Sanofi relies on the *Lilly* Court's citation to a news report quoting a HRSA official as stating that the agency "had no plans to create a binding ADR process" and "does not plan to move forward on issuing a regulation," Sanofi Mot. 58, but nowhere does Sanofi allege that the HRSA official actually withdrew or purported to withdraw the existing NPRM. More importantly, Sanofi does not cite, and HHS is not aware of, any caselaw supporting the contention that a public statement from an individual agency official without decisionmaking authority can provide any evidence as to whether a rulemaking has been withdrawn.

In a final attempt to invalidate the procedurally proper ADR Rule, Sanofi argues that the ADR Rule violates the APA because it is not a logical outgrowth of the 2016 NPRM. HHS addressed this claim at length in their motion, *see* HHS Mot. 49-50, and Sanofi fails to contest or meaningfully engage with a single argument raised therein. At bottom, the NPRM gave Sanofi adequate notice of the topics covered by the ADR Rule, and thus, Sanofi's logical outgrowth claim fails as a matter of law. *See Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 249 (3d. Cir. 2010).

For all of these reasons, the Court should reject Sanofi's claims challenging the procedures by which HHS issued the ADR Rule.

D. THE ADR RULE IS NOT ARBITRARY, CAPRICIOUS, OR CONTRARY TO LAW

Sanofi identifies no sound basis on which to set aside the ADR Rule under 5 U.S.C. § 706(2).

First, Sanofi maintains that HHS has no statutory authority to award monetary or equitable relief through the ADR process. *See* Sanofi Mot. 77–78. But § 256b(d)(3)(A) explicitly authorizes the Secretary to create "procedures for the provision of remedies and enforcement of determinations made pursuant to [the ADR] process through [the] mechanisms and sanctions described" under subsections (d)(1)(B) and (d)(2)(B). These provisions identify both monetary and equitable remedies for 340B violations—*e.g.*, the issuance of refunds for overcharges, the imposition of civil monetary penalties, and removal from the 340B Program. *See* 42 U.S.C. § 256b(d)(1)(B)(ii), (vi); *id.* § 256b(d)(2)(B)(v). Thus, the authority delegated to HRSA under the ADR Rule to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities" falls

squarely within the Secretary's statutory authority. *See* 42 C.F.R. § 10.24(e); *see also* 85 Fed. Reg. 80,632, 80,642 (Dec. 14, 2020).[18]

Second, Sanofi attempts to draw a distinction between HHS's statutory authority to resolve ADR "claims by covered entities that they have been overcharged for drugs," *see* 42 U.S.C. § 256b(d)(3)(A), and a panel's authority under the ADR Rule to decide, in resolving an overcharge claim, whether a drug maker has unlawfully denied a covered entity the "ability to purchase covered outpatient drugs at or below the 340B ceiling price," 42 C.F.R. § 10.21(c)(1). But this is a distinction without any apparent difference. Where a drug maker denies a covered entity the ability to purchase 340B drugs at discounted prices, the covered entity is being offered those drugs at a price in excess of the applicable ceiling price, which is, by definition, an "overcharge." Sanofi nevertheless suggests that, to bring an overcharge claim, a covered entity must point to a "specific transaction[]" in which it purchased a drug above the applicable ceiling price. This fabricated requirement not only has no basis in the statute, it would leave covered entities who are *unable* to purchase 340B drugs at facially unlawful prices without any remedy. *See, e.g.*, VLTR_005827 (covered entity deterred from purchasing 340B drugs because the drug maker was denying the 340B price for covered outpatient drugs). "Congress cannot have intended this bizarre result." *See Caron v. United States*, 524 U.S. 308, 315 (1998).

Third, Sanofi argues that certain "industry changes" occurred in the years preceding promulgation of the final ADR Rule, and that HHS should have taken these changes into account. Sanofi Mot. 79. Sanofi points specifically to an increase in the use of contract pharmacies by covered entities, evidence of compliance issues in the 340B Program, and various drug makers' extra-statutory restrictions on purchases made by covered entities with contract-pharmacy arrangements. *Id.* But HHS had no obligation to consider these purported "changes" within the industry, because they have no relevance to HHS's development of a dispute-resolution mechanism under 42 U.S.C. § 256b(d)(3), and Sanofi offers no argument to the contrary. *See NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d

[18] To the extent Sanofi is still challenging the authority of ADR Panels to grant self-executing monetary awards or judicial-style injunctions, its argument on this score fails for reasons addressed in HHS's opening brief. *See* HHS Mot. 39–40.

182, 190 (3d Cir. 2006) ("Reversal [under the arbitrary-and-capricious standard] is appropriate *only* where the administrative action is irrational or not based on *relevant* factors.").[19]

III. THE COURT LACKS JURISDICTION TO REVIEW THE GENERAL COUNSEL'S LEGAL ADVICE, WHICH HAS BEEN WHOLLY SUPERSEDED BY ISSUANCE OF HRSA'S VIOLATION LETTERS

A. UNLIKE HRSA'S VIOLATION LETTER, THE ADVISORY OPINION IS NOT FINAL AGENCY ACTION

Because it is the violation letter from "which rights or obligations have been determined" and from which "legal consequences will flow" rather than the AO, and the AO merely reiterated the agency's longstanding position, the AO is not final agency action and the Court should dismiss Sanofi's claims challenging the AO.[20] *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *see also* HHS Mot. 16-19. None of Sanofi's arguments to the contrary have merit.

Sanofi incorrectly states, "the Advisory Opinion is the first time the agency addressed manufacturers' legal obligations under Section 340B." Sanofi Mot. 51. To the contrary and as explicitly explained in the AO, HHS's "longstanding interpretation" of the 340B statute "is that manufacturers are required to offer ceiling prices even where contract pharmacies are used." AO at 4. This interpretation was expressed not only in HRSA's 1996 and 2010 guidance, *see* 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996) ("if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price,"); 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) ("if 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

[19] By offering no response to HHS's arguments, *see* HHS Mot. 51–53, Sanofi has abandoned its claims that the agency acted arbitrarily and capriciously by (i) not responding to comments regarding HRSA's audit guidelines, (ii) not considering PhRMA's petition for rulemaking, and (iii) not adequately explaining the design of the ADR process. *See Yucis v. Sears Outlet Stores, LLC*, No. CV 18-15842, 2019 WL 2511536, at *4 n.4 (D.N.J. June 18, 2019).

[20] Dismissal is proper regardless of whether the Court construes the APA's requirement for final agency action as jurisdictional, *see Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 247 (3d. Cir. 2011), or as a necessary element to state a claim under the APA, *see Wayne Land & Min. Grp. LLC v. Del. River Basin Comm'n*, 894 F.3d 509, 525 n.10 (3d Cir. 2018).

340B discount price"), but was also recognized by the pharmaceutical industry itself since the mid-1990s when the leading pharmaceutical lobbying organization, PhRMA, challenged HHS's interpretation of the statute with respect to contract pharmacy arrangements, *supra* Sec. III.B.

Sanofi also misinterprets the AO as filling a "statutory gap in Section 340B," Sanofi Mot. 52,[21] when, in fact, the AO concludes that HHS's interpretation is compelled by the text of the statute. AO at 3 (relying on the "lack of ambiguity in the plain text of the statute"). And, while blindly stating that it will be exposed to penalties in future enforcement proceedings as a result of the AO, Sanofi Mot. 52, Sanofi fails to acknowledge that such exposure stems from the *statute's* alternative dispute resolution process, 42 U.S.C. § 256b(d)(3)(B)(i), and delegation of authority to HRSA to impose monetary penalties, *id.* § 256b(d)(1)(B)(vi). Indeed, HRSA's Violation Letter, which actually threatens the imposition of civil monetary penalties, does not rely on the AO at all. And the ADR petitions, which Sanofi claims are a direct result of the AO, are in fact a result of Sanofi's abrupt shift in policy. The ADR proceedings simply represent the covered entities availing themselves of the statutorily mandated administrative dispute resolution process. Thus, the AO did not "directly [lead] to the . . . proceedings," and did not have an "immediate impact on [manufacturers'] day-to-day operations." *Tomasi v. Twp. of Long Beach*, 364 F. Supp. 3d 376, 390 (D.N.J. 2019).

While the Advisory Opinion does involve a "pure question of law," as Sanofi suggests, Sanofi Mot. 53, HRSA has engaged in further factual development of its position with respect to the legality of Sanofi's policy in particular, as evidenced by the Violation Letter, which counsels against Sanofi's argument that the final agency action test is satisfied by the AO. *See Ocean Cnty. Landfill Corp. v. EPA, Region III*, 631 F.3d 652, 656 (3d. Cir. 2011) (noting that decision would "benefit" from "additional facts" relevant to the plaintiffs' specific harms); *see also* Compl. ¶ 95 ("By its own terms, the HRSA Letter represents the consummation of HHS's decision-making process about the legality of Sanofi's integrity initiative."). For that reason as well, it is judicial review of the Violation Letter that would

[21] Sanofi's reliance on *Dia Nav. Co. v. Pomeroy*, 34 F.3d 1255 (3d. Cir. 1994) to support its argument is also entirely misplaced, as that case analyzes the difference between legislative and interpretative rules and does not even mention final agency action.

"speed enforcement" of the statute, rather than the AO, which simply reiterated the agency's longstanding position in general terms. *See Ocean Cnty.*, 631 F.3d at 656.

At bottom, the AO is a restatement of the agency's prior interpretation of the 340B statute. Accordingly, this Court should hold, in accordance with the decisions in *Menominee Indian Tribe of Wisc. v. EPA*, 947 F.3d 1065 (7th Cir. 2020); *Clayton Cnty. v. FAA*, 887 F.3d 1262 (11th Cir. 2018); *Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426 (4th Cir. 2010); and *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420 (D.C. Cir. 2004), that the AO is not final agency action and dismiss Sanofi's claims challenging the AO.

B. THE AGENCY'S INTERPRETATION OF MANUFACTURERS' STATUTORY OBLIGATIONS HAS BEEN CONSISTENT FOR DECADES

Sanofi's insistence that HHS has changed its position on *manufacturers'* 340B obligations is refuted by historical evidence. Far from having been "articulat[ed] for the first time" in the AO, Sanofi Mot. 47, Sanofi's obligations have been consistently expressed for decades. What Sanofi derides as "offhand remarks" and "isolated sentences that the government cherry-picks from the 1996 and 2010 guidance documents," *id.* 48, in truth confirmed unequivocally that, when "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." 75 Fed. Reg. at 10,278. HRSA was unambiguous in confirming that this interpretation imposed no new obligations on manufacturers because *the statute itself* requires drug makers to fill covered-entity orders even "if the entity directs the drug shipment to its contract pharmacy." 61 Fed. Reg. at 43,549. Sanofi cannot wish these statements out of existence.

Even were there any doubt on that score, additional historical evidence disproves Sanofi's claim that it "could not have challenged HHS's interpretation of the statute any earlier" because the "earlier guidance[s] did not impose any legal obligations on drug manufacturers." Sanofi Mot. 55. On the contrary, the pharmaceutical industry demonstrated in 1996 its understanding both that HHS considered manufacturers to be obliged to honor contract-pharmacy dispensing models and that such transactions involve purchases by covered entities, not pharmacies. In 1996 the leading

pharmaceutical-industry trade organization, PhRMA, filed suit to challenge HRSA's contract-pharmacy guidelines. *See PhRMA v. Shalala*, No. 1:96-cv-1630 (D.D.C. July 12, 1996), ECF No. 1 Compl., ¶ 3.[22] The drug companies alleged that, as a result of the 1996 guidelines, "covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies … , and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities." *Id.* ¶ 18. And they correctly demonstrated awareness that, "[i]f a manufacturer attempted to mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, *there is a substantial risk that the [Public Health Service] would terminate the manufacturer's agreement with the Secretary of HHS*." *Id.* ¶ 21 (emphasis added). Appended to that complaint was a letter from the Administrator of HRSA confirming that, "recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, [the agency] does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs." *Id.* Ex. D. PhRMA stipulated to dismissal of the suit shortly after filing.

That lawsuit demonstrates that, not only *could* Sanofi have mounted the same challenge in 1996 that it now brings, a trade association of which it currently is a member[23] did just that. Sanofi's repeated insistence that the AO "for the first time *requires* manufacturers" to honor *all* covered-entity sales, Sanofi Mot. 39, is flatly disproven by the legal theories set forth in that twenty-five-year old litigation. PhRMA pleaded that "[u]nder the contract pharmacy guidelines, [] a manufacturer is *required* to make sales to unlicensed entities [that do not operate a pharmacy] or be in violation of its Pharmaceutical Pricing Agreement with the Secretary—which would jeopardize … the manufacturer's future sales in all states." *PhRMA*, Compl. ¶ 38; *see also id.* ¶ 21 (acknowledging that manufacturer which refused

[22] The lawsuit was filed one month before the official guidance was published in the Federal Register; it challenged the same statutory interpretation, which first was published on an HHS electronic database. *PhRMA*, Compl. Exs. B, C. This Court can take judicial notice of the complaint and stipulation of dismissal from the *PhRMA* litigation as official judicial records. *See* Fed. R. Evid. 201. Attached to this motion is a true and correct copy from official archives of the Department of Justice. *See* Ex. 3. (Talmor Decl.).

[23] *See* PhRMA, About, Members, https://www.phrma.org/en/About/Members.

contract-pharmacy sales, even "where diversion is proven or suspected," would face termination from the program). PhRMA relied on a letter to the industry conveying HRSA's position that, when "an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," and does not "exempt[] the manufacturer from compliance." *Id.* Ex. D. These are not "offhand remarks." Sanofi Mot. 48. And clearly it is Sanofi—not the General Counsel, through his legal advice—that is seeking to "radically alter[] the 340B drug program," *id.* 1, through a counterfactual portrayal of its historical operation.[24]

Sanofi further attempts to demonstrate a change in position by pointing to the fact that what it calls "the 'must offer' provision did not exist when HHS issued its 1996 and 2010 guidance[s]," so according to Sanofi, HHS could not have construed it "to impose a binding obligation on manufacturers to ship 340B-priced drugs to contract pharmacies." *Id.* 40. This claim again rests on the baseless assertion that, before 2010, the 340B statute imposed *no obligations whatsoever* on manufacturers—but only required the Secretary to enter into PPAs. As explained *supra* § I.A, manufacturers most certainly were obliged to honor purchases by covered entities from the 340B Program's inception (and before Congress added the non-discrimination provision in 2010).

Sanofi also attacks the AO as inconsistent with what it portrays as "a longstanding position that manufacturers *are* permitted to impose certain conditions." Sanofi Mot. 45 (citing 59 Fed. Reg. 25,112, 25,114). But as thoroughly rebutted, *supra* § I, the statement from guidance that Sanofi takes out of context said no such thing. On the contrary, that decades-old guidance was clear that manufacturers may *not* condition access to 340B discounts, even on covered entities' express agreement to follow the statute. HHS long has prohibited manufacturers from placing conditions and restrictions on covered entities' access to discounted drugs, and its acknowledgement that manufacturers may collect "standard information" to *facilitate* covered entities' purchases in no way

[24] It matters not that PhRMA's 1996 challenge was dismissed without prejudice and thus not entitled to preclusive effect. It both demonstrates the falsity of Sanofi's portrayal of the AO's interpretation as novel—and evidences the pharmaceutical industry's historic understanding of its obligations.

authorizes the denial of purchases unless manufacturer-imposed restrictions are followed. 59 Fed. Reg. 25,112-14.

Aside from manufacturer-imposed conditions, that early guidance also confirms that pharmaceutical companies may not restrict the *methods* by which covered entities obtain and dispense drugs. Contrary to Sanofi's insistence that its obligation to "offer" discounted drugs first was imposed through the 2010 amendments, the 1994 guidance interpreted the statute to require that "manufacturers must offer covered outpatient drugs at or below the section 340B discount prices," and that, "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." *Id.* at 25,113. Furthermore, that guidance—in response to a comment urging the agency *not* to require manufacturers to honor contract-pharmacy sales—confirmed that use of contract pharmacies "is a customary business practice," that "[e]ntities often use purchasing agents or contract pharmacies," and that "[b]y placing such limitations on sales transactions," drug makers would "be discouraging entities from participating in the program." *Id.* at 25,111. In other words, since other commercial customers are freely able to purchase drugs through intermediaries and dispense to their patients through outside pharmacies, so too are 340B purchasers. *Id.* It also stated plainly that "[a] covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts." *Id.* at 25,113.

HRSA's guidance *to covered entities* on how to utilize neighborhood pharmacies while complying with *their* statutory obligations may have changed from the 1996 to 2010 guidance[25]. But from the 340B program's inception, HRSA has not wavered in its pronouncements that *manufacturers* must sell

[25] Sanofi contends that, because the 1996 and 2010 guidances differed as to the number of contract pharmacies *covered entities* could rely upon, that "bel[ies] the government's assertion that the statute is unambiguous." Sanofi Mot. 47; *see also id.* 6 (relying on HRSA statement in 1996 guidance that statute contained "gaps" and "silen[ce] as to permissible drug distribution systems"). But the inconsistency between covered entities' allowances is immaterial because the statute is unambiguous that *manufacturers* must honor *purchases by* covered entities. Besides, although the 1996 guidance did instruct covered entities to initially rely on one contract pharmacy, it expressly indicated that HRSA "will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor." 61 Fed. Reg. at 43,555. And regardless what it may have said as to covered entities, the guidance was crystal clear twenty-five years ago in mandating that manufacturers may not refuse purchases by covered entities regardless how they dispense the purchased drugs. *Id.* at 43,549.

340B discounted drugs to covered entities regardless how those drugs are dispensed (and that any refusal to do so, including on the basis of manufacturer conditions, risks termination from the program). There has been no question throughout previous decades that covered entities are entitled to purchase discounted drugs regardless whether they operate a pharmacy or use community pharmacies—and the pharmaceutical industry has long understood that failure to fulfill its obligations will lead to termination from the program. Sanofi's sudden reinterpretation of its statutory obligations is unavailing, as is its one-paragraph attempt to avoid the consequences of its failure to challenge HRSA's interpretation at any point in previous decades, Sanofi Mot. 55. The General Counsel's reiteration of the agency's longstanding statutory interpretation is time-barred from judicial review.

IV. EVEN IF THE GENERAL COUNSEL'S LEGAL ADVICE WAS REVIEWABLE, SANOFI'S CLAIMS FAIL

A. NOTICE-AND-COMMENT RULEMAKING IS NOT REQUIRED

Because the AO simply reflects HHS's interpretation of the 340B statute, and does not create new obligations outside of the statute, it is an interpretive rule not subject to the APA's notice and comment requirements. *See* 5 U.S.C. § 553(b)(3)(A); *see also* HHS Mot. 24-26. Sanofi's arguments to the contrary are misplaced, and cannot be reconciled with binding Third Circuit precedent.

First, Sanofi argues that the AO's use of "mandatory language" evidences a "binding intent" indicative of a legislative rule, relying on *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002). *See* Sanofi Mot. 41. But the AO's supposedly "mandatory" language merely explains what the *statute* requires. *See* AO at 3 ("Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive."). The AO does not impose a new obligation on Sanofi or other regulated parties like the guidance document at issue in *General Electric*, which required the use of certain methodology to comply with statutory and regulatory requirements. *See Gen. Elec.*, 290 F.3d at 384. Indeed, in a later case distinguishing *General Electric Company*, the D.C. Circuit rejected a similar argument in classifying an agency document as a non-legislative rule, explaining that the purportedly "mandatory" language "does not create new burden," but instead "merely reiterates the statutory requirements." *Catawba*

Cnty., v. EPA, 571 F.3d. 20, 34 (D.C. Cir. 2009); *see also Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994) (Interpretive rules "state the agency's view of what existing law *requires*.") (emphasis added).

Second, Sanofi argues that the AO now attempts to fill what HHS has previously interpreted as a "gap" in Section 340B. Sanofi Mot. at 42. Sanofi's argument cherry-picks phrases out of context from prior HHS guidance documents, and its argument does not survive closer scrutiny. Although HHS acknowledged that the statute is "silent as to permissible drug distribution systems" in the 1996 Guidance, it also interpreted the "statute" to "*direct*[] the manufacturer to sell [340B drugs] at the discounted price" regardless of the drug distribution system a covered entity employs in the very same paragraph. 61 Fed. Reg. at 43,549-50 (emphasis added). In ignoring the second part of the paragraph after the language it cites, Sanofi incorrectly attempts to force a "gap" and "inconsistency" where none exists. Sanofi Mot. 42. Further evidencing the lack of a "gap" in the statute, 42 U.S.C. § 256b(a)(1) "was fully operative" without the AO, *see Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 113 (3d Cir. 1996), and the AO did not add a requirement for manufacturers that did not already exist before the AO was issued.

Third, Sanofi's conclusory statement that the AO will be accorded "weight in the adjudicatory process," is pure speculation. *See* Sanofi Mot. 42-43. The ADR Rule and AO are independent of each other, and nothing in the ADR Rule suggests that ADR Panels are bound by documents such as the AO. That the AO may "change the way in which" Sanofi or covered entities "present themselves to the agency" during ADR proceedings does not mean that the AO is a legislative rule. *See Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003).

Sanofi's remaining argument distorts the holding of *PhRMA v. HHS*, 138 F. Supp. 3d 31 (D.D.C. 2015), by suggesting that the court rejected HHS's attempt to express its interpretation of a statute through a non-binding interpretive rule. *See* Sanofi Mot. 49-50. Such a ruling is found nowhere in the court's opinion in *PhRMA*, which addressed only the *finality* of an interpretive rule under § 704, *id.* at 47. The court never even considered the notice-and-comment requirements of § 553(b)(3)(A), or whether an interpretive rule is a proper vehicle for an agency to address a question of statutory

interpretation. In fact, the court found without hesitation that the rule at issue in *PhRMA*, was undoubtedly an interpretive rule, *id.* at 40. Thus, Sanofi's reliance on *PhRMA* is misplaced.

As in *Pennsylvania Department of Human Services v. United States*, the AO did not create new rights and obligations, but merely "represent[ed]" what the General Counsel "thinks" the statute means, and also "clarifie[d] and explain[ed] the statute." 897 F.3d 497, 505 (3d. Cir. 2018). Accordingly, the AO is an interpretive rule exempt from the APA's notice and comment requirements and Sanofi's procedural APA claim should be dismissed.[26]

B. THE GENERAL COUNSEL'S LEGAL ADVICE COMPORTS WITH THE STATUTE

HHS demonstrated in its opening brief that the General Counsel's reiteration of prior agency guidances' interpretation of the 340B statute is correct. HHS Mot. 27-31. In its opposition Sanofi offers no persuasive reason to disagree with that analysis. Even were this Court to review the AO on its merits, it does not exceed statutory authority for the same reasons that HRSA's violation letter comports with the statute, *see supra* § I.A.

C. THE ADVISORY OPINION FULLY SATISFIES APA REVIEW

Sanofi's arbitrary-and-capricious claims provide no sound basis on which to set aside the Advisory Opinion.

First, Sanofi faults the General Counsel for neither citing nor considering evidence to support a finding that contract pharmacies do *in fact* function as agents of covered entities under "state agency law." Sanofi Mot. 34–35. But that was obviously not the question the AO sought to answer. Indeed, the AO never suggested that a drug maker's obligation to sell discounted drugs to covered entities

[26] In a meager attempt to revive its "good guidance" claim after HHS pointed out that the Good Guidance Rule post-dated issuance of the AO and thus could not apply to the AO, *see* Def.'s Mot. 27, Sanofi now argues that HHS is violating the Rule because it will "use" the AO in ADR proceedings. Pl.s' Mot. 43 n.16. But, as explained previously, HHS has not, in fact "use[d]" the AO in ADR proceedings and there is no reason to believe it will. Moreover, the Good Guidance Rule prohibits the use of guidance documents only "for the purposes of requiring" an entity to "take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute." 45 C.F.R. § 1.3(a)(2). Here, the requirement to sell discounted drugs to covered entities is compelled by the statue, *supra* § I.A, so the Rule would not apply in any event.

distributing those drugs through contract pharmacies depends on whether an agency relationship can be established under the precise laws of any given state. Rather, it was in rebutting the contention that a covered entity's mere use of a contract pharmacy for distribution is *itself* unlawful drug diversion that the AO explained that the relationship between these entities generally functions like a principal-agent relationship, "in that [a contract pharmacy] would not resell a … drug but rather distribute [it] *on behalf of* the covered entity" who purchases the drug.[27] ADVOP_6 (emphasis added and citation omitted). And it was only in that sense that the AO referred to contract pharmacies as "agents" of a covered entity. Analyzing the relationships of individual covered entities and their contract pharmacies under various state laws would have been a useless exercise irrelevant to the narrow question the AO addressed. *See NVE, Inc.*, 436 F.3d at 190.[28]

Second, Sanofi suggests that the AO's interpretation of the 340B statute would preclude a drug maker from asking a covered entity for even standard logistical information, such as "the time and place of delivery" of 340B-purchase drugs, the "means of payment" for those drugs, and "who will accept the drugs upon delivery." Sanofi Mot. 36. This perplexing assertion has no conceivable basis in the AO, however, which acknowledges only that a drug maker is statutorily prohibited from imposing extra-statutory *restrictions* on the *purchase* or *sale* of 340B drugs based on the dispensing mechanism used by a covered entity. For example, for covered entities that dispense drugs through multiple contract pharmacies, Sanofi demands that they provide the drug maker with claims data as a *condition* on their *eligibility to purchase* 340B-discounted drugs. *See* ADVOP_2128 ("[C]overed entities that elect not to provide 340B claims data will no longer be *eligible to place … orders* for Sanofi products dispensed through a contract pharmacy."). This patently unlawful restriction on a covered entity's

[27] This has been the settled definition of a "contract pharmacy" for decades. *See, e.g.*, 61 Fed. Reg. at 43,550 (1996); *accord* ADVOP_1406, HHS's OIG Rep. (Feb. 4, 2014) ("A pharmacy dispensing 340B-purchased drugs *on behalf of* a covered entity is referred to as a contract pharmacy.").

[28] Sanofi's reliance on the 1996 Guidance is misplaced, as it too acknowledges that a contract pharmacy "act[s] as an agent of the covered entity, in that it would … distribute the drug on behalf of the covered entity," 61 Fed. Reg. at 43,550, but explains that "it is not essential to characterize the relationship as meeting or not meeting the standards which would serve under applicable law to establish an agency relationship," *id.* at 43,554.

ability to make 340B purchases cannot fairly be equated to a drug maker's request for information necessary to *facilitate the delivery* of 340B-purchased drugs. Sanofi muddles this obvious distinction. [29]

Third, Sanofi criticizes the General Counsel for not taking into account how Sanofi's specific contract-pharmacy policy operates in his development of the AO. Sanofi Mot. 37–38. The drug maker suggests that, had the General Counsel considered Sanofi's policy, he would have understood that it imposes "no meaningful financial or logistical burden[s]" on covered entities and is "highly effective" in collecting data on program compliance. *Id.* at 38. As an initial matter, Sanofi's complaint is belied by the record, as the General Counsel *did* review Sanofi's contract-pharmacy policy, ADVOP_2127–28, and the drug maker's own explanation of how that policy operates, *see id.* at 2108–10, 2114–16. And yet, because the AO aimed to interpret the meaning of the 340B statute as a *general* matter, without applying the statute to any individual drug maker's policy (as HRSA would later do through its 340B-violation letter), *see* AR 8 n.9, the General Counsel was under no obligation to consider Sanofi's policy. *See NVE, Inc.*, 436 F.3d at 190. Whether a drug maker believes its extra-statutory restrictions on 340B purchases will improve program compliance or will impose little to no burden on covered entities are not "relevant factors" in determining drug makers' general obligations under the 340B statute. *Id.*

Similarly, the General Counsel was under no obligation to consider whether there have been instances of duplicate discounting among covered entities with contract-pharmacy arrangements, *see* Sanofi Mot. 39, because this information also has no relevance in determining what is *generally* required of a drug maker under the 340B statute. *See NVE, Inc.*, 436 F.3d at 190. The 340B statute does not permit drug makers to unilaterally "condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *See* AO at 5 (quoting 82 Fed. Reg. 1210, 1223). Instead, as the AO explained, a drug maker must pursue claims of

[29] Sanofi further contends that HHS has found "routine data collection efforts … permissible under Section 340B," citing agency guidance from 1994. Pl's. Mot. at 36. As already explained, however, *see supra* pp. 38–39, this guidance, although permitting ministerial requests for "standard information," explicitly prohibits the type of extra-statutory data demands made by Sanofi as a *condition* on a covered entity's ability to *purchase* 340B drugs. *See* 59 Fed. Reg. at 25,113–14 ("A manufacturer may not condition the offer of statutory discounts" on a covered entity's willingness to "submit[] information related to drug acquisition, purchase, and inventory systems.").

duplicate discounting in HHS's administrative dispute-resolution process, *see* AO at 5, the forum in which Congress has required such claims to be adjudicated, *see* 42 U.S.C. § 256b(d)(3)(A).

Fourth, Sanofi contends that HHS was obligated to acknowledge that the AO marked a change in the agency's position on the question of whether the 340B statute requires drug makers to sell drugs to covered entities regardless of how those drugs are distributed. Sanofi Mot. 39–40. Sanofi's arguments on this score are meritless, for reasons already explained. *See supra* § III.B.

CONCLUSION

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

Dated: June 16, 2021

Respectfully submitted,

BRIAN NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Kate Talmor
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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

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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
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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 Two

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

EXHIBIT 3

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

SANOFI-AVENTIS U.S., LLC, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 3:21-CV-634

DECLARATION

I, Kate Talmor, make the following Declaration pursuant to 28 U.S.C. § 1746, and state that under the penalty of perjury the following is true and correct to the best of my knowledge and belief:

1. In 1996 the Pharmaceutical Research and Manufacturers of America sued the Department of Health and Human Services and its Secretary, challenging the agency's guidelines on use of contract pharmacies under the 340B Program. The docket number is 1:96-cv-1630 (D.D.C.).
2. Attached to this declaration is a true and correct copy, obtained from official archives of the Department of Justice, of the Complaint and Stipulation of Dismissal for that litigation.

Dated: June 16, 2021

KATE TALMOR
Trial Attorney
Federal Programs Branch, Civil Division
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Washington, DC 20052
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
1100 15th Street, N.W.
Washington, D.C. 20005

Plaintiff,

v.

DONNA SHALALA, in her official capacity as Secretary, United States Department of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendants.

CASE NUMBER 1:96CV01630
JUDGE: June L. Green
DECK TYPE: Civil General
DATE STAMP: 07/12/96

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), as representative of its member companies, brings this action against Defendants Donna Shalala and the United States Department of Health and Human Services ("HHS"), and for its Complaint alleges:

Nature of the Action, Jurisdiction and Venue

1. This is an action brought pursuant to 5 U.S.C. § 706(2)(A) and 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment that the contract pharmacy

guidelines adopted by the Office of Drug Pricing Program ("ODPP") of the Public Health Service ("PHS") of HHS are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA seeks a declaration that HHS has violated the Administrative Procedure Act (the "APA") and the Federal Register Act (the "FRA") by failing to comply with the statutory notice, comment, and publication provisions concerning rulemaking in issuing the contract pharmacy guidelines and that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. PhRMA also seeks a preliminary and permanent injunction directing HHS to withdraw the contract pharmacy guidelines and to give them no force or effect, and to refrain from facilitating or encouraging any entity from taking action based on the contract pharmacy guidelines in a manner that is contrary to law.

2. Jurisdiction is conferred upon this Court by 28 U.S.C. §§ 1331, 1337, and 1361, and venue is proper in this district under 28 U.S.C. § 1391(e).

Parties and Related Persons

3. The Pharmaceutical Research and Manufacturers of America is an organization that represents the country's leading research-based pharmaceutical and biotechnology companies. Investing nearly $16 billion a year in discovering and developing new medicines, PhRMA companies are the source of nearly all new drug discoveries worldwide. The interests that PhRMA seeks to protect in this litigation are germane to its organizational purposes in representing and protecting the interests of companies that discover, develop and bring

prescription drug products to market. As explained more fully below, members of PhRMA are directly affected by, and suffer substantial injury from, the actions complained of herein.

4. Defendant Donna Shalala is Secretary, United States Department of Health and Human Services, and is sued in her official capacity.

5. Defendant HHS is an agency of the United States within the meaning of the APA and is charged with the responsibility of administering a wide variety of federal programs related to health and human services, including programs implemented by the Public Health Service. The Public Health Service is responsible for overseeing and administering a variety of programs concerned with public health and health care services, including the Health Resources and Services Administration ("HRSA").

6. ODPP, an office of the Health Resources and Services Administration of the Public Health Service, is responsible for implementing the pharmaceutical price controls established by Congress under Section 340B ("Section 340B") of the Public Health Service Act (the "PHS Act"), 42 U.S.C. § 256b.

Factual Allegations

7. Section 340B provides that the Secretary of HHS "shall enter into an agreement with each manufacturer of" outpatient prescription drugs under which the manufacturer agrees to sell such drugs to "covered entities" at a discounted price determined by a statutory formula, for their use in treating "patients of the entity." Under the statutory formula, the discounted price is at

least 15.1 percent lower than the weighted average price available from the manufacturer for drugs distributed to the retail pharmacy class of trade. 42 U.S.C. §§ 256b(a)(1) & 1396r-8(c).

8. Copies of the "Pharmaceutical Pricing Agreement" are available from the Secretary and neither the form nor specific terms may be modified by participating manufacturers. Upon information and belief, certain members of PhRMA have entered into such agreements. Under the statute, if a manufacturer fails to enter into such an agreement, no federal funding will be available to states to pay for that manufacturer's covered outpatient drugs furnished to any Medicaid beneficiaries.

9. Section 340B defines "covered entities" to include a variety of recipients of identified federal grants under the PHS Act, State block grant programs, and various health care providers to whom Congress has given special Medicare and/or Medicaid reimbursement status.

10. Section 340B also includes restrictions intended to protect participating manufacturers from certain types of economic harm that could result from abuse of the pricing program. The statute prohibits diversion of the discounted drugs to the greater commercial market by prohibiting a covered entity from "resell[ing] or otherwise transfer[ing] the drug to a person who is not a patient of the covered entity." 42 U.S.C. § 256b(a)(5)(B). In addition, the statute seeks to protect manufacturers from the harm of "double discounting" by prohibiting a covered entity from submitting a claim for Medicaid reimbursement for drugs

purchased at the discounted price where the state Medicaid agency, under separate statutory authority, will itself claim a comparable rebate from the manufacturer based on its reimbursement of the entity for such drug. 42 U.S.C. § 256b(a)(5)(A)(i).

11. Some entities included on the list of entities that may participate in the PHS pricing program do not purchase or directly furnish outpatient drugs to their patients. Many of these entities are not licensed by the state in which they are located to purchase and dispense prescription drugs and do not employ personnel who are authorized to do so. Historically, some of these entities, such as community health centers, have referred patients to nearby retail pharmacies for prescriptions. Such pharmacies are not "covered entities" under Section 340B and the statute makes no provision for sales of discounted drugs to such pharmacies.

12. In implementing the statute through the standard Pharmaceutical Pricing Agreement signed on behalf of the Secretary on December 14, 1992, PHS made arrangements only to enable participation by those covered entities that can purchase and dispense prescription drugs; it made no arrangements to enable entities that use contract pharmacies to obtain the benefits of the PHS price. PHS acknowledged this in a February 23, 1993 letter to PhRMA (attached as Exhibit A), in which the Director of ODPP stated: "The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed."

13. PHS published "proposed guidelines" on contract pharmacy issues for notice and comment in the Federal Register on November 1, 1995, with the statement that "[a]fter consideration of the comments submitted, the Secretary will issue the final guidelines."

14. PhRMA and several of its member companies, as well as non-member companies, covered entities and competitors of the covered entities which are ineligible to participate in the PHS pricing program, submitted comments in this proceeding. The comments identified numerous substantive problems with the proposed contract pharmacy guidelines. In particular, comments filed by manufacturers noted that the guidelines provided no effective mechanism for preventing or detecting diversion of drugs to ineligible entities or patients or for preventing duplicate discounting. Some commented that the inclusion of contract pharmacies in the program was in violation of the statute.

15. Some time thereafter, without publicly acknowledging or responding to many of the comments, PHS posted an undated copy of the proposed contract pharmacy guidelines on the electronic bulletin board that ODPP uses to disseminate information necessary for day-to-day operation of the PHS pricing program. This electronic bulletin board, known as the Electronic Data Retrieval System ("EDRS"), is accessed by means of a computer with a modem. While EDRS has been available to manufacturers to verify the eligibility of entities to participate in the PHS pricing program, upon information and belief, PHS is aware that some

manufacturers do not or cannot use EDRS, but obtain current eligibility information by calling ODPP.

16. The electronic file initially posted by PHS (attached as Exhibit B) stated that "[p]ending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy guidelines." PhRMA has met with ODPP and HRSA staff in an attempt to persuade the agency to comply with the notice and comment procedures and to revise the posted guidelines to correct deficiencies before requiring manufacturers to comply with any such guidelines. PhRMA's counsel also has written to the Administrator of HRSA to express PhRMA's concerns and, to no avail, has sought a meeting with the Administrator to discuss these concerns.

17. Some time after the initial posting, in an undated file, PHS revised the preamble of the electronically-posted guidelines to state that the guidelines constitute a "suggested model agreement provided for informational purposes only," and stated that it was reviewing the comments that had been received in response to its initial notice of proposed rulemaking. A copy of the revised posting is attached as Exhibit C.

18. Despite the agency's efforts, in light of the legal inadequacies of its procedures, to minimize the effect of the guidelines by (belatedly) claiming that they were posted only "for informational purposes," the guidelines are currently in effect. Upon information and belief, covered entities are permitted to become eligible to obtain access to discounted prices through contracting pharmacies by

following the requirements of the electronically-posted guidelines, and pharmaceutical companies, including PhRMA members, are thereby required to make discounted drug sales to these covered entities. A letter written by the Administrator of HRSA (attached as Exhibit D), responding to a specific request by PhRMA's counsel for clarification of PHS policy, states: "If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." The guidelines therefore constitute final agency action.

19. Issuance of the contract pharmacy guidelines has had and will have an immediate and detrimental impact upon members of PhRMA. Among other things, as a direct and immediate result of the contract pharmacy guidelines, entities other than those permitted by statute are able to take advantage of the PHS discounted prices by requesting that prescription drugs purchased in the entity's name be shipped to contract pharmacies, which are commercial establishments that are in business to make money on the purchase and dispensing of prescription drugs. Such pharmacies purchase drugs for their own patients at commercial prices, not the discounted prices mandated by section 340B, and the guidelines fail to provide safeguards that would ensure the accountability of these independent businesses for their actions, or for agency oversight or monitoring of contract pharmacy arrangements. The lack of accountability and oversight will subject PhRMA's members to economic harm from the potential diversion of PHS-priced products to patients of the pharmacy, and from potential double discounting

through the combined effect of the PHS discount program and state Medicaid programs.

20. The damage to PhRMA members from implementation of the guidelines is irreparable. While the guidelines provide that a manufacturer may recover economic damages, such damages are payable to the manufacturer only by the covered entity, and recovery is authorized only after the manufacturer audits a covered entity and its contract pharmacy. Neither the statute nor ODPP guidelines provide for the manufacturer to recover the costs of any such audits, or to recover interest on any amount found to have been illegally diverted.

21. The manufacturers, moreover, have no adequate remedy at law. If a manufacturer attempted to mitigate damages by disregarding the contract pharmacy guidelines in instances where diversion is proven or suspected, there is a substantial risk that the PHS would terminate the manufacturer's agreement with the Secretary of HHS. Under the Pharmaceutical Pricing Agreement, a manufacturer is entitled only to a post-termination hearing. A termination would preclude states from receiving federal Medicaid funds to reimburse providers for the manufacturer's products, resulting in both irreparable losses to manufacturers and irreparable problems with continuity of access to covered health care for needy patients. The contract pharmacy guidelines will also cause irreparable damage to the relationship between each member of PhRMA and its commercial customers, such as retail pharmacies and others not eligible for PHS prices, whose business will be captured by those with access to PHS prices.

22. In addition, as explained more fully below, the contract pharmacy guidelines expand the scope of Section 340B by requiring manufacturers to fill orders at the mandatory discount on behalf of entities to whom manufacturers cannot legally sell under the laws of various states. Complying with the guidelines therefore places the members of PhRMA in the position of being required to violate the laws of these states, subjecting themselves to civil and criminal penalties, as well as potential loss of licenses to engage in their primary business of selling prescription pharmaceuticals in interstate commerce.

23. An actual controversy exists between the parties, and PhRMA and its members have no adequate remedy at law.

Count I

24. Plaintiff incorporates by reference the allegations contained in paragraphs 1-23 above as if fully set forth herein.

25. The Federal Register Act requires the publication in the Federal Register of any "order, regulation, rule, certificate, code of fair competition, license notice or similar instrument, issued, prescribed, or promulgated by a Federal agency," 44 U.S.C. § 1501, and of "documents or classes of documents that may be required to be published by Act of Congress." 44 U.S.C. § 1505(a)(3). The APA, in turn, requires the publication in the Federal Register of "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency." 5 U.S.C. § 552(a)(1)(D).

26. Under these provisions of law, the contract pharmacy guidelines are required to be published in the Federal Register whether they are considered substantive rules of general applicability, statements of general policy, interpretations of general applicability, or an order, regulation, rule or similar instrument issued by PHS.

27. HHS failed to publish the final contract pharmacy guidelines in the Federal Register, in violation of the APA and the FRA.

Count II

28. Plaintiff incorporates by reference the allegations contained in paragraphs 1-27 above as if fully set forth herein.

29. The contract pharmacy guidelines constitute a rule under the APA, which defines a "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy * * * ." 5 U.S.C. § 551(4).

30. Section 340B makes the discounted price available on "purchases" by covered entities, while the guidelines expand the scope of the program to make the benefits of such prices available to entities that cannot, under state law, purchase prescription drugs. For this and other reasons, therefore, HHS in issuing the contract pharmacy guidelines has done more than simply state what it believes the statute means, but has instead attempted to fill in what it views as statutory gaps based on policy rationales. *See* Exhibit D. The contract pharmacy guidelines accordingly do not constitute either interpretive rules or general

statements of policy, but rather substantive rules which the APA requires to be issued only after following notice and comment procedures. 5 U.S.C. § 553. These procedures include a requirement that in issuing final rules the agency must "consider [ ] the relevant matter presented" including comments received, and provide a "statement of their basis and purpose" 5 U.S.C. § 553(c).

31. While HHS recognized the applicability of the APA's notice and comment procedures when it first proposed the contract pharmacy guidelines -- requesting comments and announcing its intention to publish final guidelines after consideration of comments received -- it has bypassed the required procedures by largely ignoring the comments and purporting to promulgate the guidelines without publicly responding to comments received. HHS failed to comply with the notice and comment requirements of the APA, therefore, by failing to consider many of the comments that were submitted, publicly respond to comments, or publish a statement of the basis for and purpose of the guidelines in light of the comments received.

Count III

32. Plaintiff incorporates by reference the allegations contained in paragraphs 1-31 above as if fully set forth herein.

33. Even if the guidelines are considered to be statements of general policy or interpretive rules, rather than substantive rules, the APA nevertheless requires their publication in the Federal Register "for the guidance of the public" 5 U.S.C. § 552 (a)(1). *See* Count I above. The APA further provides that a person

without actual and timely notice of the terms of any such agency action "may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published." Id.

34. The EDRS system has failed to provide the actual and timely notice, as required by 5 U.S.C. § 552(a)(1), to bind all manufacturers to honor contract pharmacy arrangements in making Section 340B prices available to covered entities.

35. Upon information and belief, many manufacturers -- including members of PhRMA -- have no actual or timely notice of the contract pharmacy guidelines yet have been or will be adversely affected by the guidelines, in violation of the APA.

Count IV

36. Plaintiff incorporates by reference the allegations contained in paragraphs 1-35 above as if fully set forth herein.

37. Upon information and belief, there are a number of state laws that prohibit manufacturers from selling prescription drugs or controlled substances to covered entities that are not licensed by the state to purchase and dispense such drugs. *See, e.g.*, GA. CODE ANN. § 16-13-72(1) (Any drug manufacturer * * * may sell, give away, exchange, or distribute dangerous drugs within this state, but only to a pharmacy, pharmacist, a practitioner of the healing arts, and educational institutions licensed by the state * * *"); FLA. ADMIN. CODE. ANN. r.10D-45.0365 ("Prohibited Acts. (10) Selling or distributing a medicinal drug

to a person or establishment not licensed, permitted, or otherwise authorized by state law to possess, manufacture, repackage, wholesale, store, stock, distribute, use, sell, offer for sale, expose for sale or use, keep for sale or use, or use medicinal drugs.").

38. Nothing in Section 340B preempts state laws prohibiting manufacturers from selling drugs to unlicensed entities. Under the contract pharmacy guidelines, however, a manufacturer is *required* to make sales to unlicensed entities or be in violation of its Pharmaceutical Pricing Agreement with the Secretary -- which would jeopardize states' ability to receive federal Medicaid funding for the manufacturer's drugs, 42 U.S.C. § 1396r-8(a)(1) & (5), and consequently the manufacturer's future sales in all states.

39. As a result of the issuance of the contract pharmacy guidelines, and without authorization in the PHS Act, HHS has purported to permit entities not authorized under state laws to purchase prescription drugs and controlled substances to make such purchases, and has required manufacturers to sell to such unlicensed entities in ways that would cause manufacturers to be in violation of state licensing laws. This point was raised in the Comments filed by PhRMA in response to the Federal Register notice and has not been addressed by the agency in posting the guidelines and making them binding on manufacturers. The guidelines are for this reason arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

40. Alternatively, if the purchase is construed as a purchase by the pharmacy rather than the covered entity, the contract pharmacy guidelines exceed the authority delegated by section 340B of the Public Health Service Act, and for this reason are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count V

41. Plaintiff incorporates by reference the allegations contained in paragraphs 1-40 above as if fully set forth herein.

42. The agreement entered into by manufacturers with the Secretary of HHS pursuant to Section 340B provides that "covered entity" is defined as specified in the PHS Act and makes the discounted price available for "covered drugs * * * *purchased by* a covered entity." Section 340B(a)(1), 42 U.S.C. § 256b(a)(1). The February 25, 1993 letter from ODPP to PhRMA, quoted above, makes it clear that at the time the agreement was signed, participating manufacturers were not required to make the discounted price available to entities using contract pharmacies. Any modification of the agreement must be in writing and signed by both parties. The contract pharmacy guidelines do not comply with this requirement, but modify and expand the program by making it possible for entities not authorized to purchase prescription drugs and controlled substances to participate in the pricing program.

43. The guidelines for this reason are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Count VI

44. Plaintiff incorporates by reference the allegations contained in paragraphs 1-43 above as if fully set forth herein.

45. The contract pharmacy guidelines do not provide adequate protection against diversion of drugs sold at the mandatory discount or double discounting, as required by Section 340B. Accordingly, the guidelines are arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

Claim for Relief

WHEREFORE, plaintiff PhRMA prays that the Court award judgment as follows:

A. Declaring that HHS violated the provisions of the FRA and the APA in failing to publish the contract pharmacy guidelines in the Federal Register, as required by statute.

B. Declaring that HHS violated the APA in issuing the contract pharmacy guidelines, without complying with the statutory notice and comment provisions.

C. Declaring that the contract pharmacy guidelines are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, and that the guidelines are, therefore, null and void;

D. Preliminarily and permanently enjoining HHS and its successors, agents, employees, representatives and others acting in concert with it or them from in any way facilitating or encouraging the purchase of outpatient

drugs through the PHS pricing program by entities not entitled to do so in a manner violative of Section 340B of the PHS Act, 42 U.S.C. § 256b, and ordering HHS during the pendency of this action to withdraw the contract pharmacy guidelines and to give them no force and effect;

E. Awarding Plaintiff PhRMA its costs incurred herein; and

F. Granting Plaintiff PhRMA such other relief as the Court deems appropriate.

HOGAN & HARTSON L.L.P.

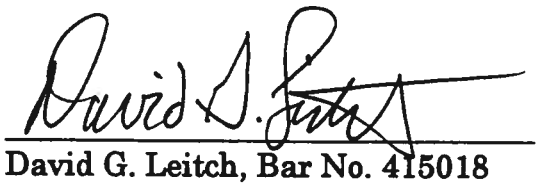

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EXHIBIT A

DEPARTMENT OF HEAL[illegible] & HUMAN SERVICES
Public Health Service
BUREAU OF PRIMARY HEALTH CARE

Health Resources and
Services Administration
Rockville MD 20857

FEB 25 1993

Mr..Joel Bobula
Manager, Public Studies
1100 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Bobula:

You have asked us to respond to a compilation of questions frequently asked by drug manufacturers regarding the implementation of section 602 of the Veterans Health Care Act of 1992. The answers reflect our current understanding of the issues and policy views and may be subject to re-evaluation. The following is a list of the Pharmaceutical Manufacturers Association's (PMA) questions followed by our answers:

1. The Public Health Service (PHS) provisions of this Act require a discount for certain eligible PHS agencies. The Department of Veterans Affairs (DVA) provisions establish another discount system. I am confused over whether those "eligible" PHS agencies can purchase under the DVA discount system instead of the PHS discount system. I am further confused as to whether the "non-eligible" PHS entities can purchase under the DVA discount system. Are PHS entities allowed to select between the PHS discount and the DVA discount? Or does this legislation and the resultant pharmaceutical pricing agreements now establish separate and different prices to the Department of Veterans Affairs and the Public Health Service?

   ANSWER: The entities eligible for discounts under the section 602 program are non-Federal recipients of specific grant assistance and certain disproportionate share hospitals. The section 603 discounts, on the other hand, are for the Federal providers within the PHS (e.g., Indian Health Service, Gillis W. Long Hansen's Disease Center and the National Institutes of Health).

2. Will PHS facilities expect a price list that is separate from (or in addition to) the Federal Supply Schedule (FSS)?

   ANSWER: If your question addresses section 603, we are not in a position to respond. As to section 602, it is the manufacturer's decision whether to provide a separate price list to each covered entity.

3. If State AIDS drug purchasing programs are qualified as PHS entities and contract with wholesaler to purchase drugs off the FSS, would they be eligible for a 24% discount or just the 15.7% price discount?

ANSWER: Unless the State AIDS drug purchasing program is a qualified FSS purchaser, they would only qualify for the PHS statutory discount. However, manufacturers may offer a greater discount, such as that offered to the FSS, if they choose to do so.

4. Section IV(a) of the draft pharmaceutical pricing agreement (page 6) states that if "a manufacturer does not sign a pharmaceutical pricing agreement with a covered entity...[it] will not be deemed to have met the requirements for a Medicaid rebate agreement." This implies a need for a separate agreement with each covered entity? Is this interpretation correct?

ANSWER: No, this was a typographical error. Signing and complying with the PHS Pharmaceutical Pricing Agreement will meet the requirements.

5. Does the PHS discount include both the basic and the CPI-U discount given to Medicaid?

ANSWER: Yes. Section 340B(a)(2)(A)(ii) of the Public Health Service Act (the "Act") describes the rebate percentage as "the average total rebate required under section 1927(c) of the Social Security Act..." Both elements are components of the section 1927(c) discount.

6. Please describe the calculations for determining the PHS discount prices for generic and over-the-counter (OTC) products.

ANSWER: To calculate the price for an over-the-counter or generic drug, the rebate percentage will be 10% of the Average Manufacturer's Price (AMP) for calendar quarters between January 1, 1991 and December 31, 1993 and 11% of the AMP for calendar quarters beginning on or after January 1, 1994. See section 340B(a)(2)(B) of the Act.

7. Is a drug that was classified as innovator multi-source under the Medicaid rebate program that now is sold as an OTC drug discounted differently under the pharmaceutical pricing agreement with PHS?

ANSWER: This determination will follow the same guidelines as utilized by the Health Care Financing Administration (HCFA). It will depend upon how the drug is reported to HCFA. If the drug is reported as an innovator multi-source product, the discount will be determined by reducing the AMP by the rebate percentage (15.7% or "best price" plus CPI-U), section 340B(a) of the Act. If the drug is reported as an OTC, the AMP is reduced by 10% between January 1, 1991 and December 31, 1993. If the drug is reported as an innovator multi-source OTC, the drug will be considered OTC.

8. The Act requires a discount to PHS entities not to exceed the preceding quarter's Medicaid effective discount. Since a quarter's Medicaid discount is not known until 30 days following a quarter, this calculation cannot be done for the first part of the quarter. How will PHS address this issue?

ANSWER: The discount should be calculated utilizing data from the most current quarter available to the manufacturer.

9. What calendar quarter do we use to calculate PHS prices effective December 1, 1992 and January 1, 1993? How often will we need to recalculate?

ANSWER: Calculations are to be performed quarterly utilizing data from the most current quarter available to the manufacturer.

10. What is to be done when the Medicaid basic rebate amount changes a few quarters after the "covered entities" price has been determined and purchases made? Do adjustments need to be made to those units purchased by "covered entities"?

ANSWER: Purchases made when a new quarterly price is in effect are governed by the new price. See section 340B(a)(1) of the Act.

11. Can you please address how PHS will assure the confidentiality of the Medicaid best price (which is assured under the Medicaid Rebate Law) and at the same time provide a discounted price to thousands of PHS entities that is based on the effective Medicaid rebate?

ANSWER: "Best Price" and AMP information will be requested only from those manufacturers who do not participate in the Medicaid program, and then, only for audit purposes to ascertain compliance with statutory requirements. PHS will consider this data and pricing data obtained from HCFA as confidential. Further, the Secretary will require, under a reasonable schedule of implementation, that covered entities not reveal confidential drug pricing information. See the PHS Pharmaceutical Pricing Agreement, section III(f).

12. The Medicaid Rebate Law exempts certain drugs. Does the PHS Act include or exclude such drugs?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." The term incorporates both section 1927's general definition, (k)(2), and the limiting definition, (k)(3), of "covered outpatient drug." Section 340B of the Act does not incorporate the list of drugs subject to restriction, section 1927(d)(2) of the Social Security Act; therefore, these are not excluded.

13. How has the interpretation been made that generic drugs are covered under the PHS provisions of the Act, but not under the VA provisions?

ANSWER: Section 340B(b) of the Act refers to section 1927(k) of the Social Security Act for the definition of "covered outpatient drug." This definition does not exclude generic drugs. The DVA program is governed by a different statute.

14. Is the discount to PHS entities for "outpatient" drugs only?

ANSWER: Yes. See section 340B(a)(2) of the Act.

15. Does a manufacturer have to provide discounts to disproportionate share hospitals for "covered outpatient drugs" used by inpatients, or are the discounts limited to drugs utilized by outpatients?

ANSWER: A covered outpatient drug does not include any drug, biological product or insulin provided as part of, or incident to and in the same setting as inpatient services (and for which payment is made

as part of payment for the services and not as direct reimbursement for the drug). See section 340B(b) of the Act and section 1927(k)(3) of the Social Security Act.

16. Is only a portion of the hospital's drug purchases, that is the disproportionate share portion, covered by the Act?

ANSWER: The discount is for all covered outpatient drugs, without regard to whether they are for low-income individuals who are not Medicare or Medicaid beneficiaries.

17. How will PHS validate that a disproportionate share hospital does not obtain outpatient drugs through a group purchasing organization?

ANSWER: After receiving a list of eligible disproportionate share hospitals, a manufacturer may verify what covered outpatient drugs, if any, are purchased through a group purchasing organization or other group purchasing arrangement. See PHS Pharmaceutical Pricing Agreement, section IX(c). These drugs need not be sold at a discount to the hospitals.

18. When will manufacturers receive a list of covered disproportionate share hospitals?

ANSWER: On December 15, 1992, a PHS Pharmaceutical Pricing Agreement along with a computer disc containing a list of covered entities (including a list of covered disproportionate share hospitals) was mailed to all manufacturers participating in the Medicaid program. Other manufacturers will be notified by Federal Register Notice to contact the Drug Pricing Program for a copy of the list.

19. With respect to the other covered entities, how many entities are included? What are their 1991 estimated pharmaceutical purchases?

ANSWER: There are approximately 9,800 entries on the disc of covered entities mailed to Medicaid-participating manufacturers. This disc lists covered entities receiving grant funds in the eligible programs. Because entities can receive funds from several grant programs, this list contains some entities entered more than once. An unduplicated list of approximately 7,000 covered entities has been prepared and will be mailed to manufacturers.

At this time, we do not have the estimated pharmaceutical purchases for the covered entities.

20. When will the pharmaceutical companies receive the list of eligible PHS entities? If it is after December 1, 1992, does the manufacturer need to rebate the entities?

ANSWER: A computer disc of covered PHS entities was mailed to Medicaid-participating drug manufacturers on December 15, 1992. All entities contained on the disc are eligible for drug discounts retroactive to December 1, 1992.

21. What are we supposed to do about customers that say that they are a "covered entity" and entitled to provisions under the law before we have the list of covered entities (between December 1, 1992 and the date the list is available)?

ANSWER: Medicaid-participating drug manufacturers should have received a copy of the disc containing the covered entities. Any manufacturer who has not as yet received a list of covered entities may contact:

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

22. If hospitals that initially do not qualify as disproportionate share hospitals later meet the necessary requirements, will HCFA send notices of the newly qualified hospitals eligible for the PHS discounts, or is it up to the hospital and the manufacturer to make this determination?

ANSWER: HCFA will notify PHS of changes in entity eligibility, and the Drug Pricing Program will provide timely notification to participating drug manufacturers of additions to and deletions from the list of disproportionate share hospitals.

23. If we have a question concerning whether a clinic or health center is a covered entity, who can we call and what is their phone number?

ANSWER: Marsha Alvarez, R. Ph.
Director, Drug Pricing Program
Health Resources and Services Administration
Bureau of Primary Health Care
Rm 7A-55 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (301) 443-0004

24. When a community health center has multiple service sites, who purchases drugs for those sites? Do they purchase as a group and distribute drugs to individual sites?

ANSWER: For information concerning the community health center drug distribution system, you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

25. What is the PHS intent regarding the discounting of drugs dispensed by retail pharmacies to community and migrant health center patients? Will we be required to give contract prices to all of the covered entities regardless of type of pharmacy (in-house, contracted, physician dispensing)?

ANSWER: Discount pricing for covered outpatient drugs must be offered to all in-house pharmacies and in-house physician dispensing systems of eligible covered entities. The issue of including contract pharmacies and outside physician dispensing systems in the discount chain is currently being considered. The potential for drug diversion is a consideration, and a mechanism for its prevention has not as yet been developed.

26. Since the vast majority of entities listed as community and migrant health centers have contract pharmacies, how can these pharmacies segregate drugs purchased by patients of PHS entities and other patients? It would appear that there is a tremendous potential for diversion, fraud and unfair competition to other local retailers. How will PHS address this issue?

ANSWER: PHS is sensitive to the potential for drug diversion and is currently considering mechanisms for its prevention. The issue of including contract pharmacies in the drug discount chain has yet to be resolved.

27. When a community health center arranges for pharmacy services through a commercial retail pharmacy, who purchases the drug that is dispensed to the patient? Does the community health center "reimburse" the retailer, or does the retailer file the Medicaid claim if the beneficiary is eligible?

ANSWER: For information concerning the community health center drug distribution system you can contact the National Association of Community Health Centers (tel: (202) 659-8008).

28. Hasn't the duplicate discount prohibition of H.R. 5193 financially handicapped PHS clinics with a significant percentage of Medicaid patients?

ANSWER: We interpret section 340B(a)(5)(A)(i) of the Act to refer to Medicaid rebates and not Medicaid reimbursements.

29. How will a PHS covered entity that contracts for pharmaceutical services with a retail pharmacy benefit (if at all) from H.R. 5193?

ANSWER: The issue of including a contract pharmacy in the drug discount chain has yet to be resolved.

30. The duplicate discount provision precludes requests for payments for covered drugs subject to a Medicaid rebate. How will PHS enforce this provision?

ANSWER: The statute gives the Secretary one year from the date of enactment to devise a mechanism to prevent potential duplicate discount/rebates, section 340B(a)(5) of the Act. The Secretary of PHS has agreed to develop this mechanism within 120 days after the effective date of the PHS Pharmaceutical Pricing Agreement or the provisions of section 1927(a)(5)(C) of the Social Security Act will become effective.

31. What is the manufacturer supposed to do about potential duplicate discounts before an enforcement mechanism is in place?

ANSWER: The manufacturer and the entity can, in good faith, attempt to resolve the dispute. If unsuccessful, the manufacturer may provide written notice of the discrepancy to the Secretary. The manufacturer and the Secretary will devote their best efforts to resolving the dispute within sixty days. If the Secretary believes that a violation

has occurred, the Secretary will initiate the notice and hearing process. If a violation is found to have occurred, the entity will be liable to the manufacturer of the covered drug that is the subject of the violation in an amount equal to the reduction in the price as required by section 340B(a) of the PHS Act. See the PHS Pharmaceutical Pricing Agreement, section VI(a).

32. How are manufacturers to know that the PHS clinics are only purchasing products for non-Medicaid use?

ANSWER: A drug discount is available for all clinic patients, Medicaid or not, provided that a Medicaid rebate is not also requested for the discounted drug.

33. Example: In March a clinic is added as a covered PHS entity, and as of March the state excludes the clinic's drug purchases from Medicaid rebate invoices. Do we have to provide that clinic the "effective Medicaid price" for sales that occurred in January or February? If so, why, especially given that the manufacturer has already paid a rebate to the state. In general, who comes first, the state or the clinic?

ANSWER: Only those entities included on the initial computer list mailed to drug manufacturers on December 15, 1992, are eligible for retroactive drug discounts to December 1, 1992. All entities added to the list of covered entities at a later date will be eligible for drug discounts as of the date of their inclusion on the list.

34. Is the manufacturer permitted to terminate an agreement to any PHS facility that violates the resale prohibition?

ANSWER: No. See answer #31.

36. Some manufacturers do not sell to retail pharmacies, doctors and other entities identified in H.R. 5193. How can these entities participate in a prime vendor arrangement?

ANSWER: The prime vendor program has not as yet been developed.

37. Is the "prime vendor" requirement applicable only to specifically identified PHS eligible entities?

ANSWER: The prime vendor program has not as yet been developed.

38. Do manufacturers have the right to audit wholesalers under the prime vendor requirement? Where is this spelled out for the parties in question?

ANSWER: The prime vendor program has not as yet been developed.

We hope the answers have clarified our current position regarding implementation of the Act. If you have any further questions, please do not hesitate to contact Kathryn Lotfi, Office of General Counsel (tel: (301) 443-2006).

Sincerely yours,

Marsha Alvarez

Marsha Alvarez, R. Ph.
Director, Drug Pricing Program

EXHIBIT B

Guideline: Contracted Pharmacy Services

Pending publication of final regulations, the Office of Drug Pricing has developed the following contracted pharmacy service guidelines. These guidelines are designed to facilitate program implementation in covered entities that wish to utilize contracted pharmacy services to dispense section 340B outpatient drugs but do not have access to an "in-house" pharmacy. The agreement between the covered entity and the pharmacy should include the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each facility which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per facility does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these facilities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding

office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services

Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain

to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

File: CONTRACT.GDL

EXHIBIT C

Guideline: Contracted Pharmacy Services

The following is a suggested model agreement provided for informational purposes. The Department is currently reviewing comments to the proposed contract pharmacy model agreement published in the Federal Register on November 1, 1995 (60 FR 55586). All comments received in response to the notice will be considered in developing the final model agreement. Covered entities that do not have access to an appropriate "in-house" pharmacy, and wish to use contracted pharmacy services to access section 340B pricing, are encouraged to sign and have in effect an agreement with the pharmacy contractor which includes the following provisions:

(a) The covered entity will purchase the drug. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these entities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records, if applicable.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. See section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal panalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price of the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors". These regulations are codified at 42 C.F.R. 100.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion for violations of the anti-kickback statute. Two of the safe harbors that may pertain to arrangements between contractors and covered entities involve discounts and personal services or management contracts.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a notarized self certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

MAY 7 1996

Mr. Russel A. Bantham
General Counsel and Senior Vice President
Pharmaceutical Research
and Manufacturers of America
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

Dear Mr. Bantham:

This is in response to your letter of April 4 concerning the contracted pharmacy interpretative policy guideline drafted by the Office of Drug Pricing (ODP). These guidelines were published in the Federal Register for notice and comment on November 1, 1995.

You state that the ODP "has gone forward without modifications of its proposal as if no comments were received." On the contrary, PhRMA comments, as well as all other comments submitted in response to the request for public comment, were considered in drafting the final contracted pharmacy services guideline. During this review process, the ODP revised the guideline in response to comments and placed the revised guideline on the Electronic Data Retrieval System (EDRS).

Public comments with program responses will be posted on the EDRS in the near future. We anticipate publishing a further notice in the Federal Register which will include a discussion of the comments received and the reasons for accepting or not accepting particular comments.

In addition, you characterize the contracted pharmacy services guideline as a "substantive rule," subject to the rule-making requirements of the Administrative Procedure Act. We believe this guideline is an interpretative policy guideline and was published in the Federal Register for informational purposes and to determine any need for further safeguards. Therefore, we do not believe this guideline generates regulatory concern.

It is important to understand that section 340B requires manufacturers to use a ceiling price for covered outpatient drugs purchased by the covered entity. The statute is silent as to permissible drug distribution systems and does not require the entity to purchase directly from the manufacturer or dispense the drug itself. It is apparent that Congress envisioned various types of drug delivery mechanisms - those that would be appropriate to meet the needs of the various covered entities.

In addition, the legislation would be advantageous only to a very small percentage of the covered entities, if it were to limit the program to only those entities which use in-house pharmacies. Therefore, recognizing the congressional mandate that all covered entities wishing to participate in the program have access to such discount pricing, ODP does not recognize a distinction in a manufacturer's obligation based on the manner in which entities purchase and dispense drugs. However, because of concerns expressed to ODP about the potential for drug diversion in the contract pharmacy approach, ODP thought it wise to develop guidelines (with public input) which would recognize at least one arrangement for contract pharmacy services that greatly reduces the risk of such diversion.

The guidelines were made available for the benefit of both participating manufacturers and covered entities. The mechanism described in the guidelines has been used by a number of large organizations such as the American Red Cross, the National Association of Community Health Centers, the Association for Utah Community Health Center, and the New York Blood Consortium.

Of course, this mechanism is not the only method of reducing the potential for drug diversion, but it is the system developed by ODP. If entities can propose other systems which would be equally as effective, ODP is very willing to review all proposed mechanisms.

If an eligible covered entity utilizing this mechanism requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs that shipment to its contracted pharmacy, we see no basis to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from compliance with the agreement.

We hope that this information has been helpful. Should you have further questions, please do not hesitate to call Stephen Wickizer, Acting Director, ODP, at (301) 594-4353.

Yours sincerely,

Ciro V Sumaya

Ciro V. Sumaya, M.D., M.P.H.T.M.
Administrator

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

DONNA SHALALA, et al.

Defendants.

Let this be filed this 7th day of Oct. 1996

C.A. No. 96-1630 (JLG)

STIPULATION OF DISMISSAL

The parties to this litigation hereby stipulate, pursuant to Federal Rule of Civil Procedure 41(a)(1), to the dismissal without prejudice of this action and all claims asserted herein, each party to bear its own attorney's fees and costs.

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