IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	C.A. No. 21-27-LPS

JOINT STATUS REPORT

Undersigned counsel respectfully submit this joint status report pursuant to the Court's oral order at the hearing held on October 18, 2021 (D.I. 103). The Court directed the parties to inform the Court of "anything you want to tell me," including "your perspectives on the urgency" of a ruling on the pending cross-motions for summary judgment, as well as "any developments in the ADR process" or "any response to the inquiries that AstraZeneca has made." *Id.* at 95-96.

The parties' respective statements are set forth below:

1. **Plaintiff**

AstraZeneca respectfully urges the Court to facilitate resolution of the parties' dispute with the greatest expedition possible. Notwithstanding this Court's ruling that their view of the 340B statute is "legally flawed," D.I. 78 at 17, Defendants have resolved to press forward administratively on multiple fronts, threatening punitive and persistently accumulating sanctions

against AstraZeneca. The *only* thing that can keep Defendants from inflicting these harms is a ruling by this Court making clear that doing so would be inconsistent with the law.

ADR: As the Court is aware, four separate ADR petitions have been filed against AstraZeneca, which HRSA has now assigned to panels for formal proceedings. AstraZeneca believes that the ADR proceedings are unfair and legally faulty, including on multiple constitutional grounds. *See* 2d Am. Compl. (D.I. 86) at ¶¶ 117-131 (describing violations of the Appointments Clause and Article III). AstraZeneca is currently challenging the ADR process through a suit filed by Pharmaceutical Research and Manufacturers of America (PhRMA), of which AstraZeneca is a member. *See PhRMA* v. *Becerra*, No. 21-cv-198-PWG (D. Md.); *see also Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393 (S.D. Ind. Mar. 16, 2021) (agreeing with Eli Lilly that the ADR Rule violated the APA and preliminarily enjoining Defendants "from implementing or enforcing" the ADR Rule against Eli Lilly). In addition, as this Court has explained, ADR proceedings do not provide a meaningful venue for contesting Defendants' interpretation of the 340B statute: "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained." D.I. 78 at 17.

Upon being informed of the assignment of the four ADR petitions against it, AstraZeneca sent HRSA a letter inquiring about the composition of the panels and the deadlines (if any) for responding to the petitions, including the opportunity to seek a stay pending this Court's decision on the parties' fully briefed dispositive motions. As of the hearing held by this Court on October 18, AstraZeneca had not received a response. Following the hearing, AstraZeneca filed motions with HRSA to extend any responsive deadlines that may apply until after this Court's ruling.

On October 23, one of the ADR panels issued a scheduling order directing AstraZeneca to respond to the petition, move to dismiss, or seek a stay by November 21. The order also

indicated that the parties will be granted, as a matter of right, one 30-day extension. Should AstraZeneca seek and receive a 30-day extension of its initial deadline, its new deadline would be December 21.

Also on October 23, HRSA informed AstraZeneca that its extension motions had been "forwarded to" the other three ADR panels assigned to the petitions against it. AstraZeneca has received no further information about the relevant deadlines for responding to those petitions, however, nor any further response to its earlier inquiries regarding the composition of the panels and the opportunity to seek a stay pending this Court's ruling. As a consequence, if AstraZeneca's motions for an extension are not granted, AstraZeneca's responses to those three ADR petitions could be due as soon as November 4. *See* 85 Fed. Reg. at 80,639 (providing for a response deadline of 30 days from notification).

CMP: As the Court is also aware, on September 22, AstraZeneca received a letter from HRSA referring AstraZeneca to the agency's Office of the Inspector General (OIG) for proceedings to impose CMPs against AstraZeneca for its contract pharmacy policy. Following this Court's summary judgment hearing, and in light of the Court's order to file a joint status report, AstraZeneca reached out to counsel for Defendants with several questions regarding the CMP proceedings: Who within OIG is handling the proceedings; what is the current status and timeline for those proceedings; and will they proceed in advance of this Court's ruling on the parties' summary judgment motions?

Counsel for Defendants did not answer AstraZeneca's questions, but provided AstraZeneca with email addresses for two OIG officials to whom AstraZeneca's questions about the CMP proceedings could be directed. AstraZeneca emailed those officials with its questions on October 22. On October 25, an OIG official responded that they would be willing to meet but

"will not discuss specific issues related to eventual CMPL enforcement of this matter at this time."

Need for prompt decision: Throughout this litigation, AstraZeneca has proceeded with expedition commensurate with the harms presented as a result of Defendants' actions. AstraZeneca filed suit against the Advisory Opinion on January 12, less than two weeks after the Opinion was first issued. At the outset of the litigation, AstraZeneca initially moved for a preliminary injunction in view of the irreparable harms that it faced, but agreed to stay its motion in favor of expedited briefing and argument on the parties' cross-motions. D.I. 23 ¶ 7. When HRSA threatened to refer AstraZeneca for CMPs on May 17—shortly before this Court's scheduled hearing on the first round of fully briefed summary judgment motions—AstraZeneca filed an emergency motion for administrative stay or, in the alternative, for expedition. D.I. 66. This Court denied the stay but granted the request for expedition, accelerating the motions hearing by two weeks. D.I. 71. The Court then ruled on the parties' motions 20 days after the hearing. D.I. 78.

AstraZeneca had hoped and expected that this Court's ruling—which, among other things, observed that Defendants' position was "legally flawed," D.I. 78 at 17—would cause Defendants to alter their conduct in conformity with the principles articulated by this Court. Instead, Defendants have escalated their efforts to punish AstraZeneca for its contract pharmacy policy. As counsel for Defendants have repeatedly made clear, Defendants will press forward unless and until this Court definitively rules on the meaning of the 340B statute in a way that precludes further administrative action. 1st Summ. J. Hr'g Tr. (D.I. 76) at 84, 109; 2d Summ. J. Hr'g Tr. (D.I. 103) at 69-71.

The ongoing administrative proceedings (CMP and ADR) threaten to inflict imminent harm on AstraZeneca. For every month that AstraZeneca does not acquiesce to Defendants' erroneous view of the 340B statute, it risks hundreds of millions of dollars in CMPs. *See* D.I. 66 at 4 (citing Caprisecca Decl. ¶¶ 8-10). These threatened penalties will continue to accumulate pending this Court's decision: As this Court aptly explained, the propriety of CMPs "ultimately [depends on] whoever wins on the statutory interpretation," because in the wake of that ruling, "either there is going to be a basis for penalties or there isn't." 1st Summ. J. Hr'g Tr. (D.I. 76) at 100. And AstraZeneca simultaneously faces an unconstitutionally structured ADR process, in which "the result is preordained," D.I. 78 at 17, which is a form of irreparable harm in itself. Indeed, given the "important individual liberty interests" protected by separation-of-powers principles, the Third Circuit has held that such a structural violation is "presumed" to cause constitutional harm to the litigant, such that an immediate "hearing on the merits is favored." *Cirko ex rel. Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 154-55 (3d Cir. 2020). In addition, Defendants' administrative actions—which incorrectly accuse AstraZeneca of violating its statutory obligations—have caused and will continue to cause significant "damage to [AstraZeneca's] reputation, which constitutes irreparable injury that is difficult to quantify" or to correct through litigation. *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 212 (3d Cir. 2014); *see* D.I. 66 at 4 (summarizing declaration describing "reputational harms, including among AstraZeneca's customers, covered entities, and investors").

For the foregoing reasons, AstraZeneca respectfully asks the Court to rule on the parties' motions as expeditiously as possible. Despite its diligent efforts over the past year, AstraZeneca remains in an administrative vacuum on multiple fronts, with no clear timetable for resolution

and no assurance that the agency will respect this Court's ruling. Absent relief from this Court, AstraZeneca has nowhere else to turn.

2. **Defendants**

As mentioned above, today an employee of HHS's Office of Inspector General responded to Plaintiff's email posing questions regarding HRSA's CMP referral. OIG's response read, in full: "OIG is available to speak with you and will attempt to answer any questions you have; however, we will not discuss specific issues related to eventual CMPL enforcement of this matter at this time. Please contact Susan Gillin and me directly with all issues related to this matter."

In this report Plaintiff argues that it faces irreparable harm due to the unconstitutional nature of the administrative process, yet Plaintiff has not challenged the ADR Rule either on constitutional or any other grounds, nor is any motion for relief from those proceedings pending.

As Plaintiff mentions above, on October 22, 2021, one of the ADR panels assigned to review a petition pending against AstraZeneca entered an initial scheduling order. Not only did that order grant Plaintiff 30 days from its issuance to file a response, plus the ability to obtain an additional 30-day extension as of right (meaning that, as a practical matter, no response is due until December 21, 2021), the scheduling order specifically contemplated that Plaintiff's response can take the form of "a motion to stay the proceedings in this matter" or a motion to dismiss under Federal Rule of Civil Procedure 12. Should Plaintiff file such a motion, the petitioner will have 21 days to respond, and Plaintiff will have an additional 14 days to reply in support of its motion. Although the panels assigned to review the other three petitions pending against Plaintiff have not yet entered a scheduling order, there is no reason to believe that Plaintiff will need to respond to those proceedings significantly more quickly than the

proceeding in which a scheduling order has been entered.

Although Defendants do not believe that the ADR proceedings necessitate a quick ruling from this Court, Defendants respectfully request an expeditious ruling from this Court due to the continuing overcharges and accruing harms caused by Plaintiff's unlawful refusal to honor its statutory obligations. As discussed at the hearing on October 18, 2021, HRSA's most-recent data show that Plaintiff is continuing to sell 340B drugs directly to covered entities in their 340B accounts at full commercial pricing (wholesale acquisition cost). In August 2021 alone, HRSA documented $2.5 million in overcharges, specifically on AstraZeneca's drugs, to covered entities directly in their 340B accounts. These continuing overcharges threaten the viability of resource-strapped safety-net providers, as documented in the administrative record. Defendants respectfully contend that an expedited ruling is preferable so that covered entities can once again access the discounts they have received for decades and to which they are statutorily entitled.

Dated: October 25, 2021

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

950 F Street N.W., Suite 300, Washington, D.C., on behalf of itself and its members,

Plaintiff,

vs.

NORRIS COCHRAN,

200 Independence Avenue S.W., Washington, D.C. 20201, in his official capacity as Acting Secretary of the U.S. Department of Health and Human Services;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue S.W., Washington, D.C. 20201;

DIANA ESPINOSA,

5600 Fishers Lane, Rockville (Montgomery County), Maryland 20852, in her official capacity as Acting Administrator of the Health Resources and Services Administration; and

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

5600 Fishers Lane, Rockville (Montgomery County), Maryland 20852,

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) brings this suit on behalf of itself and its members, and alleges as follows:

INTRODUCTION

1. PhRMA challenges a final rule that the U.S. Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) rushed to publish in the final days of the Trump Administration in an effort to moot several recently-filed lawsuits filed against those agencies. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80632 (Dec. 14, 2020) (ADR Final Rule). The ADR Final Rule governs disputes that arise in the 340B Drug Pricing Program (340B Program), which Congress enacted in 1992 to help underserved and vulnerable patients. Under the 340B Program, pharmaceutical manufacturers that participate in the Medicaid and Medicare Part B programs must offer steep discounts on their prescription medications (at or below a statutorily-set ceiling price) to qualifying hospitals and clinics (known as "covered entities") that provide medical care to these patients.

2. PhRMA and its members support the goals of the 340B Program. But, as Congress recognized, the legitimacy of this program depends on enforcement of statutory safeguards that prohibit covered entities from (1) causing "duplicate discounts" on the same drug (one under Medicaid and another under the 340B Program), or (2) diverting drugs to persons not entitled to them under the 340B law, *i.e.*, "resell[ing] or otherwise transfer[ing]" a drug they purchase under the 340B program "to a person who

is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Congress also directed HHS to establish an Administrative Dispute Resolution (ADR) process to resolve disputes over violations of these safeguards, as well as claims by covered entities that they have been denied discounts. *Id.* at § 256b(d)(3)(A).

3. After failing for a decade to establish this process, HRSA suddenly revived and altered a moribund ADR proposal, then published it as a final rule within weeks of being sued for its failure to comply with the statute. In its haste, HRSA issued a rule that is arbitrary and capricious—not the product of reasoned decision-making—and unconstitutional.

4. Overwhelming evidence demonstrates that the 340B Program is now plagued by problems of diversion and duplicate discounts. These problems, moreover, are directly attributable to decisions that HRSA has made in overseeing the program over the course of two decades. HRSA has allowed covered entities to use an unlimited number of third-party commercial pharmacies, or so-called "contract pharmacies," to acquire and distribute drugs under the 340B Program. And it has failed to provide a precise definition of the "patients" of covered entities that are entitled to receive the discounted drugs. Together, these decisions have created an environment in which the 340B Program's "good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription drugs." Letter from Adam J. Fein to the Hon. Lamar Alexander and the Hon. Greg Walden (Oct. 30, 2020) ("Fein Letter").

5. Making matters worse, HRSA has imposed undue burdens on manufacturers' statutory right to audit covered entities to determine whether these entities are complying with the prohibitions on diversion and duplicate discounts. *See* 42 U.S.C. § 256b(a)(5)(C). And HRSA has repeatedly failed to police and remedy these abuses itself, making it all the more critical that manufacturers be able to seek the "fair[], efficient[], and expeditious[]" resolution of claims of diversion and duplicate discounts through the ADR process, 42 U.S.C. § 256b(d)(3)(B), as Congress intended.

6. In a 2010 Advance Notice of Proposed Rulemaking (ANPRM) on ADR, as well as its 2016 ADR proposed rule, HRSA explicitly asked if it should alter its manufacturer audit guidelines, because audits are a prerequisite to a manufacturer's ability to initiate ADR claims under the statute. 42 U.S.C. § 256b(d)(3)(B)(iv). Manufacturers responded by submitting evidence of the then-growing problems of diversion and duplicate discounts, and explaining (among other things) that, because an audit is a statutory pre-condition to manufacturer-initiated ADR, HRSA's burdensome and legally flawed audit guidelines should be revised so manufacturers can meaningfully police such abuses.

7. HRSA failed to take any action on its proposed rule for several years. Late last year, however, several covered entities sued the agency over its inaction. Shortly thereafter, HRSA hurriedly finalized its long-dormant ADR rule for the expedient purpose of mooting those lawsuits.

8. In doing so, HRSA failed to modify the flawed audit guidelines. Moreover, HRSA acted on the basis of a stale record, refusing to consider new evidence that

highlighted the growth in 340B Program abuse and the now even more urgent need for manufacturer-initiated ADR to address statutory violations and seek relief. In addition, HRSA failed to offer any meaningful response to comments explaining the need for revised audit guidelines. Instead, by leaving them in place, HRSA effectively ratified—and gave new legal force to—guidelines that severely restrict manufacturers' ability to audit covered entities for diversion and duplicate discount violations, and thus restrict manufacturers' ability to bring ADR claims (as a manufacturer audit is a precondition to such claims). Further, because the guidelines exceed HRSA's statutory authority to regulate only the "number, duration, and scope of audits," they are themselves contrary to law. 42 U.S.C. § 256b(a)(5)(C). Most significantly, the guidelines improperly require manufacturers to have "reasonable cause" to conduct an audit, when the very purpose of audits is to detect whether a given entity is committing violations.

9. At the same time, HRSA failed to address significant policy questions critical to the fair and efficient operation of the 340B Program, such as defining who is a "patient" of a covered entity entitled to receive drugs subject to the 340B discount. Instead, HRSA punted the resolution of these and other critical policy questions to ADR panels. But these panels are composed of politically unaccountable agency employees who are not appointed by the President and confirmed by the Senate. And HRSA chose, in the ADR Final Rule, to give panel decisions binding and precedential effect, without further review by agency officials who are so appointed and confirmed. In doing so, HRSA violated the Appointments Clause of Article II of the Constitution.

10. As PhRMA explains in greater detail below, these defects render the ADR Final Rule unlawful and unconstitutional. The Court should therefore set aside, vacate, and remand that rule to the agency.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, because this is an action arising under federal law, and pursuant to 28 U.S.C. § 1346(a)(2), because this is a civil action against the United States based on a regulation of an executive department.

12. Venue is proper under 28 U.S.C. § 1391(e)(1)(A), because this is a civil action in which a defendant is an officer or employee of the United States, sued in her official capacity, who performs her official duties in this District. Venue is also proper under 28 U.S.C. § 1391(e)(1)(B), because a substantial part of the events or omissions giving rise to PhRMA's claims occurred in this District.

13. Plaintiff brings this action under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

14. This Court has the power to grant injunctive and declaratory relief pursuant to 5 U.S.C. §§ 701–706 and 28 U.S.C. §§ 2201–2202.

PARTIES

15. Plaintiff PhRMA is a non-profit Delaware corporation, with offices located in Washington, D.C. PhRMA's members are the country's leading research-based pharmaceutical and biotechnology companies, devoted to creating new medications that allow people to live longer, healthier, and more productive lives. (A list of PhRMA members can be found at www.phrma.org.) PhRMA's members develop life-saving and

life-enhancing medicines that are prescribed and sold throughout the nation, including vaccines and therapeutics to prevent, diagnose, and treat COVID-19. *See* PhRMA, *The Biopharmaceutical Industry Is Leading the Way in Developing New Vaccines and Treatments for COVID-19* 1 (Nov. 2, 2020), *available at* https://onphr.ma/35Up8la. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state policymakers, and the courts. This suit seeks to protect interests that are germane to PhRMA's core concerns, including its interest in ensuring that regulations governing the resolution of disputes that concern discounts pharmaceutical manufacturers provide under government benefit programs—and that can lead to potential enforcement actions—are fair, reasonable, and designed to further the proper functioning of that program consistent with applicable law.

16. Numerous PhRMA members have entered into pharmaceutical pricing agreements with HHS under the 340B Program, and will be adversely affected by the ADR Final Rule. Some covered entities have already invoked the ADR process and filed claims against PhRMA members. *See Nat'l Ass'n of Community Health Ctrs. v. Eli Lilly and Co., et al.*, Petition No. 210112-2 (HHS Jan. 13, 2021).

17. Neither the claims asserted nor the relief sought in this Complaint requires the participation of any individual PhRMA members.

18. Defendant Norris Cochran is the Acting Secretary of HHS. He oversees HRSA and the 340B Program, and performs his official duties at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity only.

19. Defendant HHS is an executive department of the United States, headquartered in Washington, D.C. and responsible for HRSA and the 340B Program.

20. Defendant Diana Espinosa is the Acting Administrator of HRSA. She administers the 340B Program—including the ADR Rule—and oversees HRSA's other activities. She performs her official duties at 5600 Fishers Lane, Rockville, Maryland 20857. She is sued in her official capacity only.

21. Defendant HRSA is an administrative agency within HHS that is headquartered at 5600 Fishers Lane, Rockville, Maryland 20857, and administers the 340B Program.

BACKGROUND

A. The 340B Program

22. In 1992, Congress established the 340B Program to improve access to certain outpatient drugs for health care providers providing clinical care to poor, uninsured, underinsured, and otherwise vulnerable patient groups. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602(a), 106 Stat. 4943, 4967 (adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b); *see also* H. Rep. No. 102-384 (II), at 11-13 (1992). Under the 340B Program, drug manufacturers must charge no more than a deeply discounted "ceiling price" for covered outpatient drugs purchased by specified "covered entities." 42 U.S.C. § 256b(a)(1). Pharmaceutical manufacturers must participate in the 340B Program as a condition of receiving federal reimbursement for their products under Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1), (5).

23. Manufacturers participate in the 340B Program by signing a form contract, the Pharmaceutical Pricing Agreement, with HHS. The 340B statute directs the Secretary of HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act . . . , reduced by the rebate percentage" set by the statute. 42 U.S.C. § 256b(a)(1). These agreements, composed by HHS, "contain no negotiable terms" and "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011). The statute and agreements "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." 42 U.S.C. § 256b(a)(1).

24. The statute specifically limits and enumerates the types of health care providers that qualify as covered entities. 42 U.S.C. § 256b(a)(4) ("Covered entity defined"). The eligible types of "covered entities" include, for example, federally-qualified health centers, family planning projects, black lung clinics, certain public hospitals, and other specified categories of health care providers that "provide direct clinical care to large numbers of uninsured Americans." *See id.*; *see also* H.R. Rep. 102-384(II), at 12 (1992). In subsequent amendments to the 340B statute, Congress has expanded the definition of a "covered entity" to include children's hospitals excluded from the Medicare prospective payment system, free-standing cancer hospitals excluded

from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals. 42 U.S.C. § 256b(a)(4); *see also Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 31-32 (D.D.C. 2014).

25. Congress recognized that this program needed careful limits to ensure that the steep manufacturer discounts on drugs extend only to the covered entities specified in the 340B statute and the patients of those entities. It therefore included three crucial safeguards to protect against abuse and to ensure that the program serves its intended public purpose. First, the statute prohibits "duplicate discounts," providing that "[a] covered entity shall not request payment" under the Medicaid Drug Rebate Program if it obtains the 340B discounted price. 42 U.S.C. § 256b(a)(5)(A)(i) ("A covered entity shall not request payment under [Medicaid] . . . with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under the [Medicaid Drug Rebate Program]."). Second, the statute prohibits diversion of the discounted drugs, providing that "[w]ith respect to any covered outpatient drug that is subject to [a 340B] agreement," "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Third, covered entities must allow manufacturers (as well as the agency) to conduct audits of the covered entity's compliance with the 340B Program's requirements. *Id.* § 256b(a)(5)(C) ("A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense

the records of the entity that directly pertain to the entity's compliance with the requirements described in [§ 256b(a)(5)(A) & (B)] with respect to drugs of the manufacturer."). Under subsection (d)(3)(B)(iv), the Secretary is directed to promulgate regulations requiring that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) "as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." *Id.* § 256b(d)(3)(B)(iv).

26. Congress amended the 340B Program in 2010 as part of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. *See* Patient Protection and Affordable Care Act § 7102, Pub. L. No. 111-148, 124 Stat. 119, 826–27 (Mar. 23, 2010); Health Care and Education Reconciliation Act of 2010 § 2302, Pub. L. No. 111-152, 124 Stat. 1029, 1082–83 (Mar. 30, 2010) (collectively, the Affordable Care Act ("ACA")). As part of those 2010 amendments, Congress directed HHS to improve covered entity compliance with the program's diversion and duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(2)(A). Congress also instructed the agency to establish and implement "an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under [the 340B Program], and [of] claims by manufacturers" that covered entities have violated the statutory prohibition on duplicate discounts or diversion. *Id.* § 256b(d)(3)(A). The statute required that this ADR process be established "not later than 180 days after March 23, 2010," the date of enactment of the Patient Protection and Affordable Care Act. *Id.*

B. HRSA Guidances Lead to Serious Compliance Issues

27. As discussed further below, numerous sources (including Congressional and other governmental reports), have shown widespread and pervasive issues with covered entity compliance in the 340B Program. *See* ¶ 52, *infra*. These compliance issues have increased at an alarming rate in recent years. *See* ¶ 51, *infra*. HRSA guidance on three key issues—the use of "contract pharmacies," the definition of "patient," and auditing guidelines for manufacturers—created or exacerbated these widespread issues with duplicate discounts and diversion in the 340B Program.

28. Shortly after the creation of the 340B Program in 1992, some covered entities that lacked an in-house pharmacy sought permission from HRSA to contract with independent pharmacies to dispense 340B covered drugs. *See* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996). HRSA issued guidance stating that the agency would permit covered entities that lack an in-house pharmacy to enter into an agreement with one contract pharmacy, for the purpose of allowing the covered entity to dispense 340B-discounted drugs to the covered entity's patients. *See id.* at 43551-52. The agency stressed that "the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing" and that "[t]he mechanism does not in any way extend this pricing to entities which do not meet program eligibility." *Id.* at 43550 (emphasis added).

29. Starting in 2001, covered entities could apply to the Office of Pharmacy Affairs for an Alternative Methods Demonstration Project (AMDP) to contract with multiple pharmacies. HRSA approved eighteen AMDPs over the next nine years.

30. In 2010, HRSA revised its contract pharmacy guidance to permit any covered entity to contract with an unlimited number of contract pharmacies, with no geographical limitations. 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). When HRSA had proposed this sweeping expansion of its contract pharmacy guidance in 2007, 72 Fed. Reg. 1540 (Jan. 12, 2007), several stakeholders raised serious concerns that the proposal, if finalized, would lead to rampant issues with diversion and duplicate discounts, in addition to concerns that the proposal was unlawful. *See, e.g.*, 75 Fed. Reg. at 10273-75. HRSA dismissed these concerns, opining that advances in inventory management would permit more covered entities to utilize multiple contract pharmacies without an increase in duplicate discounts and diversion. *Id.* HRSA stated that covered entities were responsible for ensuring no duplicate discounts were charged and no diversion occurred, for maintaining auditable records, and for entering adequate contracts with each contract pharmacy. *See id*. at 10272-74.

31. HRSA's 2010 guidance unleashed an explosive growth of contract pharmacies, from 1,256 in 2010 to more than 27,928 in 2020. Adam. J. Fein, *A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts (video)*, Drug Channels (Oct. 22, 2020), *available at* https://bit.ly/3iy0Qlj. This explosive growth outran HRSA's capacity to properly oversee the 340B Program and greatly increased the risk of duplicate discounts and diversion, without corresponding benefit to patients. *See* ¶¶ 54-57, *infra.*

32. While the extent of these problems has expanded dramatically in recent years, *see* ¶¶ 50-52, *infra,* government reports warned from the outset that the rapid expansion spurred by HRSA's 2010 guidance could lead to diversion and duplicate

discounts. *See* GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011) ("2011 GAO Rep."), *available at* https://bit.ly/3p4brqS. In 2011, for example, a report by the U.S. Government Accountability Office (GAO) concluded that "[o]perating the 340B Program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." *Id.* GAO further warned that the "[i]ncreased use of the 340B Program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program." *Id.*

33. HHS itself reached similar conclusions. In 2014, the HHS Office of the Inspector General (OIG) found that 340B contract pharmacies create "complications" in preventing diversion and duplicate discounts. HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 1–2 (Feb. 2014) ("2014 OIG Rep."), *available at* https://bit.ly/2Nrink1. HHS OIG also concluded that a number of covered entities "did not report a method to avoid duplicate discounts," and that "most covered entities in [OIG's] study do not conduct all of the oversight activities recommended by HRSA" in connection with their contract pharmacy arrangements. *Id.* at 2.

34. Lack of precision regarding the definition of a "patient," and lack of oversight of contract pharmacy arrangements, has also led to problems with duplicate discounts and diversion. *See, e.g.*, 2011 GAO Rep., at 22–23 ("patient" definition); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-

480, at 35, 43–44 (June 2018) ("2018 GAO Rep.") (oversight guidance), *available at* https://bit.ly/39WY3yd. As noted above, the statute prohibits a covered entity from "resell[ing] or otherwise transfer[ring]" a 340B-discounted drug "to a person who is not *a patient* of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). In 1996, HRSA stated that an "individual is a 'patient' of a covered entity" if:

> 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
>
> 2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55156, 55157-58 (Oct. 24, 1996). The definition excludes anyone who receives no health care from the covered entity other than "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *Id*. at 55158. This definition lacks necessary specificity and clarity regarding, among other things, patients who are referred from covered entities to outside providers, patients treated by affiliates of covered entities, and when treatment qualifies as "outpatient" as required under the 340B Program. Despite GAO's specific recommendation that HRSA issue a revised and clearer "patient" definition, 2011 GAO Rep. at 34, and despite

repeated requests from manufacturers and other stakeholders for a more precise definition, HRSA has not updated this definition since 1996.

35. HRSA's failure to issue a revised "patient" definition is all the more troubling in light of HRSA's own recognition that the definition may be leading to 340B Program abuses. For example, HRSA has stated that "it is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B program." HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient,"* 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (providing examples of specific ways that covered entities "may have interpreted the definition too broadly"). Similarly, GAO has recognized that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for purposes of 340B" and that this has "raised concerns that the guidance will be interpreted too broadly." 2011 GAO Rep. at 22. GAO further noted that, "[a]s a result of the lack of specificity in the guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care." *Id*. at 23.

36. On two separate occasions, HRSA has proposed revisions to its definition of "patient" to add clarity. *See* 72 Fed. Reg. at 1544; 80 Fed. Reg. 52300, 52306 (Aug. 28, 2015). Yet the agency did not finalize either proposal, and the 340B Program abuses

resulting from the vague and imprecise existing definition not only continue to occur, but have dramatically accelerated in recent years. *See* ¶¶ 50-52, *infra*. Meanwhile, HRSA is not enforcing the existing definition, *see* ¶ 53, *infra*, further exacerbating these unchecked program abuses.

37. In 1996, HRSA also issued guidelines that established procedures for manufacturer audits of covered entities. 61 Fed. Reg. 65406 (Dec. 12, 1996). Under the 340B statute, covered entities are required to permit manufacturers to audit the entity's compliance with the statutory prohibitions on duplicate discounts and diversion with respect to the manufacturer's covered outpatient drugs. 42 U.S.C. § 256b(a)(5)(C). The guidelines issued by HRSA create significant hurdles that impede manufacturers' statutory right to address diversion and duplicate discount violations by covered entities.

38. Among other things, the guidelines require a manufacturer, before initiating an audit, to "notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B" and to direct the parties to "attempt in good faith to resolve the matter" for "at least 30 days." 61 Fed. Reg. at 65410. If those attempts fail and a manufacturer seeks to proceed with the audit, the guidelines require the manufacturer to first "file an audit work plan" with HRSA setting forth "why it has reasonable cause to believe that a violation of section 340B(a)(5)(A) or (B) has occurred, along with sufficient facts and evidence in support of the belief." *Id.* According to the guidelines, HRSA will then "review the documentation submitted to determine if reasonable cause exists," permitting a manufacturer to proceed with the audit only if this threshold is satisfied. *Id.* HRSA has stated that "utilization of more than one contract

pharmacy" does not "create[] automatic cause to suspect diversion." 75 Fed. Reg. *at* 10274.

39. If HRSA authorizes an audit, a manufacturer must hire an independent third-party auditor, rather than being able to conduct an audit itself, and must submit a detailed work plan. *Id.* HRSA then reviews the work plan, which also must be approved before the audit can begin. *Id.* And once the audit is complete, the manufacturer (or its third-party auditor) must complete a report in accordance with the Generally Accepted Government Auditing Standards. *Id.* The covered entity and HRSA then review the audit report, and the covered entity may provide a response. *Id*. The manufacturer must then engage in another round of "good faith" efforts to resolve the issues with the covered entity. 61 Fed. Reg. at 65408, 65412 ("[W]hen a covered entity disagrees with the audit report[] . . . the manufacturer and the covered entity must make a good faith effort to resolve the issue before requesting review using the dispute resolution process.").

40. In practice, these guidelines have proved to be so resource-intensive and burdensome that they serve as an unfair obstacle to legitimate manufacturer audits. Despite the well-documented and widespread problems with duplicate discounts and diversion, *see* ¶ 52, *infra*, audits have been exceedingly rare, and have provided little ability to check such unlawful activities.[1]

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[1] In 2017, President Trump issued Executive Order 13891, which instructed each federal agency to perform a substantive review of its guidance to determine whether it was and should still remain in effect, and to post such guidance to a Guidance Portal; any guidance not posted to the portal was rescinded. As of June 29, 2020, HHS completed its

C. The Development of the ADR Rule

41. Shortly after passage of the Affordable Care Act, HRSA issued an Advance Notice of Proposed Rulemaking regarding the 340B administrative dispute resolution process. 75 Fed. Reg. 57233 (Sept. 20, 2010). Among other things, the advance notice recognized that "over the history of the 340B program manufacturers have rarely utilized the process in the guidelines to conduct an audit." *Id.* at 57235. The advance notice invited "comment[] on whether it is appropriate to modify the guidelines concerning audits prior to implementing" the ADR process, *id.*, given that manufacturers would be required to complete an audit before they could access the dispute resolution process, 42 U.S.C. § 256b(d)(3)(A).

42. PhRMA, a number of its members, and others submitted comments to the advance notice, including comments—as invited by HRSA—regarding the need to revise the audit guidelines. *See* Comments Received, *340B Drug Pricing Program Administrative Dispute Resolution Process*, Document ID HRSA-2010-0005-0001, *available at* https://bit.ly/3sLqgk6. Despite the statutory deadline to issue the rule by September 2010, HRSA took no action on the advance notice for years. Eventually, in 2016, HRSA published a Notice of Proposed Rulemaking, 81 Fed. Reg. 53381, 53382 (Aug. 12, 2016).

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comprehensive review of its guidance documents related to the 340B Program, determined which of them have continued effect, and made them available on HHS's website. In doing so, HHS renewed and readopted the 1996 manufacturer audit guidelines. *See* https://www.hhs.gov/guidance/.

43. PhRMA, a number of its members, and other organizations likewise submitted comments in response to this proposed rule, demonstrating that HRSA's proposal was inadequate, unlawful, and contrary to the statute's requirements. *See* Comments Received, *340B Drug Pricing Program: Administrative Dispute Resolution*, Docket HRSA-2016-0002, OMB RIN 0906-AA90, *available at* https://bit.ly/2HBbCJK.

44. Commenters explained that, because a manufacturer audit of a covered entity is a statutory prerequisite to manufacturer-initiated ADR, reliance on the highly burdensome audit guidelines would fundamentally skew the process, preventing manufacturers from obtaining "fair[], efficient[], and expeditious[]" resolution of their claims. 42 U.S.C. § 256b(d)(3)(B)(ii); *see id.* § 256b(d)(3)(B)(iv); 85 Fed. Reg. at 80633, 80636. Commenters explained that having HRSA's complex and unduly burdensome audit guidelines act as a "gatekeeper" for manufacturer claims—when covered entities face no such requirement—would create unfair and lopsided administrative barriers to accessing the dispute resolution process. One commenter illustrated its understanding of the lopsided and unreasonably burdensome nature of the audit guidelines with the following side-by-side comparison—based on the commenter's direct experience with this extensive, resource-intensive, and unduly cumbersome process:[2]

Table 1: Required Steps Necessary to Submit an ADR Claim	
Covered Entity	**Manufacturer**
Identify Possible Overpayment. Review data in Ceiling Price Reporting system maintained by HRSA and populated by manufacturers. Compare reported prices to invoice prices.	**Identify Possible Non-Compliance**. Manufacturers have no readily available automated tools for monitoring duplicate discounts or diversion. The rules and practices employed by covered entities are diverse and opaque, while duplicate discounts in the Managed Medicaid context and the proliferation of Contract Pharmacy arrangements have grown and exacerbated this opacity.

[2] Excerpt from Comment of Eli Lilly and Co. on Proposed 340B Drug Pricing Program: Administrative Dispute Resolution (ADR) Process, OMB RIN 0906-AA90 (Oct. 11, 2016), *available at* https://bit.ly/3qEYaoU.

Communicate with Manufacturers	**Communicate with Covered Entity**
Engage in Good Faith Dispute Resolution	**Engage in Good Faith Dispute Resolution (Round 1)**
Submit ADR Claim	**Evaluate Case, Obtain Internal Approvals to Conduct Audit**
	Provide Formal Notice of Audit to Entity. The manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B.
	Engaged in Formal Good Faith Dispute Resolution (Round 2).The manufacturer and the covered entity shall have at least 30 days from the date of notification to attempt in good faith to resolve the matter.
	Develop and Submit to HRSA Evidence of "Reasonable Cause"
	Await "Reasonable Cause" Review By HRSA. The Department will review the documentation submitted to determine if reasonable cause exists. If the Department finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene. In cases where the Department determines that the audit shall be performed by the Government, the Department will so advise the manufacturer and the covered entity within 15 days of receipt of the audit work plan.
	Seek, Interview and Engage Independent Auditor
	Submit Audit Work Plan to HRSA. The manufacturer must file an audit work plan with the Department. The manufacturer must set forth a clear description of why it has reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, along with sufficient facts and evidence in support of the belief. In addition, the manufacturer shall provide copies of any documents supporting its claims.
	Await HRSA Review of Audit Workplan. Upon receipt of the manufacturer's audit work plan, the Department, in consultation with an appropriate audit component, will review the manufacturer's proposed workplan. As requested by GAS, the audit workplan shall describe in detail the following: (1). audit objectives (what the audit is to accomplish), scope (type of data to be reviewed, systems and procedures to be examined, officials of the covered entity to be interviewed, and expected time frame for the audit), and methodology (processes used to gather and analyze data and to provide evidence to reach conclusions and recommendations); (2). skill and knowledge of the audit organization's personnel to staff the assignment, their supervision, and the intended use of consultants, experts, and specialists; (3). tests and procedures to be used to assess the covered entity's system of internal controls; (4). procedures to be used to determine the amounts to be questioned should violations of section 340B(a)(5) (A) and (B) be discovered; and (5). procedures to be used to protect patient confidentiality and proprietary information.
	Submit Revision(s) to Audit Workplan
	Await HRSA Review of Revisions to Audit Workplan
	Provide Notice to Covered Entity of Audit. The covered entity will have at least 15 days to prepare for the audit.
	Work with Covered Entity to Find Time for On-Site Audit (Auditor)
	Conduct the Audit (Auditor). This involves at least the following steps:
	1. Review the covered entity's policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs.
	2. Obtain an understanding of internal controls applicable to the policies and procedures identified above (step a) when necessary to satisfy the audit objectives.
	3. Review the covered entity's policies and procedures to prevent the resale or transfer of drugs to a person or persons who are not patients of the covered entity.
	4. Test compliance with the policies and procedures identified above (step c) when necessary to satisfy the audit objectives.
	5. Review the covered entity's records of drug procurement and distribution and test whether the covered entity obtained a discount only for those programs authorized to receive discounts by section 340B of the PHS Act.
	6. Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5) (A) or (B), identify (1) the procedures or lack of adherence to existing procedures which caused the violation, (2) the dollar amounts involved, and (3) the time period in which the violation occurred.
	7. Following completion of the audit field work, provide an oral briefing of the audit findings to the covered entity to ensure a full understanding of the facts.
	Draft Audit Report (Auditor). At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the GAS. The manufacturer shall submit the audit report to the covered entity.
	Review Audit Report. The manufacturer will review the audit findings.
	Await Covered Entity Review of Audit Report. The covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 30 days from the date of receipt of the audit report. When the covered entity agrees with the audit report's findings and

	recommendations either in full or in part, the covered entity shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report's findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.
	Submit Copies to HRSA and HHS OIG. The manufacturer shall also submit copies of the audit report to the Department.
	Good Faith Dispute Resolution (Round 3). Engage in discussions with Covered Entity related to repayment pursuant to Audit findings.
	Submit ADR Claim

45. Commenters also explained, among other things, that the proposal to have ADR panels composed of HHS employees rather than Administrative Law Judges would increase the risk of bias, given that HHS employees would also be involved in initiating enforcement actions and in issuing guidances regarding the 340B Program, including on key interpretive issues that could arise in the course of ADR proceedings or subsequent enforcement actions (such as potential civil monetary penalties).

46. On January 20, 2017, the Trump administration issued a memorandum freezing certain regulatory actions. According to HRSA, this memorandum "had the effect of pausing action on the proposed rule." 85 Fed. Reg. at 80633. The proposed rule was then abandoned on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), *available at* https://bit.ly/3q1t37o.

47. HRSA took no action regarding the ADR rulemaking for more than four years. In fact, on March 12, 2020, a HRSA official told *The 340B Report*, a 340B-focused news publication, that the agency had no plans to issue an ADR rule. According to the official, "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" that defendants understood to be legally unenforceable. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B

Report (Mar. 12, 2020), *available at* https://bit.ly/35kU6lw; *see also id.* (quoting HRSA official as stating, "While HRSA believes that its program policies are sound, guidance does not provide HRSA appropriate enforcement capability.").

48. HRSA reversed course almost immediately after several covered entities filed suit against the agency in October 2020. The suits sought a writ of mandamus ordering HRSA to promulgate the ADR Rule on the ground that the agency was long past the 2010 statutory deadline for doing so and had unreasonably delayed taking action. *See Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 1 (D.D.C. Oct. 9, 2020); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar & U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-3032, ECF No. 1 (D.D.C. Oct. 21, 2020). On November 17, 2020, HRSA forwarded a final rule to the Office of Management and Budget's Office of Information and Regulatory Affairs for review and approval.

D. PhRMA's Petition Regarding the ADR Rulemaking

49. On November 24, 2020, PhRMA filed a petition to express its deep concern with HRSA's apparent plan to finalize the previously-abandoned 2016 proposed rule without considering both the changes in circumstances in the years since the prior comment period, and the numerous deficiencies with the proposed rule outlined in the prior comments. *See* PhRMA, Petition for Rulemaking Regarding an Administrative Dispute Resolution Process for the 340B Drug Pricing Program (RIN 0906-AA90 and RIN 0906-AB26) (Nov. 24, 2020), *attached as* Ex. A. PhRMA requested that HRSA instead reopen the record so that HRSA could consider these issues in light of new evidence,

arising after the close of the prior comment period, of increased diversion and duplicate discounts.

50. PhRMA cited evidence showing that since 2016 the number of covered entities and the use of contract pharmacies had skyrocketed. According to GAO, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 20,000 in 2017. 2018 GAO Rep. at 2. As of October 2020, there were approximately 25,000 unique contract pharmacy locations across the country and more than 170,000 arrangements between contract pharmacies and 340B covered entities. *See* HRSA, *340B Contract Pharmacy Database*, *available at* https://bit.ly/39qpNNp (last visited Nov. 22, 2020). And the number of contract pharmacy arrangements between 340B and vertically-integrated specialty pharmacies increased more than 1000 percent between 2016 and 2020 alone. *See* Aaron Vandervelde et al., Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* (Oct. 2020), *available at* https://bit.ly/2KzNFDD;. By 2019, discounted drugs purchased through the 340B Program accounted for at least 8% of the total U.S. drug market, amassing $29.9 billion in sales that year, an "astonishing" 23% increase over sales in 2018. Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), *available at* https://bit.ly/39P3z6f.

51. In its petition, PhRMA also cited evidence showing that the explosive growth of the 340B Program—and in particular the increasingly "widespread use of contract pharmacy arrangements"—is connected to burgeoning "challenges and inconsistencies," specifically in ensuring that uninsured patients benefit from the

program. PhRMA Petition, Ex. A at 6 (citing HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program, Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions, at 5 (May 15, 2018)).

52. In 2018, the House Energy and Commerce Committee found that nearly half—and in some years more than half—of covered entities audited by HRSA unlawfully sold or transferred 340B drugs to nonpatients. *See* House Energy and Commerce Committee, *Review of the 340B Drug Pricing Program*, at 38 (Jan. 2018) ("2018 House Report"). In 2018 and 2020, GAO likewise observed that the dramatic growth in contract pharmacy arrangements had increased the risk of both duplicate discounts and unlawful diversion. *See* GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,* GAO-20-212, at 2 (Jan. 2020) ("Jan. 2020 GAO Report"), *available at* https://bit.ly/3qWxTmr; *see also* 2018 GAO Rep. at 45. For example, GAO observed that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." *Id*. at 44; *see also* HHS, HRSA, *Program Integrity: FY18 Audit Results*, *available at* https://bit.ly/3o0g6Zo. Similar results were posted for Fiscal Year 2019, with numerous audits identifying instances of diversion and duplicate discounts as a result of the use of contract pharmacies. HHS, HRSA, *Program Integrity: FY19 Audit Results*, *available at* https://bit.ly/3nUPqJK.

53. Equally troubling, recent evidence shows that HRSA often does not terminate covered entities from the 340B Program even when there are findings of serious noncompliance. For instance, in one case where HRSA initially concluded that a covered

entity had violated 340B requirements, the lack of a clear definition of "patient" hampered its enforcement efforts, and HRSA ultimately withdrew both the enforcement measures and audits. *See Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107 (Dec. 2020) ("Dec. 2020 GAO Rep.") (discussing *Genesis Health Care Inc. v. Azar*, 2019 WL 6909572 (D.S.C. Dec. 19, 2019)), *available at* https://bit.ly/3c36FGl.

54. PhRMA's petition further stated that, while the growth in covered entities and contract pharmacies has coincided with a massive growth in diversion and duplicate discounts, it has not resulted in corresponding benefits to the low income and vulnerable patients the 340B program is intended to help. While manufacturers must offer the drugs to covered entities at steep discounts, private insurers (and until 2018, Medicare as well) provide *full* reimbursement when the drugs are dispensed to patients. *See, e.g.*, 2018 GAO Rep. at 1; GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), *available at* https://bit.ly/3bZ3e3E; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020) (describing the "large gap between the amount a 340B hospital would spend to acquire a [prescription drug] and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug."). Moreover, HRSA imposes no requirement on covered entities to share 340B discounts with their patients, nor does the agency require contract pharmacy arrangements to ensure that 340B patients receive any portion of the 340B discounts. Instead, covered entities are permitted to keep all of the

revenue for 340B discounts if they choose to do so, or even to share it with contract pharmacies.

55. Pharmacies and covered entities have therefore been able to generate substantial profits from the difference between the low acquisition price mandated by the 340B Program and the higher reimbursement value of the drug. As Senator Chuck Grassley has stated, "hospitals are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, Senate Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Res. and Servs. Admin. (March 27, 2013), *available at* https://bit.ly/3kFquVS. Indeed, according to HHS in its own rulemaking for the Medicare Part B program, this hospital outpatient reimbursement gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs," 82 Fed. Reg. 52356, 52494 (Nov. 13, 2017)—at the expense of the Medicare program and seniors exposed to higher cost-sharing.

56. One study estimated that, due to the steep discounts mandated under Section 340B, "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines"—more than triple the average margin. Vandervelde, *For-Profit Pharmacy Participation in the 340B Program* 7. The study found that "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018." *Id*. HHS itself estimated that it would save Medicare $1.6 billion in 2018 alone by merely reducing the large gap between

340B hospitals' acquisition costs for 340B-discounted drugs and their Medicare reimbursement amounts for those drugs. 82 Fed. Reg. at 52509; *see also Am. Hosp. Ass'n*, 967 F.3d at 822.

57. These huge profits are frequently not passed on or used to benefit patients. Instead, covered entities are charging patients—including uninsured patients—full price for the drugs that the entities themselves receive at a deep discount. *See* Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), *available at* https://bit.ly/2J5qvok; *see also* Sunita Desai & J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, 378 N. Engl. J. Med. 539, 546-47 (Feb. 8, 2018) (finding "no evidence of hospitals using the surplus . . . generated from [the 340B Program] to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups," and suggesting that "hospital responses [have been] contrary to the goals of the program"), *available at* https://bit.ly/362pcz5. Indeed, 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies. 2018 GAO Report at 30. And many of the remaining 55% reported that they provide discounts to patients obtaining medicines through contract pharmacies only in limited cases. *Id*. In 2014, HHS OIG similarly found that a number of contract pharmacies failed to offer 340B-discounted prices to uninsured patients at all. 2014 OIG Rep. at 2. Rather, "uninsured patients pa[id] the full non-340B price for their prescription drugs at contract pharmacies." *Id.*

58. In short, the 340B Program's "good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription drugs." Fein Letter; *see also* PhRMA, Press Release, *New Analysis Shows Contract Pharmacies Financially Gain from 340B Program with No Clear Benefit to Patients* (Oct. 8, 2020), *available at* https://onphr.ma/3itN57s.

59. The unchecked expansion of the 340B Program has also resulted in increased treatment costs. Covered entities have acquired distant child sites in affluent communities to turn previously independent physician offices and clinics into 340B sites, thereby expanding their opportunities to dispense discounted 340B drugs to commercially insured patients (and non-eligible individuals). This expansion drives care away from less expensive physician office settings into more expensive hospital settings. Aaron Vandervelde & Eleanor Blalock, Berkeley Research Group, *Site-of-Care Shift for Physician-Administered Drug Therapies* 3 (Oct. 16, 2017), *available at* https://bit.ly/2NpEeYR. The 2018 House Report provided an illustrative example, noting that after one Atlanta oncology practice was acquired by a major hospital network in 2013, "the out of pocket cost of treatment for one patient rose from $20 to $212, a more than 1000 percent increase." 2018 House Report at 68.

60. Several government entities have raised concerns about market distortions caused by the program's expansion. The 2018 House Report noted that the 340B Program appears to be affecting "market dynamics" in ways that "should be concerning to everyone focused on improving patient care":

> The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B Program. Given the widespread agreement between all covered entities that the aim of the 340B Program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

2018 House Report at 70. Likewise, the GAO has identified rapid program growth as an area of significant concern. *See, e.g.*, GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight*, at Highlights (July 18, 2017), *available at* https://bit.ly/3612ZRD.

61. PhRMA's petition explained that, in light of the widespread and serious issues that had arisen since the promulgation of the proposed rule, it would be arbitrary and capricious for HRSA to simply resurrect its moribund proposal in a transparent attempt to stave off litigation, without considering whether changed circumstances warranted changes to the rule. Among other things, the growth of unchecked abuses relating to contract pharmacy arrangements underscored the need to alter the audit requirements to eliminate the serious restrictions manufacturers would otherwise face in accessing the ADR process at all.

62. HRSA proceeded to issue the final rule on December 14, 2020, without addressing PhRMA's petition. *See* 85 Fed. Reg. 80632. The same day that the final rule was published, the government moved to dismiss as moot one of the two suits seeking promulgation of an ADR process. *See* Defs.' Mem. in Support of Motion to Dismiss at 10-11, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 41-1 (Dec. 14, 2020).

Both suits were subsequently stayed on the ground that the ADR Rule the plaintiffs sought had been issued. *See* Joint Motion to Stay, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 20-cv-3032, ECF No. 12 (D.D.C. Dec. 17, 2020) (motion granted Jan. 7, 2021); Joint Motion to Stay, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 58 (D.D.C. Jan. 13, 2021) (motion granted Jan. 13, 2021).

E. HHS Issues the ADR Final Rule Without Responding to Significant Comments or PhRMA's Petition to Reopen

63. HRSA's final rule creates an unfair and fundamentally skewed process that, while nominally available for both manufacturers and covered entities to resolve issues, in actuality is inaccessible and unworkable for manufacturers.

64. The final rule reiterates that manufacturers can bring claims only after completing an audit in accordance with the 1996 audit guidelines. 85 Fed. Reg. at 80635, 80638. Notably, the final rule does not substantively respond to comments regarding those audit guidelines' flaws. Neither does it meaningfully address the changes in circumstances arising during the more than four-year delay between the proposed rule and the final rule.

65. Furthermore, the final rule provides that the Secretary will create an ADR Board "consisting of at least six members appointed by the Secretary with equal numbers" from HRSA, the Centers for Medicare and Medicaid Services (CMS), and the HHS Office of the General Counsel (OGC). *Id.* at 80634. From this Board, HRSA will select three-member panels with "relevant expertise and experience" for each dispute. *Id.* The rule provides that individual members can be removed from a panel, but only "for

cause." *Id.* The final rule lists "a conflict of interest" as the only grounds for a panelist's removal. *Id.*

66. In a significant and unexplained departure from the proposed rule, the final rule provides that ADR panel decisions are both "binding" on the parties and "precedential" for purposes of future adjudications. 42 C.F.R. § 10.20. Specifically, the regulation provides that the ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." *Id*. § 10.24(d).

67. The ADR Rule does not provide for any internal review of ADR panel judgments by a superior (much less Senate-confirmed) Executive Branch official.

68. The final rule went into effect on January 13, 2021. On that same date, a covered entity trade association filed an ADR complaint against PhRMA members Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and Astrazeneca PLC, seeking declaratory and injunctive relief. *Nat'l Ass'n of Cmty. Health Ctrs. v. Eli Lilly and Co.*, Petition No. 210112-2 (HHS Jan. 13, 2021).

F. After the Issuance of the Rule, a GAO Report Finds HRSA is Not Enforcing Program Requirements for Covered Entities, and HRSA Issues an Advisory Opinion Regarding Contract Pharmacies

69. The day after HRSA published the final rule, GAO released a report on deficiencies in the 340B Program. *See generally* Dec. 2020 GAO Rep. The report found that HRSA has hired an outside organization to conduct 200 audits per year. *Id.* at 11. It revealed that, since 2012, HRSA's auditors have made 1,536 findings of noncompliance in the 1,242 audits conducted. *Id.* at 13. But, beginning with its Fiscal Year 2019 audits of

covered entities, HRSA requires corrective action only when the "audit information presents a clear and direct violation" of the statute, and HRSA officials stated that they believed they lacked "appropriate enforcement capability." *Id.* at 15.

70. Among other things, GAO found that in numerous instances HRSA officials "did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility"; "did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies . . . because the 340B statute does not address contract pharmacy use"; and "did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements . . . because the agency does not have statutory authority to enforce state Medicaid requirements." *Id.* at 15-16. There were instances where the agency did not require corrective action regarding duplicate discounts due to its perceived lack of statutory authority. *Id.* at 17. GAO stated that it "remain[ed] concerned" that HRSA was not taking adequate steps to ensure that covered entities complied with 340B Program requirements. *Id.* at 21. Indeed, the GAO report makes clear that HRSA is fundamentally failing to take enforcement actions adequate to deter violations by covered entities.

71. HRSA was aware of these findings before it finalized the ADR Rule. GAO had previously sent a draft of the report to HRSA for review, and HRSA provided a comment letter on November 16, 2020. *See* Dec. 2020 GAO Rep., Appendix II.

72. In marked contrast to its lax stance regarding covered entity compliance, the HHS Office of General Counsel in December 2020 issued an Advisory Opinion

announcing the agency's definitive position that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020). Under the ADR Final Rule, employees of this same office will be appointed as members of ADR panels to resolve disputes between covered entities and manufacturers, and will presumably rely on this Advisory Opinion rather than impartially weighing the legal arguments without pre-judgment.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Declaratory/Injunctive Relief—The ADR Rule is Arbitrary and Capricious, an Abuse of Discretion and Otherwise Not in Accordance with Law)

73. The prior paragraphs of the Complaint are incorporated by reference.

74. Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). To satisfy the APA, agency action must at a minimum be the product of "reasoned decisionmaking." *Tradeways Ltd. v. U.S. Dep't of the Treasury*, 2020 WL 3447767, at *15 (D. Md. June 24, 2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)).

75. The ADR Rule should be vacated and remanded to HHS to correct at least two interrelated shortcomings. These shortcomings create a one-sided process that improperly hampers the ability of manufacturers to address violations of program

requirements by covered entities, while imposing no such burdens on the ability of covered entities to bring claims against manufacturers.

76. First, HRSA failed to adequately address comments regarding the audit guidelines, which, under the ADR Rule, govern the audit prerequisite for manufacturers to initiate ADR claims.

77. The 2010 ANPRM specifically requested comment on whether the audit guidelines were appropriate, given that they would serve as a gatekeeper to manufacturers' ability to initiate claims in the ADR process. *See* 75 Fed. Reg. 57233, 57234 (requesting comments regarding "Manufacturer Audits"); *see also id.* at 57235. In response to both the 2010 Advance Notice of Proposed Rulemaking and the 2016 Notice of Proposed Rulemaking, a number of commenters raised concerns about those audit guidelines, explaining in considerable detail that they create an unduly cumbersome precondition to commencing ADR for manufacturers.

78. In issuing the 2020 ADR Final Rule, HRSA failed to adequately address these comments. Indeed, HRSA acknowledges that many commenters discussed this question, but in response cites only the inapposite 340B Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) regulation and states, in a conclusory manner, that "updated manufacturer audit guidelines" are not "needed to finalize the ADR process," and that the ADR panels can "determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts." 85 Fed. Reg. at 80633.

79. This response reflects a complete failure to engage in reasoned decisionmaking. At the threshold, the fact that ADR panels can determine violations

during a proceeding is plainly irrelevant to the question of whether the audit guidelines unduly and unreasonably burden the ability of manufacturers to *initiate* a proceeding in the first place. And the agency's peremptory assertion that updated guidelines are not "needed" is pure—and impermissible—*ipse dixit*. Insofar as this assertion is meant to express HRSA's conclusion that the audit guidelines do not unduly and unreasonably burden the ability of manufacturers to initiate ADR, HRSA wholly failed to explain the basis for any such conclusion.

80. "An agency establishing a rule need not address every comment," but it must "reasonably respond to those comments that raise significant problems." *North Carolina v. FAA*, 957 F.2d 1125, 1135 (4th Cir. 1992); *see also Casa de Maryland, Inc. v. Wolf*, — F. Supp. 3d —, 2020 WL 5500165, at *23 (D. Md. Sept. 11, 2020) (explaining that the agency "must actually give meaningful consideration to these concerns," and "cannot 'brush aside' important facts, or [merely] offer 'conclusory statements.'") (citations and modifications omitted); *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n. 58 (D.C. Cir. 1977) (Significant comments are those "which, if true, raise points relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule."). Here, the agency itself acknowledged that, as a result of its audit guidelines, manufacturers had rarely engaged in audits, and it therefore explicitly invited comment "on whether it is appropriate or necessary to modify the guidelines concerning audits prior to implementing" the ADR process. 75 Fed. Reg. at 57235. PhRMA and numerous other organizations responded to this invitation by providing detailed, reasoned explanations of the significant problems the audit guidelines pose to manufacturer-

initiated ADR. HRSA's total failure to provide any substantive response to these comments violates the APA. For this same reason, HRSA acted arbitrarily and capriciously, because it "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

81. Second, HRSA's complete failure to justify the cumbersome requirements for manufacturer audits is compounded by its failure to refresh the record and to consider the evidence submitted in PhRMA's petition.

82. After issuing the 2010 advance notice and the 2016 proposed rule, HRSA abandoned the proposed rule and for more than four years took no action towards creating an ADR process. Yet, when faced with litigation in late 2020 regarding its decade-long delay in undertaking its statutory obligation to promulgate an ADR rule, the agency hastily issued a final rule on December 14, 2020. Because this was hurriedly done in response to litigation, the agency blatantly disregarded PhRMA's request in its petition to consider evidence showing that the existing record was not adequate given the lapse of time and changed circumstances.

83. Indeed, HRSA entirely failed to respond to PhRMA's petition to reopen the record so that PhRMA could submit new, material evidence of how circumstances have changed. That petition set out numerous *government* findings, issued after the comment period on the 2016 proposed rule had closed, showing that the 340B Program is increasingly plagued by significant compliance issues associated with the recent explosive growth of contract pharmacies, as well as the lack of a clear "patient" definition. That evidence shows that manufacturer-initiated ADR claims are essential to identifying

and preventing diversion and duplicate discounts, particularly in light of HRSA's general failure to enforce these requirements, and that it is all the more unreasonable to require manufacturers to comply with burdensome audit guidelines in order to bring such claims. HRSA's decision to turn a blind eye to that evidence, and to press forward based on a stale record, was arbitrary and capricious. *See Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 585 (D.C. Cir. 1994).

SECOND CAUSE OF ACTION

(Declaratory/Injunctive Relief—The Manufacturer Audit Guidelines, Which HRSA Effectively Incorporated in the ADR Rule, are Contrary to Law)

84. The prior paragraphs of the Complaint are incorporated by reference.

85. Section 340B authorizes HHS to create "procedures . . . relating to the number, duration, and scope of audits" conducted by manufacturers. 42 U.S.C. § 256b(a)(5)(C). The 1996 audit guidelines, as re-adopted by HHS on June 29, 2020, *see* note 1, and as further reiterated and readopted in the ADR Final Rule as a required precondition to manufacturer-initiated ADR, exceed this limited grant of authority and are therefore unlawful in at least two ways.

86. First, the audit guidelines impermissibly require manufacturers to establish "reasonable cause" to believe that a covered entity has violated the prohibitions on diversion or duplicate discounts before they can even commence an audit. *See* 61 Fed. Reg. at 65409. That requirement is not a "procedure[] . . . relating to the number, duration, [or] scope" of audits. It is an extra-statutory substantive restriction on manufacturers' ability to institute audits. Indeed, HRSA's authority to prescribe audit guideline

"procedures" appears in a part of the statute that imposes requirements on covered entities, not on manufacturers, *see* 42 U.S.C. § 256b(a)(5). This provision immediately follows the prohibitions on duplicate discounts and diversion, *id.* § 256b(a)(5)(A)&(B), and it is set forth in a subsection that requires covered entities to permit audits by HRSA and manufacturers.

87. The statutory context makes clear that HRSA's authority is limited to preventing misuse of the manufacturers' audit right—*i.e.*, to ensure that a manufacturer does not engage in too many audits, or audits that are overbroad and unduly long. The reference to the "number" of audits is not a grant of authority to limit the circumstances in which a manufacturer can commence any audit at all. Indeed, it is valid and reasonable for manufacturers to conduct audits based on general risk factors, just as HRSA recognizes that covered entities may conduct "spot audits" of their contract pharmacies, 75 Fed. Reg. at 10278, and just as HRSA itself—pursuant to its audit authority under the 340B statute—conducts both "targeted" and "risk-based" audits of covered entities, Dec. 2020 GAO Rep. at 11 n.22 ("HRSA's audits include covered entities that are randomly selected based on risk-based criteria . . . and those that are targeted based on information from stakeholders such as drug manufacturers about potential noncompliance."); *see also* HRSA, *Program Integrity: Audits of Covered Entities*, *available at* https://bit.ly/39NXQxt (Date Last Reviewed: April 2020). The ADR Final Rule thus establishes a Catch 22 for manufacturers who cannot institute an ADR proceeding without completing an audit first: Manufacturers may not initiate the required audit without "reasonable cause," but they may not use a risk-based audit to uncover potential violations in the first place.

88. Second, the guidelines' requirement that manufacturers employ third parties to conduct audits, *see* 61 Fed. Reg. at 65409, conflicts with the plain language of Section 340B, which directs covered entities to "permit the Secretary and *the manufacturer* . . . to audit at the . . . manufacturer's expense the records of the entity that directly pertain to the entity's compliance." 42 U.S.C. § 256b(a)(5)(C) (emphasis added).

THIRD CAUSE OF ACTION

(Declaratory/Injunctive Relief—Selecting ADR Board Members Without Senate Confirmation Violates the Appointments Clause)

89. The prior paragraphs of the Complaint are incorporated by reference.

90. The Appointments Clause, Article II, Section 2, Clause 2 of the U.S. Constitution, provides that executive branch officers shall be appointed by the President "by and with the advice and consent of the Senate," except that "Congress may by law vest the appointment of such inferior officers, as they think proper, in the President alone, in the courts of law, or in the heads of departments." "The Appointments Clause prescribes the exclusive means of appointing 'Officers.'" *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018).

91. The Appointments Clause "is among the significant structural safeguards of the constitutional scheme." *Edmond v. United States*, 520 U.S. 651, 659 (1997). "By vesting the President with the exclusive power to select the principal (noninferior) officers of the United States, the Appointments Clause prevents congressional encroachment upon the Executive and Judicial Branches." *Id.* Although it may be administratively convenient for other persons to appoint officers, "that convenience was

deemed to outweigh the benefits of the more cumbersome procedure only with respect to the appointment of 'inferior Officers.'" *Id*. at 660.

92. ADR Board members are "officers" of the United States. They are appointed for a "continuing" term, *Lucia*, 138 S. Ct. at 2051, and because they control the proceedings before them and issue final precedential decisions, they "exercise significant authority pursuant to the laws of the United States," *id.* at 2051-53; *see also Free Enter. Fund v. PCAOB*, 561 U.S. 477 (2010); *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868 (1991). Indeed, under the ADR rule, HHS has directed them to make critical legislative policy judgments. Further, they can "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders." *Id*. (quoting *Freytag*, 501 U.S. at 881-82); *see also* 42 C.F.R. §§ 10.23, .22(b)-(c); 85 Fed. Reg. at 80641.

93. Moreover, ADR Board members are "principal officers" of the United States. They independently determine how to conduct proceedings, and make final precedential determinations for HHS that are not subject to any further executive branch review, much less by agency officials who are appointed by the President and confirmed by the Senate. By statute, the decision under the ADR process is "a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C).

94. ADR Board members are "principal officers" because they may be removed from panels only "for cause." 85 Fed. Reg. at 80634. Thus, in their conduct of ADR panels, they are not supervised or directed by any superior officer. *See Edmond*, 520 U.S. at 662 ("Generally speaking, the term 'inferior officer' connotes a relationship with some higher

ranking officer or officers below the President: Whether one is an 'inferior' officer depends on whether he has a superior.").

95. Because ADR Board members are principal officers, they must be appointed by the President with the Senate's advice and consent. The ADR Rule therefore violates the Appointments Clause by vesting the power to appoint Board members in the Secretary alone.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests judgment against Defendants as follows:

- A declaration that the ADR Rule is arbitrary, capricious, an abuse of discretion, and otherwise contrary to law, that the 1996 manufacturer audit guidelines are contrary to law, and that the mode of appointment for ADR Board members violates the Appointments Clause of the Constitution;
- A permanent injunction prohibiting Defendants from implementing or enforcing the ADR Rule, and vacating and setting the ADR Rule aside;
- Award of PhRMA's attorney fees and costs; and
- Such other relief as this Court may deem just and proper.

Date: January 22, 2021

By: _____/s/ *Sujit Raman*_____

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