IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECCERA, *et al.*, Defendants.	CASE NO.: 1:21-CV-00027-LPS

COMBINED BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT AND BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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This case culminates a brazen strategy by a cohort of large, highly profitable pharmaceutical companies unilaterally to upend the decades-old, settled operation of a statutory program that provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients. Nearly thirty years ago Congress struck a bargain with drug companies by creating the "340B Program": Participating manufacturers gain access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs to certain safety-net healthcare providers. The providers, in turn, can generate much-needed revenue through sale of those drugs (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has served a crucial role in facilitating healthcare for vulnerable patients ever since.

But late in 2020 Plaintiff AstraZeneca Pharmaceuticals, LP (hereafter, "Astra") and several of its peers unilaterally imposed onerous and non-statutory restrictions on providers' access to 340B-discounted drugs. Specifically, the manufacturers announced that no longer will they honor (or honor without significant restrictions) discounted-drug orders placed by eligible healthcare providers but shipped to, and dispensed by, outside pharmacies. These outside-pharmacy arrangements (called "contract pharmacies") have been an integral part of the 340B Program's operation for decades, since the vast majority of 340B-eligible providers do not operate an in-house pharmacy and thus rely on contract pharmacies. Astra and other manufacturers' changes—impacting healthcare entities serving the most vulnerable patients—have upended the settled operation of the 340B Program and spawned a raft of litigation against the Department of Health and Human Services ("HHS"), the agency to which Congress delegated oversight and implementation of the 340B Program.

Astra's goal in this suit is clear: It seeks to have this Court sanction Astra's rewrite of its statutory obligations in a way that would restrict many providers' access to discounted drugs. Astra seeks to advance that goal by asking this Court to declare unlawful and set aside a reiteration by HHS's General Counsel of the agency's consistent, twenty-four-plus-year interpretation of the 340B statute—an interpretation with which Astra and its peers had complied, without question, for decades. There is no cause for this Court to grant this request because Astra's claims lack merit. This Court cannot opine on the merits of the General Counsel's legal advice because its issuance is not a final agency

action and because Astra's challenge is time-barred, since the analysis reiterated the agency's position since at least 1996. Even if Astra's challenge to the legal advice were justiciable, it would fail on the merits because the opinion imposes no new requirements on manufacturers and only confirms obligations imposed when Congress created the 340B Program. Astra's claim that HHS unreasonably failed to post Astra's notice on its website fails for the reason that HHS had no statutory obligation to do so. The Court should dismiss each of Astra's claims or grant summary judgment to HHS.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of Health and Human Services ("HHS"), through which certain safety-net healthcare providers (collectively known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b. The program has dual benefits: Drug discounts "enable these entities 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), and also may benefit uninsured and underinsured patients, when covered entities opt to pass along the discounts by helping patients afford costly medications. Congress expressly conditioned drug makers' access to coverage of their products under Medicaid and Medicare Part B on manufacturers' participation in this scheme, known as the "340B Program." 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). Pharmaceutical companies thus may opt out of the 340B Program, but then lose access to a large annual revenue stream through drug coverage in federal health-insurance programs.

During the early years of the 340B Program, it became clear that fewer than five percent of the covered entities statutorily eligible to participate in the 340B Program operated in-house pharmacies; instead, the vast majority of safety-net providers relied on arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg.

43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). And because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing." AR 370. Covered entities participating in the 340B Program thus began relying on these contract pharmacies to take delivery from manufacturers of drugs purchased by the covered entity and then to dispense those drugs to the covered entities' low-income patients. *Id.*

In 1996 HHS issued interpretive guidance to aid covered entities in best practices for the use of contract pharmacies. *Id.* HHS explained that "[i]t would defeat the purpose of the 340B program if … covered entities could not use their affiliated pharmacies … to participate," because they would otherwise "be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 371. Rather than imposing any new requirements, the 1996 Guidance confirmed: "It has been [HHS's] position that 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," and that, "[i]f the entity directs the drug shipment to its contract pharmacy," *id.*, that in no way "exempts the manufacturer from statutory compliance," *id.* at 371. Thus decades ago HHS interpreted the statute to preclude manufacturers from denying purchases by covered entities using contract pharmacies without suggesting that this statutory obligation was voluntary for drug makers. HHS explained that restricting covered entities' access to 340B discounts to those operating an *in-house* pharmacy would not further "the interest of the covered entities, the patients they serve, [or be] consistent with the intent of the law." *Id.* The agency explicitly rejected the argument that the use of contract pharmacies was an unauthorized expansion of the 340B Program: "The statute is silent as to . . . drug distribution systems," and does not require "a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 370.

The pharmaceutical industry quickly demonstrated 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 the contract-pharmacy guidelines. *See PhRMA v. Shalala*, No. 1:96-cv-1630 (July 12, 1996 D.D.C.) Compl., ¶ 3.[1] The drug companies alleged that "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. They further 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.

Contract pharmacy arrangements proved so pivotal that, in 2010, HHS issued additional guidance specifying that covered entities need not be limited to a single contract pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) ("2010 Guidance"). After issuing notice and soliciting comments, the agency agreed with commenters that allowing "the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" would significantly benefit patients, especially those that "face transportation barriers or other obstacles that limit their ability to fill their prescriptions," and more-flexible use of contract pharmacies would permit covered entities to more effectively utilize the 340B program and create wider patient access. AR 387. The 2010 Guidance includes "essential elements" to prevent

[1]The lawsuit was filed one month before the official Guidance was published in the Federal Register; it challenged guidelines (containing the same statutory interpretation) that first were 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. 1 (Talmor Decl.). Astra currently is a member of PhRMA. *See* PhRMA, About, Members, https://www.phrma.org/en/About/Members.

unlawful duplicate discounts or drug diversion: a "covered entity will purchase the drug, [and] maintain title to the drug"; "the manufacturer … bill[s] the covered entity … but ships the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations, and must maintain auditable records, track prescriptions to prevent diversion, and verify patient eligibility. *Id.* at 391-92.

Most importantly for the present case, the 2010 Guidance again confirmed HHS's earlier interpretation that, "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 340B discount price*," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* (emphasis added). As before, that interpretation was framed in mandatory terms—the guidance did not suggest that manufacturers can choose whether or not to honor 340B purchases by a covered entity that relies on contract-pharmacy arrangements. HHS also explained that the guidance neither created new obligations on manufacturers nor new rights for covered entities because it merely interpreted the 340B statute "to create a working framework for its administration," rather than issuing "a substantive rule[] under the APA." *Id.* at 387. Not only were there *no* legal challenges from drug makers or trade associations to the substance of the 2010 Guidance but, for more than a decade, *all* participating drug makers have complied with the guidance.

Also in 2010, Congress opted "to strengthen and formalize [HHS's] enforcement authority" over the 340B program. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 121-22 (2011). Specifically, Congress included provisions in the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), to amend the Program to "Improve[] … program integrity" related to manufacturer and covered-entity compliance. For example, the Secretary was granted authority to issue new regulations imposing civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 42 C.F.R. § 10.11(a).

A neighboring provision also instructed the Secretary to establish a 340B Program

administrative dispute-resolution process ("ADR process") for covered entities and manufacturers. 42 U.S.C. § 256b(d)(3)(A). The Secretary issued a notice of proposed rulemaking on the development of an ADR process in 2016, *see* 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381, 53,382 (Aug. 12, 2016). After considering the comments received on the 2016 NPRM and adjusting its proposal in response to several comments, the agency published the final ADR Rule in the Federal Register on December 14, 2020. *See* 85 Fed. Reg. 80,632.

II. DRUG COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS.

In 2020 several drug makers took abrupt, unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients. These actions began with a July 2020 notice by Eli Lilly that, with certain caveats, it would not offer 340B pricing through contract-pharmacy arrangements for one of its drugs. *See Eli Lilly v. HHS*, No. 21-cv-81 (S.D. Ind.), Compl. ¶ 78. But that restriction opened the floodgates: One month later, Eli Lilly extended its contract-pharmacy restrictions to *all* its covered drugs (while purporting to allow providers without an in-house pharmacy to contact the manufacturer to designate a single contract pharmacy), *see id.* Ex. G, and several other drug companies promptly followed suit.

For its part, Astra announced that it would begin *refusing* purchases by covered entities for shipment to a contract pharmacy if the covered entity also operates an in-house pharmacy, and unilaterally restricting those covered entities that lack an on-site pharmacy to only one, pre-designated contract-pharmacy site. *See* Am. Compl. ("Compl.") ¶¶ 48-50, ECF No. 13. To effect this change, Astra notified covered entities of its decision to "stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020," unless a covered entity "that does not have an outpatient, on-site dispensing pharmacy" contacts Astra to designate a single, off-site dispenser. *Id.* Ex. A. In response, HRSA wrote to Astra conveying its concern that the new policy "could have the effect of severely limiting access [to medications] for underserved and vulnerable populations served by these covered entities' access to 340B discounted drugs," which "would undermine the 340B Program and the Congressional intent" behind the statute. *Id.* Ex. D. HRSA

informed Astra that its new policy may subject it to sanctions, including but "not limited to, civil monetary penalties." *Id.* And HRSA explained that concerns regarding violations should be addressed by submitting to the agency "any evidence of specific duplicate discount and diversion violations … including the alleged covered entities and drugs involved," rather than instituting a potentially unlawful restriction on purchases. *Id.* Undeterred, Astra proceeded to implement its new policy. *Id.* ¶¶ 58-59.

Although HRSA published on its official website Eli Lilly's July 2020 notice, it refused to post that drug maker's later notice expanding the 340B restrictions or those of other companies, including Astra. HRSA then told an industry reporter that it was "considering whether manufacturer policies … violate the 340B statute and whether sanctions may apply." AR 1597. HRSA warned that drug makers refusing "to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations," and "encourage[d] all manufacturers to sell [these] drugs … directly and through contract pharmacy arrangements." *Id.* at 1659.

Unsurprisingly, the pharmaceutical manufacturers' abruptly announced, unilateral restrictions on 340B access caused upheaval to covered entities, prompting various safety-net providers to urge HHS to take action by filing emergency motions *against the agency* seeking to compel HHS to reverse the drug makers' changes. *See* Mot. for TRO and Prelim. Inj., *Ryan White Health Clinics for 340B Access v. Azar*, No. 20-cv-2906-KBJ (D.D.C. Nov. 23, 2020), ECF No. 24-1; Mot. for Prelim. Inj., *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020), ECF No. 7. HHS moved to dismiss those suits while confirming that its investigation of the manufacturers' actions is ongoing. In February one court agreed with HHS that the legality of drug makers' new 340B restrictions must be decided, in the first instance, by the agency. *See Am. Hosp. Ass'n,* 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) (refusing to "short-circuit the foundational regime that Congress has enacted in the 340B Program").

In response to growing public outcry, HHS's General Counsel issued legal advice on December 30, 2020, confirming his view (in alignment with HHS's longstanding guidance) "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 Gen. Counsel,

Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("AO"), AR 1. The AO opined that the 340B statute requires manufacturers, in exchange for access to Medicaid and Medicare Part B, to *offer* discounted drugs for *purchase by* covered entities, without qualifying or restricting a covered entity's method of distribution. *Id.* at 2. Contract-pharmacy arrangements involve purchase by a covered entity, the AO explained, regardless whether the purchased drugs are delivered to, and dispensed by, a covered entity's in-house pharmacy or an outside, local pharmacy. *Id.* at 3. Moreover, the AO continues, covered entities have relied on contract pharmacies for decades—and that system is wholly compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations." *Id.* at 4. The AO confirmed that this interpretation is compelled by the statute itself; as in 1996 and 2010, no rulemaking was required, and no expansion of the 340B Program was effected, because Congress did not permit drug makers to condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. *Id.* at 2-4.

III. COMPANIES SUE TO PREVENT HHS's ENFORCEMENT OF THE 340B STATUTE

The pharmaceutical companies' concerted actions to upend the 340B status quo continued in litigation. Three manufacturers filed suit on the same day challenging the Advisory Opinion.[2] Two additional, similar suits were filed shortly thereafter.[3] As for this action, notwithstanding the advisory nature of the legal advice and the fact that it reiterated guidance the agency long ago had issued (and with which Astra had complied for decades), Astra now asks this Court to declare the AO unlawful and to bless its intention not "to offer 340B discounts to contract pharmacies." Compl., Prayer for Relief C. In other words, Astra asks this Court to sanction a more-sweeping change to the 340B Program than that which Astra already imposed.

STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff

[2] *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021); *Eli Lilly v. HHS*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Jan. 12, 2021); *Sanofi-Aventis v. HHS*, No. 3:21-cv-634 (D.N.J. Jan. 12, 2021.

[3] *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

bears the burden to establish a court's jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). It is "presume[d] that federal courts lack jurisdiction unless the contrary appears affirmatively from the record." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (citation omitted).

Under both Rules 12(b)(1) and 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face" to defeat a motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). And while the Court accepts well-pleaded factual allegations as true, "mere conclusory statements" and "legal conclusion[s] couched as … factual allegation[s]" are not entitled to a "presumption of truth." *Id.* at 678, 681 (citation omitted).

In a case involving review of final agency action under the APA, the "customary summary judgment standard" under Rule 56 "does not apply." *Bintz v. FEMA*, 413 F. Supp. 3d 349, 360 (D. Del. 2019). Rather, "[s]ummary judgment is the 'mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.'" *Id.* (quotation omitted). The party challenging agency action bears the burden of demonstrating a violation of the APA. *Washington v. Donley*, 802 F. Supp. 2d 539, 546 (D. Del. 2011).

ARGUMENT

Astra and its peers are attempting to effect a unilateral sea change in the operation of the 340B Program. Congress devised the program to help vulnerable patients and safety-net providers, and expressly conditioned the coverage of drug manufacturers' products in the nation's largest health-insurance programs, on agreement to provide discounts on *purchases by* covered entities. Now a cohort of highly profitable pharmaceutical companies seek to litigate out of their obligations. Astra and other manufacturers' abruptly imposed restrictions have caused upheaval by severely curtailing access to the discounts to which covered entities are entitled. Any doubt as to Astra's intent is dispelled by the fact that its complaint is larded with grievances about the use of contract-pharmacy arrangements—complaints which ignore covered entities' twenty-five-year reliance on such agreements.

Astra's campaign to end reliance on contract-pharmacy dispensing models also mischaracterizes the transactions at issue by pretending it is the pharmacies, not covered entities, that purchase Astra's discounted drugs. As the General Counsel explained, "covered entities enter into written agreements with pharmacies ('contract pharmacies') *to distribute* their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contract pharmacy has physical possession of the drug, it has been purchased by the covered entity." AO at 1. In other words, pharmacies *cannot*—under the Advisory Opinion or at any time in the history of the 340B Program—purchase 340B-discounted drugs. Contract pharmacies perform an invaluable service by undertaking the necessary investment to maintain the lawful ability to store and dispense controlled substances, accepting delivery of controlled substances purchased by safety-net providers, and dispensing medications to patients on behalf of covered entities that often could not afford to undertake these tasks in-house. But that does not allow a pharmacy to purchase 340B drugs or participate as a covered entity. *See* 61 Fed. Reg. at 43,552.

Astra relies on artful drafting to obfuscate and confuse these undeniable facts. For example, Astra repeatedly claims that HHS newly is requiring it to "make its drugs available to contract pharmacies," Pl.'s Br. in Supp. of Summ. J., ("Mot.") 9, ECF No. 43, and that HHS is considering contract pharmacies to be "covered entities", *id.* These portrayals are inaccurate; contract pharmacies *cannot purchase* 340B-discounted drugs, but rather can only fill prescriptions written by covered entities for their own patients using 340B-discounted drugs *purchased by* the covered entities, and then pass along savings back to the covered entities. Astra's misportrayal of these relationships permeates each of its claims. This Court should not condone Astra's extra-statutory efforts to rewrite the scheme devised by Congress—and deny covered entities access to the discounts to which they are entitled.

I. THE ADVISORY OPINION IS NOT REVIEWABLE.

A. The Advisory Opinion Does Not Constitute Final Agency Action.

Because the AO is not "final agency action" subject to review under the APA, *see* 5 U.S.C. §

702, the court lacks jurisdiction to review Astra's challenge to the AO. *See Minard Run Oil Co. v. U.S. Forest Serv.*, 670 F.3d 236, 247 (3d Cir. 2011) (describing "final agency action" as "a jurisdictional issue"). Agency actions are final if two conditions are met: (1) the action "marks the consummation of the agency's decisionmaking process" and is not "of a merely tentative or interlocutory nature;" and (2) the action is one "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). Though failure to satisfy either condition is enough to deprive the court of jurisdiction, the AO fails to satisfy both conditions.

The AO is not an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* To the extent the agency has reached the consummation of its decisionmaking process at all, it did so many years ago, as expressed in the 2010 Guidance. The AO merely restates the position expressed in that guidance, and thus "tread[s] no new ground." *Indep. Equip. Dealers Ass'n ("IEDA") v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004). "It left the world just as it found it, and thus cannot be fairly described as implementing, interpreting, or prescribing law or policy." *Id.* The 2010 Guidance made clear that covered entities may enter into "complex arrangements" that include contracts with "multiple pharmacies." 75 Fed. Reg. at 10,277. It also expressly stated that, "[u]nder section 340B, 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 340B discount price." *Id.* at 10,278 (emphasis added). Thus, the 2010 Guidance reflected the agency's position that manufacturers had a statutory obligation to honor the ceiling price when covered entities utilized multiple contract pharmacies. The AO did not deviate from this prior position. It concluded 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." AO at 1.

When, as here, a later restatement of a prior interpretation is challenged, courts routinely hold that the restatement is not final agency action. *See, e.g. Menominee Indian Tribe of Wisconsin v. EPA*, 947 F.3d 1065 (7th Cir. 2020); *Clayton Cnty., Ga. v. FAA*, 887 F.3d 1262 (11th Cir. 2018); *Golden and*

Zimmerman, LLC v. Domenech, 599 F.3d 426 (4th Cir. 2010); *IEDA*, 372 F.3d 420. For example, in *Menominee Indian Tribe*, the Seventh Circuit considered whether letters from the Environmental Protection Agency and Army Corps of Engineers were final agency action. 947 F.3d at 1068. The letters reiterated the agencies' positions as set forth in a 1984 document, and thus "did little but restate what the Tribe already knew." *Id.* at 1070. The court explained that each letter "imposes no obligations," "denies no relief," and carries no other "legal consequence." *Id.* Because the letters "only reiterated the status quo," there was "nothing for [the court] to review." *Id.*

The Fourth Circuit reached the same conclusion in a similar case, *Golden and Zimmerman, LLC*. 599 F.3d 426. In that case, plaintiffs sought review of a document published by the Alcohol, Tobacco, and Firearms Bureau ("ATF") designed to help firearm licensees comply with the law, arguing that the answer to one of the Frequently Asked Questions ("FAQ") was "inconsistent" with the Gun Control Act. *Id.* at 428. The trouble was that the FAQ merely restated the ATF's interpretation published in a revenue ruling 40 years earlier. *Id.* Even though the FAQ did, in fact, "inform the regulated community of what violates the law," the court found that the FAQ did not "itself *determine* the law or the consequences of not following it." *Id.* at 432-33 (emphasis in original). "Its role, as stated in the publication, is simply to *inform* licensees of what the law, previously enacted or adopted, is, and its publication did not itself alter the legal landscape." *Id.* at 433. "If the ATF had never published [the FAQ]," it "would still have the authority to prosecute licensees for engaging in the conduct" described in the FAQ because "legal consequences" arise only from the statute and its implementing regulations." *Id.*

So too here. The AO informs the public of the General Counsel's interpretation of the statute, but it does not impose any consequence because it merely restates the interpretation set forth in the 2010 Guidance. Astra's arguments to the contrary are unpersuasive. Astra argues that the Advisory Opinion creates an "expectation of immediate compliance," Mot. 19 (quoting *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 n.7 (3d. Cir. 2003)). To the extent that HHS expects "immediate compliance," however, such expectation was created by the 2010 Guidance, not by the AO. For the same reason, it cannot be the AO that "leaves AstraZeneca with no further agency action to invoke

or exhaust to plead its case," as the AO is merely a restatement of the longstanding agency position expressed in the 2010 Guidance. Mot. 20.

Astra also argues that, as a result of the AO, "covered entities have already filed ADR petitions against AstraZeneca that expressly rely on the Opinion," and the AO "places AstraZeneca at a heightened risk of sanction efforts by the agency." *Id.* But even if the AO or the 2010 Guidance had not been issued, covered entities would still be able to challenge Astra's practices through the administrative dispute resolution process set forth in the statute, 42 U.S.C. 256b(d)(3)(B)(i), and the authority to impose monetary penalties, etc. would still exist. *Id.* § 256b(d)(1)(B)(vi). Indeed, HRSA explicitly communicated to another pharmaceutical manufacturer, Eli Lilly, in August 2020—months before the General Counsel issued his legal advice—that the agency was "considering whether [Eli Lilly's] new proposed policy constitutes a violation of section 340B and whether sanctions apply." AR_1098-99. HHS plainly viewed contract-pharmacy restrictions as potentially violative of *the statute* before the AO was issued. Thus the "legal consequences" arise only from the statute, and not from the AO itself. *See Golden and Zimmerman, LLC.*, 599 F.3d at 433.

Astra's focus is improperly situated on the consequences that it associates with the AO. Such "practical consequences," including "the threat of having to defend itself in an administrative hearing" are "insufficient" to render agency action final or reviewable. *IEDA*, 372 F.3d at 428. Where, as here, Astra continues to operate its so-called integrity initiative until some further action is taken, it cannot claim that the finality test is satisfied. *See Ocean Cty. Landfill Corp. v. U.S. EPA Region II*, 631 F.3d 652, 656 (3d Cir. 2011). [4] Astra's challenge to the AO should be dismissed for lack of final agency action.

B. ASTRA'S CHALLENGE IS TIME-BARRED

Even if Astra were correct that the agency has imposed new obligations on manufacturers outside those imposed directly by the 340B statute—and it assuredly has not, *see infra* § II.B—Astra's challenge to the General Counsel's legal advice still fails because it is jurisdictionally barred by the six-

[4] Astra also fails to establish that the AO marks the "consummation of the agency's decisionmaking process" *Bennett*, 520 U.S. at 177-78, because the agency's position on the statutory question has not changed since the 1996 Guidance was issued. *See* Part I.B., *infra*.

year statute of limitations. After Astra and others engaged in a self-serving attempt to upend the long-settled 340B status quo, the General Counsel issued the AO to reiterate the agency's established interpretation, first published in the Federal Register in 1996 and reaffirmed in 2010, both after public comment. Astra's failure to challenge the agency's statutory interpretation when it was published twenty-five years ago, and republished more than a decade ago, is fatal to its claim here. The General Counsel *repeated* the agency's longstanding position but did not *reopen* the previous interpretations and thus did not restart the six-year limitations clock.

"[E]very civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues," 28 U.S.C. § 2401(a), and this express limitation on the ability to sue the federal government applies with equal force to challenges to agency action brought under the APA. *Nat'l Ass'n of Mfrs. v. Dep. of Defense*, 138 S. Ct. 617, 626-27 (2018); *see also Paucar v. Att'y Gen. of the U.S.*, 545 F. App'x 121, 124 (3d Cir. 2013). "Once the challenged agency action becomes final and invades a party's legally protected interest, the party's right to redress that injury under the APA accrues, and § 2401(a)'s six-year clock starts ticking." *Herr v. U.S. Forest Serv.*, 803 F.3d 809, 818-19 (6th Cir. 2015) (internal citation omitted). This restriction is not subject to waiver or tolling because the government enjoys sovereign immunity "save as it consents to be sued … and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit." *Diliberti v. United States*, 817 F.2d 1259, 1261 (7th Cir. 1987) (citation omitted). "Courts have consistently held that where the government's consent as sovereign to be sued is conditioned upon the filing of suit within a specified period of time, strict compliance with that condition is a jurisdictional prerequisite." *Id.*; *see also Kannikal v. Att'y Gen. of the U.S.*, 776 F.3d 146, 150 (3d Cir. 2015).

An agency's reiteration or application of an earlier decision does not constitute a new decision subject to challenge or start the limitations clock anew. In *IEDA*, 372 F.3d at 421-24, as in this case, the plaintiff challenged an agency's statement of its definitive legal interpretation, as set forth in an official letter from an EPA Director to regulated entities. The D.C. Circuit nonetheless explained that, because the most recent interpretation "reflects no change in the position announced" in earlier guidance, it was not a new agency action. *Id.* at 426; *id.* at 427. The court explained that, under the

"reopening doctrine," an agency's existing legal interpretations and regulations "are not newly reviewable" unless they have been reopened by agency action—*i.e.*, unless the administrative record evinces an intent by the agency to reevaluate and reconsider its earlier position, as opposed to merely explaining the earlier decision and applying it in a new context. *Id.* at 428. "Just as it would be folly to allow parties to challenge a regulation anew each year upon the annual re-publication of the Code of Federal Regulations, so too it is silly to permit parties to challenge an established regulatory interpretation each time it is repeated," because a contrary rule "would quickly muzzle any informal communications between agencies and their regulated communities." *Id.*

This holding repeatedly has been applied. In *General Motors Corp. v. EPA*, the court of appeals dismissed as untimely a challenge to an agency's legal interpretation, as embodied in official letters reiterating the agency's earlier position. 363 F.3d 442, 451 (D.C. Cir. 2004). Because the letters did not announce any intention to reevaluate the earlier pronouncement and instead "stated that outstanding violations would have to be addressed on the basis of EPA's long-held interpretation," the agency had not reopened its earlier decision. *Id.* at 449-50. Even though the earlier "interpretation was not published in the Federal Register," the court explained, the agency "can inform those affected simply by posting its new guidance or memoranda or policy statement on its website." *Id.* at 451. And because the plaintiff had failed to challenge the agency's interpretation within the applicable period for judicial review, its later attempt to attack that same position when embodied in an official letter was time-barred. Indeed, a contrary rule "to permit review whenever [an agency] reiterates" an interpretation but "has not changed its position," "would allow [plaintiff] to avoid the consequences of its failure to adhere to the congressionally prescribed jurisdictional window" of the relevant statute. *Edison Elec. Inst. v. OSHA*, 411 F.3d 272, 277-78 (D.C. Cir. 2005); *see also Biggerstaff v. FCC*, 511 F.3d 178, 155-56 (D.C. Cir. 2007); *Pub. Citizen v. Nuclear Reg. Comm'n*, 901 F.2d 147, 150 (D.C. Cir. 1990); *Peri & Sons Farms, Inc. v. Acosta*, 374 F. Supp. 3d 63, 71-73 (D.D.C. 2019). Stated simply, the reopening doctrine confirms that a policy established in an earlier action is not subject to fresh challenge when reiterated or applied subsequently unless a plaintiff can show that the agency has reopened its previous position for renewed consideration—as distinguished from explication.

Astra's challenge to the AO is an untimely collateral attack on the agency's consistent, twenty-five-year statutory interpretation. As explained *supra*, Background § I, in 1996 HHS concluded that the 340B statute does not allow manufacturers to refuse discounted-drug purchases by covered entities that rely on contract pharmacies. *See* 61 Fed. Reg. 43,549 (interpreting 340B statute to affirmatively require drug makers to honor purchases by covered entities, confirming if the "entity directs the drug shipment to its contract pharmacy," that in no way "exempts the manufacturer from statutory compliance"). The only voluntary aspect of the 1996 guidance was the choice of covered entities to use contract-pharmacy arrangements, given that covered entities remain liable to prevent duplicate discounting and diversion regardless of the dispensing mechanism chosen. *See id.* at 43,549-50.

Again in 2010 HHS promulgated contract-pharmacy guidelines after issuing notice and providing a 60-day comment period for interested parties, such as Astra, to participate. *See* 75 Fed. Reg. at 10,272. Once again HHS definitively set forth its statutory interpretation: "Under section 340B, 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 discount price." *Id.* at 10,278 (emphasis added). That mandatory language reiterated the agency's considered decision on what the 340B *statute* requires—not, as Astra inaccurately portrays, a "mere[] recommend[ation of] its approach." Compl. at ¶ 77. Indeed, HHS specifically explained that the 2010 Guidance does not "represent a substantive rulemaking under the APA" because it "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law" and instead constitutes "interpretive guidance" of the statute itself. 75 Fed. Reg. at 10,273. And as in 1996, there was no ambiguity in the agency's view that manufacturers are obliged to honor purchases by covered entities regardless whether contract pharmacies are used. True, the agency's interpretation of the obligation imposed on manufacturers was coupled with other voluntary guidance, advising covered entities on best practices to structure pharmacy agreements so as to prevent diversion or duplicate discounting. *See, e.g.*, *id.* at 10,279 (outlining "suggested contract provisions … for illustrative purposes … not intended to be comprehensive, exhaustive or required"). But the coupling of HHS's interpretation of the statutory obligations on manufacturers with other, voluntary provisions

advising covered entities in no way indicated that manufacturers had a choice unilaterally to opt out of providing 340B discounts whenever a covered entity serves its patients through outside pharmacies.

Had Astra disagreed with the agency's decision that the 340B statute requires manufacturers to honor purchases from covered entities regardless whether a contract-pharmacy model is used, Astra should have brought suit challenging the 2010 Guidance (or the earlier, equally mandatory interpretation in 1996). Likewise, had Astra contended that this obligation exceeded the 340B statute and thus must be imposed through legislative rulemaking, not an interpretive rule, Astra could have mounted a procedural challenge to the 2010 or 1996 Guidance. Indeed, in its complaint Astra inaccurately portrays the 2010 Guidance as having effected "a transformation of the scheme that Congress created," Compl. ¶ 2, but nowhere does Astra attempt to excuse its failure to challenge the agency's interpretation in the intervening years. On the contrary, Astra and other drug companies complied fully with HHS's interpretation for the past two and half decades—a timeframe in which covered entities have relied heavily on contract pharmacies to access 340B-discounted drugs.

Indeed, not only *could* Astra have mounted the same challenge in 1996 that it now brings, a trade association of which it currently is a member did just that. Astra's assertion that, "[i]n the Advisory Opinion [] HRSA for the first time took the position" that the statute requires manufacturers to honor contract-pharmacy dispensing, Mot. 14, 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 "disregard[ed] the contract pharmacy guidelines … where diversion is proven or suspected" would face "terminat[ion] [of] the manufacturer's agreement with the Secretary"). PhRMA relied on a letter from the HRSA Administrator to the industry conveying 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. Clearly it is Astra—not the Secretary—

that is attempting to transform 340B through a counterfactual portrayal of its historical operation.[5]

Nor did the General Counsel's legal advice reopen those earlier interpretations. Far from a "sudden reinterpretation of Section 340B," as Astra portrays (Compl. ¶ 79), the General Counsel simply reaffirmed the agency's "longstanding interpretation of the statute," AO at 4, in response to havoc wrought by manufacturers' unilateral contract-pharmacy restrictions. The AO does not rely on changed circumstances or even assert that anything *has* changed in the operation of the 340B Program (aside from recent, disruptive restrictions by drug makers). Abjectly false is Astra's claim that, "[i]n the Advisory Opinion … HRSA *for the first time* took the position that 'the plain meaning' of Section 340B's text *alone* requires manufacturers to sell covered drugs at 340B discounts to *unlimited* contract pharmacies." Mot. at 14 (first emphasis added). Putting aside the fact that it is covered entities, not contract pharmacies, which enjoy the legal right to obtain discounted medications, Astra cannot ignore the 1996 and 2010 Guidances out of existence (indeed, even Astra admits that the agency's contract-pharmacy interpretation has been in place "over the last three decades," Compl. ¶ 30). The agency could hardly have been clearer in its mandatory phrasing regarding what the statute requires of manufacturers, 75 Fed. Reg. at 10,278, and Astra points to *nothing* in the guidance to support its assertion that the interpretation was viewed as voluntary. Rather than break any new ground, the General Counsel's recent legal advice simply confirmed the agency's "consistent position over the past 24-plus years." AO at 4. That reiteration does not permit Astra to launch an untimely collateral attack on HHS's 1996 and 2010 decisions; any claim Astra might have had to challenge the agency's contract-pharmacy interpretation became time barred on March 5, 2016, six years from publication of the 2010 Guidance in the Federal Register. *Id.* at 10,271 (publication date of March 5, 2010).

II. EVEN IF THE ADVISORY OPINION WAS REVIEWABLE, ASTRA'S CLAIMS FAIL.

A. Notice-and-Comment Rulemaking is Not Required Because the Advisory Opinion Is An Interpretive Rule.

[5] 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 Astra's portrayal of the AO's interpretation as novel—and evidences the pharmaceutical industry's historic understanding of the agency's position.

Even if the AO were final agency action, and Astra's claims were not time-barred, its notice-and-comment claim would still fail for the additional reason that the AO is not a legislative rule. The AO is, at most, an interpretive rule that advises the public of HHS's interpretation of a statute, and is exempted from the APA's notice and comment requirements. *See* 5 U.S.C. § 553(b)(3)(A). "[T]he critical feature of interpretive rules is that they are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015). These rules do not "have the force and effect of law," *id.*, or "alter legal rights." *Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994); *see also Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003). Instead, they "state the agency's view of what existing law requires," "merely clarify[ing] or explain[ing] existing law or regulations." *Sekula*, 39 F.3d at 457.

The AO is a quintessential interpretive rule. It does not "alter legal rights," *id.*, but rather explains the agency's interpretation of the statutory phrase "purchased by." The 340B statute requires the Secretary to enter into agreements with drug manufacturers "under which the amount required to be paid" for certain drugs "purchased by a covered entity" does not exceed the ceiling price on those drugs. 42 U.S.C. § 256b(a)(1). The AO interprets this unambiguous text to conclude that the phrase "purchased by a covered entity" includes scenarios where "contract pharmacies are acting as agents of a covered entity." AO 1-2. Noting that the textual analysis is dispositive "given the lack of ambiguity in the plain text of the statute," the AO explains that "neither the agency nor a private actor" is authorized to "add requirements" to the statute. *Id.* at 2-3. It goes on to explain how the purpose and history of the 340B Program also support this conclusion, and how the contrary rationale of certain pharmaceutical manufacturers is unpersuasive. *Id.* at 3-8. Although Astra attempts to paint a different picture, 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 exists only to "advise the public of the agency's construction of [the statute]." *Mortgage Bankers Ass'n*, 575 U.S. at 97.

Courts routinely identify agency guidance as interpretive rules in analogous circumstances. For example, in *Shalala v. Guernsey Mem. Hosp.*, 514 U.S. 87 (1995), the Supreme Court considered whether the HHS Secretary's adoption of a Medicare Provider Reimbursement Manual was invalid for failure

to comply with the APA's notice and comment requirements. *Id.* 91. The dispute arose when the Secretary relied on the manual to determine that a reimbursable loss by the challenging hospital should be amortized, rather than reimbursed at once. *Id.* at 97. In promulgating the relevant provision of the manual, the Secretary determined "that amortization is appropriate" to ensure compliance with a statutory prohibition on cross-subsidizing health services at one time that were rendered over a number of years. *Id.* 97-99. Though the court noted the apparent benefits of recognizing the loss at once, it explained that the Secretary's Manual requiring amortization was a "prototypical example of an interpretive rule" because it was simply an "application of the statutory ban on cross-subsidization and the regulatory requirement that only the actual cost of services rendered to beneficiaries during a given year be reimbursed." *Id.* at 99. The court also emphasized that the manual did not adopt "a new position inconsistent with any . . . existing regulations." *Id.* at 100. So too here. The AO simply applies the statutory requirement that drugs "purchased by" covered entities be reimbursed at a certain price; it does not adopt any "new position" inconsistent with the statute or existing regulations.

Pennsylvania Department of Human Services v. United States is also instructive. 897 F.3d 497 (3d Cir. 2018). There, the court considered whether a 1994 State Medicaid Director Letter explaining that training program costs were not reimbursable under the Medicaid statute was an interpretive rule. *Id.* at 500. The court noted that, as with the AO, the agency issued the letter after an influx of questions and activities to "reiterate its longstanding policy." *Id.* at 501 (citation omitted). Emphasizing that the letter "explains . . . the statutory requirement," and "reiterates" the agency's interpretation of the statute, the court held that the letter "thus qualifies as an interpretive rule on several levels." *Id.* at 504. Because the letter "represent[ed]" what the Secretary "thinks" the statute means, and also "clarifie[d] and explain[ed] existing law," the letter was an interpretive rule. *Id.* at 505. There can be no meaningful distinction drawn between the AO and the letter at issue in *Pennsylvania Department of Human Services*. Both represent the interpretation of a statutory requirement, and are explanations of what an agency "thinks" the statutory requirement means.

Astra's arguments to the contrary cannot be reconciled with this binding precedent or the language of the AO. Astra cites to *General Electric Company v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002)

for the proposition that the AO's language creates "'a norm' by which regulated parties much shape their actions.'" Mot. 18. But in cherry picking words from the D.C. Circuit's opinion, Astra fails to acknowledge that the guidance document at issue in that case existed to fill a hole in the EPA's regulatory scheme, whereas here the AO interprets a requirement of the statute. The EPA's regulations required certain parties to conduct risk assessments, but did not "tell applicants how to conduct [them]." *Gen. Elec.*, 290 F.3d at 293. The guidance document existed to fill that void, and the court had to determine whether the mandatory language of the document required parties to conduct the risk assessments in a certain way. *Id.* That analysis has no place here, where the AO is merely explaining the preexisting requirements of a statute and is not creating a new obligation independent of the statutory or regulatory requirements.

Astra also argues that the AO improperly attempts to "implement" the statute rather than "interpret" the statute. Mot. 18. The AO does no such thing. The AO concludes that *42 U.S.C. § 256b(a)(1)* requires a participating drug manufacturer to "deliver its covered outpatient drugs" and that no one, including the agency, is *authorized by the statute* "to add requirements to the statute." AO 1-2. And, because it is the statute that creates the obligations reiterated in the AO, the AO cannot have independent "binding effect" on the ADR Panel that did not already exist by virtue of the statutory requirements. *See* Mot. 18-19. Though the AO was undoubtedly issued in response to drug manufacturers such as Astra's decision to upend the 340B program, *see* AO 1, Astra is incorrect in arguing that the timing of the AO has relevance here, *see* Mot. 18. Indeed, in *Pennsylvania Department of Human Services*, the Third Circuit concluded that a letter issued in response to an influx of questions and activities reiterating the agency's "longstanding policy" was an interpretive rule. 897 F.3d at 501.

Astra surely disagrees with the conclusions in the AO. But, the fact that Astra disagrees with the AO's statutory interpretation does not render the AO a legislative rule any more than the disagreement of the plaintiffs with the interpretations set forth in the interpretive rules in *Shalala* or *Pennsylvania Department of Human Services*. Astra's notice-and-comment claim should be dismissed.

B. Astra Fails to State a Claim on the Merits.

Even if the AO contained any new decisionmaking, Astra still would fail to state a claim that the AO exceeded statutory authority. Astra's claim relies on the false premise that, "[u]nder the Advisory Opinion, unless drug manufacturers like AstraZeneca offer 340B discounts to all contract pharmacies, they risk" severe civil penalties. *Id.* ¶ 8. This claim finds no support in the AO, both because it is healthcare providers (not pharmacies) that receive 340B discounts, and because Astra's risk of severe civil penalties flows from the statute, not the General Counsel's legal advice. Astra also implicitly urges this Court to reach the stunning conclusion that when Congress required manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1), it implicitly allowed *manufacturers*—parties with a vested interest in minimizing the volume of deeply discounted sales—unilaterally to condition safety-net providers' right to those purchases on particular dispensing models approved by the manufacturer. This claim finds no support in the statute. Far from exceeding lawful authority, the AO merely confirms what would be true in its absence, and has been true since the inception of the 340B Program: Manufacturers, including Astra, *must offer* 340B discounted drugs to covered entities in order to remain for Medicaid and Medicare Part B coverage, and any attempt unilaterally to condition those sales to covered entities on particular dispensing models runs afoul of manufacturers' statutory obligation.

The General Counsel's advice hewed closely to the statutory text, which expressly conditions access to Medicaid and Medicare Part B on a manufacturer's agreement to "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) (analyzed at AO 2). The AO further noted that each participating manufacturer has signed a contract with HHS embodying its agreement "to charge covered entities a price for each unit of the drug that does not exceed [the ceiling price]," and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," only "that the discounted drug be 'purchased by' a covered entity." AO at 2. And just as HHS cannot add new requirements to the statute, the General Counsel explained, nor can manufacturers. "It is difficult to envision a less ambiguous phrase" than "purchased by," and "no amount of linguistic gymnastics" can rework the

statute into authorization *for Astra* to condition fulfillment of its obligation to make discounted sales on a covered entity's agreement to undertake the expense of turning over detailed prescription-claims data, operate an in-house pharmacy, or select any particular drug-dispensing model. *Id.* In short, the statute is unambiguous in mandating that Astra make sales *to covered entities*, and Astra cannot skirt that obligation by erecting hurdles that limit a safety-net provider's choice among lawful dispensing models to serve its own patients. *Id.*; *see also id.* at 3 ("the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and … pays the manufacturer … [t]he situs of delivery … is irrelevant" because the covered entity maintains ownership of the discounted drug until it is dispensed to a qualified patient).[6] Moreover, the "must offer" language on which Astra exclusively focuses, Mot. 9-10, was not even added to the statute *until 2010*, *see* Pub. L. 111-148 § 7102(b)(1), yet Astra's obligation to honor *purchases by* covered entities clearly has been in place since 1992.

Although that "analysis is dispositive" in light of the total absence of ambiguity in the statute's command to honor *purchases by* covered entities, *id.*, the General Counsel went on to explain how it also fulfills Congress's purpose and comports with the decades-long operation of the 340B Program. When Congress created the program in 1992, 95+% of covered entities relied on outside pharmacies to dispense medications to their patients. AO at 4 (citing 61 Fed. Reg. at 43,550). And because Congress created the 340B Program for the purpose of providing much-needed *revenue* to covered entities, it could not have intended to require the overwhelming majority of safety-net healthcare providers to undertake the enormous expense of establishing and maintaining *a pharmacy* in order to access the discounted drugs to which they are statutorily entitled. *Id.* at 3-4 (citing H.R. Rep. No. 102-384(II), at 12 (1992)). Congress legislates against the backdrop of real-world facts and, the General

[6] Astra attacks the Advisory Opinion as having focused on the wrong phrase—insisting that "the phrase 'purchased by' … appears in a *separate sentence*" from the requirement that a manufacturer "offer" each covered entity discounted drugs. *See* Compl. ¶ 71 (emphasis added). That argument is specious; both phrases appear in the same subsection. More importantly, the statutory command read as a whole is framed as a requirement that the Secretary enter into contracts with each company conditioning access to Medicaid and Medicare Part B on the sale of discounted drugs to covered entities. *See* 42 U.S.C. § 256b(a)(1). Astra cannot shirk its responsibility by pointing out that Congress used a common device, requiring the Secretary to condition a benefit on adherence to the scheme.

Counsel noted, it directed 340B "at benefiting providers that are small, resource-limited, receiving federal assistance, or serving disadvantaged populations." *Id.* at 4. "To champion a policy" such as Astra now urges, "ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with [the] purpose of the Program and common sense." *Id.* The General Counsel persuasively explained that, had Congress intended to require the overwhelming majority of covered entities to fundamentally overhaul the method by which they provide drugs to patients, rather than for covered entities to benefit from discounted drugs *through existing dispensing models*, "it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel."

Importantly, the General Counsel also noted that HHS has interpreted the 340B statute "consistent[ly] [] over the past 24-plus years" to require drug makers "to offer ceiling prices even where contract pharmacies are used." AO at 4. Although in this suit Astra inaccurately insists that this interpretation was issued "[f]or the first time" in the AO, Mot. at 1, the AO correctly notes that both the 1996 and 2010 contract-pharmacy guidances are plain that the use of such arrangements are voluntary *for covered entities*, but the obligation for drug companies to fill orders by covered entities is, and always has been, mandatory. AO at 4.

Finally, the General Counsel demonstrated the folly in certain manufacturers' newfound objection to the 24-plus-year status quo, as reflected in certain communications from manufacturers to the agency. First, Astra and its cohort's "primary rationale offered for cutting off contract pharmacies," *id.* at 5, to prevent diversion and duplicate discounting, is an extra-statutory self-help mechanism that directly contravenes the express command of Congress. But, the 340B statute spells out precisely how suspected or actual diversion or duplicate discounting must be addressed: The manufacturer "must (1) conduct an audit, and (2) submit the claim to the [ADR] process." *Id.* at 5 (citing 42 U.S.C. § 256b(a)(5)(A), (B) and (d)(3)(A)). No language in the statute, however, permits a manufacturer to deny a covered entity's discounted-drug order on the basis of the dispensing mechanism chosen, and the "manufacturers' … unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute." *Id.* Second, HHS

already has confirmed in a previous, duly promulgated regulation that "[m]anufacturers cannot 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." *Id.* (citing 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)).

Third, the suggestion (proffered by Astra in its complaint, *e.g.* ¶ 160), that covered entities' decades-old reliance on contract pharmacies constitutes "diversion" is specious. AO at 6. The statute provides that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* (citing 42 U.S.C. § 256b(a)(5)(B)). This language quite plainly means that covered entities may not resell discounted drugs to non-patients, nor transfer the drugs to other, non-covered healthcare providers for prescribing to their own patients. But it is "absurd" to suggest that this straightforward prohibition requires a safety-net provider to ensure that 340B drugs are physically dispensed—*i.e.*, individually *handed*—to its patients by a pharmacist employed by that covered entity. AO at 7. Nothing in the statute restricts commonplace, real-world supply-chain logistics or outlaws preexisting dispensing models employed by covered entities at the program's inception. Nor does the statute require covered entities to incur the expense of *establishing a pharmacy* before accessing the program. Indeed, taken to its logical conclusion, manufacturers' argument that use of contract pharmacies constitutes "diversion" would mean that, "if a covered entity uses a courier service" or mail-delivery service "to send discounted drugs to its patient, this, too, would [] be an illegal 'transfer' to the shipper." *Id.* It also would mean that, for decades, covered entities have relied upon and manufacturers have acquiesced in a scheme that does violence to the statutory text (and that Astra's current allowance of one contract pharmacy per provider *also* would be unlawful).

The AO plainly did not "expand the statutory term 'covered entities' to include contract pharmacies," Compl. ¶ 152, because it merely confirmed what always has been true—that only covered entities may purchase 340B drugs, but they need not dispense them in-house. Similarly, the AO did not expose Astra to "claims of overcharging by covered entities and potential civil monetary penalties of up to $5,000 *per occurrence*; [] the potential revocation of [its] ability to participate in Medicare and Medicaid; and [] penalties under the False Claims Act." *Id.* ¶ 8. Rather, *the 340B statute subjects Astra to these sanctions for refusing purchases made by covered entities*, *see* 42 U.S.C. § 256b(a)(1), and it

contains no provision justifying Astra's refusal to honor such purchases based on the dispensing mechanism lawfully selected by the covered entity[7].

Each of Astra's arguments to the contrary lacks merit. First, Astra points to language from a Senate Committee report mentioning a provision initially considered by Congress but struck from the 340B statute before passage. Astra construes this passing reference as evidence that the statute as initially drafted "would have expressly permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services," so "[t]he statute's failure to mention contract pharmacies (even on-site ones) thus was no mere oversight." *See* Compl. ¶ 75 (citing S. Rep. No. 102-259 at 1-2). The omitted language provides no support for the statutory revision Astra attempts in this suit, however, because the legislative history cuts decidedly against Astra's position. The language *removed* by Congress would have restricted 340B-discounted sales to only those *dispensed by* a covered entity. *See* S. Rep. No. 102-259 at 1-2 (limiting discounted drugs to those "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with" a covered entity). But rather than codify that plain restriction—indeed, nearly the precise restriction Astra urges this Court to read into the statute—*Congress omitted it from the final bill* and instead enacted a statute that contains no requirement that 340B drugs be "dispensed by" a covered entity, *id.* The legislative history repudiates Astra's reading by demonstrating that Congress considered—but omitted—a requirement that covered entities "purchase[] and dispense[]" in-house or through "on-site pharmacy services."

Second, Astra insists that its current policy comports with the statute because a "manufacturer fully satisfies [340B] by making its medicines available to the covered entity itself." Mot. at 9. This assertion is disingenuous; an "offer" to make a purchase, made with onerous and non-statutory conditions (including that a covered entity establish a pharmacy or require its disadvantaged patients to travel great distances to fill prescriptions at a single site) cannot fulfill Astra's obligations. Congress

[7] Astra claims to have "expressed surprise that HRSA would threaten sanctions, such as civil monetary penalties," Compl. ¶ 53, in response to Astra's unilateral restrictions. That assertion strains credulity, given that the manufacturer's abrupt refusal to honor certain purchases by covered entities contravenes HHS's twenty-five-year interpretation of Astra's statutory obligations.

simply did not permit manufacturers to craft their own devices to limit access to discounted drugs, and an "offer" to sell drugs that the overwhelming majority of covered entities cannot, in practice, avail themselves of surely is not what Congress envisioned.[8] Because the General Counsel's analysis faithfully interprets the 340B statute, is grounded in Congressional intent, as expressed in its terms, and in no way expands the statute to require of manufacturers anything not already mandated by law, Astra fails to state a claim that the General Counsel's legal advice exceeded statutory authority. Even were this claim justiciable, it fails as a matter of law and must be dismissed.[9]

C. The Advisory Opinion Was Neither Arbitrary Nor Capricious.

Astra challenges the AO as an arbitrary and capricious action under the APA. *See* Mot. 13–16. Its arguments in this respect are meritless. Judicial review under the APA's arbitrary-and-capricious standard is highly "deferential," requiring only "that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Proj.* (*Prometheus*), 141 S. Ct. 1150, 1158 (2021). "[A] court may not substitute its own policy judgment for that of the agency," *id.*, and "should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–14 (2009) (citations omitted).

First, Astra suggests that the AO repudiated the agency's prior interpretation of the 340B statute *sub silentio*. *See* Mot. 6–7, 14. Specifically, Astra contends that the AO failed to acknowledge that HHS had previously considered the 340B statute to be "silent" with respect to the permissible

[8] Astra also argues that elsewhere "the 340B Statute itself carefully distinguishes … between covered entities and their agents." Mot. at 10 (citing 42 U.S.C. § 256b(d)(3)(B)(vi)). But this provision merely confirms that associations of covered entities may bring ADR claims on behalf of their members, and thus has no relevance whatsoever to the dispensing mechanisms covered entities may employ.

[9] Astra also rips from context a single phrase from the preamble to the 1996 Guidance in which the agency acknowledged "that there were many gaps in the legislation." *See* Compl. ¶¶ 32, 63, 69 (citing 61 Fed. Reg. 43,550). That passing reference does not suggest that the agency viewed its position on contract pharmacies as an addition to, or outside, the statutory text. Read in context, the reference to "gaps in the legislation" refers to the fact that "approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal Programs affected by this legislation and all [were] seeking guidance" on "how the Department intends to administer the 340B" Program. 61 Fed. Reg. 43,550. As explained *supra*, the agency used that guidance to outline best-practices for *covered entities* to access the program through outside pharmacies while guarding against duplicate-discounts and diversion, and confirmed *manufacturers'* obligation to honor all purchases by those entities.

means of drug distribution, and instead declared for the first time that the obligation to sell discounted drugs to covered entities using contract pharmacies for drug distribution was rooted in the 340B statute alone. *Id.* at 14. In so arguing, however, Astra mangles the reasoning of both HHS's prior guidance and the AO, both of which provided a consistent view of the statutory text.

The 1996 Guidance and the AO both began their interpretive analyses with the understanding that the 340B statute obligates drug makers to sell covered outpatient drugs to covered entities at ceiling prices. AR 370; *id.* at 2. With this "core requirement" in mind, *id.* at 2, both documents also acknowledged that the 340B statute does not expressly limit the permissible methods that covered entities may use to distribute those drugs, *id.* at 370 ("The statute is silent as to permissible drug distribution systems."); *id.* at 2 ("[This] requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs."). The 1996 Guidance—like the AO, *id.* at 2–4—interpreted this statutory silence as a "clear [indication] that Congress envisioned that various types of drug delivery systems would be used," *id.* at 370. It therefore found "no basis" (in the statutory text or otherwise) "on which to conclude that section 340B precludes" a covered entity from distributing drugs through a contract pharmacy, or that such an arrangement "exempts [a] manufacturer from" complying with its statutory obligations. *Id.* Thus, the 1996 Guidance concluded that it is "*the statute*" alone that "directs [a] manufacturer to sell [a covered outpatient] drug at the discounted price" to "a covered entity using contract pharmacy services." *Id.* And that is precisely the same interpretation of the 340B statute that HHS reiterated in its 2010 Guidance, *see id.* at 392, and that the General Counsel restated in the AO, *see id.* at 2–4. Astra thus fails to identify a change in the agency's interpretation of the 340B statute for which an explanation was wanting.[10]

Second, Astra argues that the General Counsel, in developing the AO, should have considered drug makers' "views" regarding their respective contract-pharmacy policies. Mot. 14–15. But the AO aimed to interpret the meaning of the 340B statute as a general matter, without applying the statute to any individual drug maker. AR 8 n.9. And Astra fails to explain how a drug maker's motivation for

[10] The AO's view that a covered entities' use of multiple contract pharmacies is permissible under the 340B statute did not mark a shift in HHS's position, which it has held for over a decade.

adopting extra-statutory restrictions on the use of contract pharmacies, or understanding how those restrictions operated, was a "relevant factor[]" in the AO's interpretive analysis. *See NVE, Inc. v. Dep't of Health & Hum. Servs.*, 436 F.3d 182, 190 (3d Cir. 2006).

Because the AO is, at most, an interpretive rule, the General Counsel did not need to accept or consider the drug maker's "comments" on the use of contract pharmacies in the 340B Program before issuing the AO. *See supra* II.A. Nevertheless, the General Counsel *did* consider Astra's and other drug makers' "views" on the matter, including explanations of their individual contract-pharmacy policies,[11] their interpretations of the 340B statute,[12] their concerns with drug diversion and duplicate discounting,[13] and their understanding of how a contract-pharmacy arrangement operates.[14] The record therefore belies Astra's complaint that drug makers' views were not adequately considered.[15]

Third, Astra faults the AO for not citing evidence to support a finding that contract pharmacies do *in fact* function as agents of covered entities under state law. Mot. 15. 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 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 and retains title to the drug. AR 6 (quoting AR 371). 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

[11] AR 1040, 1055, 1071, 1075, 1077–78, 1093–96, 1107, 1143, 1151–52, 1175–76, 1178–80, 1369, 1371–72, 2019–20, 2108–2110, 2114–16, 2127–28, 2148–49, 2166–72.
[12] AR 1041–43, 1075–76, 1175–76, 1178–79, 1373–75, 2024, 2026–36, 2114–15, 2142–43, 2157–61.
[13] AR 1035, 1046–50, 1076–77, 1093, 1144, 1176–77, 1369–71, 1383–86, 2017, 2106–07, 2147–48.
[14] AR 1043, 1051, 1055–56, 1151, 1177–78, 2017–18, 2107, 2146–47.
[15] Astra cavils that HHS acted unreasonably by not meeting with drug makers face-to-face. Mot. 14–15. But it fails to explain what additional relevant information drug makers would have provided.

irrelevant to the narrow question the AO addressed. *See NVE*, 436 F.3d at 190.

Lastly, contrary to Astra's contentions, the General Counsel was not required to consider claims that covered entities' increased use of contract pharmacies has heightened the risk of drug diversion and duplicate discounting. *See* Mot. 16. Whether there have been specific cases of program non-compliance under these circumstances is not a relevant factor in interpreting what is *generally* required under the 340B statute. *See NVE*, 436 F.3d at 190. Even so, the General Counsel neither "ignored" nor denied concerns regarding drug diversion and duplicate discounting (as Astra suggests). *See* Mot. 2, 16. Instead, the AO simply directed drug makers to pursue these claims in HHS's administrative dispute-resolution process, *see* AR at 5, the forum in which Congress has required such claims to be adjudicated, *see* 42 U.S.C. § 256b(d)(3)(A).

III. THE COURT LACKS JURISDICTION TO COMPEL AGENCY ACTION.

In its Amended Complaint, Astra seeks to compel HHS to post the manufacturer's notice of its contract-pharmacy policy on the agency's website, arguing that the agency's failure to do so is an "agency action unlawfully withheld or unreasonably delayed." Compl. ¶ 163–65 (quoting 5 U.S.C. § 706(1)). But Astra fails to mention this claim in its motion for summary judgment—a pregnant absence that speaks volumes about the merits of this claim, which the court lacks jurisdiction to review.

Under the APA, § 706(1), a court's "ability to 'compel agency action' is carefully circumscribed to situations where an agency has ignored a specific legislative command." *Massie v. U.S. Dep't of Hous. & Urb. Dev.*, 620 F.3d 340, 347 (3d Cir. 2010) (citation omitted); *accord Norton v. S. Utah Wild. All.*, 542 U.S. 55, 61 (2004). Here, there is no statutory or other legal requirement that HHS post Astra's notice on the agency's website, and Astra alleges nothing to the contrary. Indeed, Astra makes no attempt to identify a mandatory, statutory duty to underlie its § 706(1) claim. Thus, the court lacks jurisdiction to compel this action. *See Alvarado v. Table Mount. Rancheria*, 509 F.3d 1008, 1019–20 (9th Cir. 2007).[16]

CONCLUSION

The Court should dismiss each count or, in the alternative, grant summary judgment for HHS.

[16] Alternatively, for the same reasons stated above, Astra has failed to state a § 706(1) claim.

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Respectfully submitted,

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