UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, Indiana 46225

and

LILLY USA, LLC
1500 South Harding Street
Indianapolis, Indiana 46221,

Plaintiffs,

v.

XAVIER BECERRA,
in his official capacity as Secretary of HHS
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY,
in his official capacity
as Acting General Counsel of HHS
Office of the General Counsel
200 Independence Avenue, SW
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, D.C. 20201,

DIANA ESPINOSA,
in her official capacity
as Acting Administrator of HRSA
5600 Fishers Lane
Rockville, Maryland 20852,

and

HEALTH RESOURCES AND SERVICES
ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

Document Electronically Filed

NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiffs Eli Lilly and Company and Lilly USA, LLC, hereby file a copy of the recently issued opinion in *AstraZeneca Pharmaceuticals LP v. Becerra, et al.*, No. 21-27-LPS (D. Del. June 16, 2021) (Stark, J.), attached hereto as Exhibit A. The opinion addresses the language of the 340B statute, 42 U.S.C. § 256b, and the legality of the government's "Advisory Opinion" on contract pharmacies and the 340B program, both of which are at issue in the pending motions in this case.

Dated: June 17, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **June 17, 2021,** a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ John C. O'Quinn
John C. O'Quinn

Exhibit A

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

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Allon Kedem, Jeffrey L. Handwerker, Sally L. Pei, and Stephen K. Wirth, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, DC

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Attorneys for Defendants

MEMORANDUM OPINION

June 16, 2021
Wilmington, Delaware

STARK, U.S. District Judge:

At the end of 2020, the general counsel of the U.S. Department of Health and Human Services ("HHS," "the agency," or "the government") issued an advisory opinion (the "Opinion") explaining the obligations of pharmaceutical manufacturers who participate in the federal 340B Program..[1] AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "AZ") sued the government, asserting that the issuance of the Opinion violated the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. AstraZeneca now moves for summary judgment based on the administrative record ("AR"). The government cross-moves to dismiss or for summary judgment in its favor.

This case implicates numerous important issues of public policy, including access to health care, pharmaceutical companies' profit motives, and the wisdom (or not) of shifting some private profits to publicly funded health care facilities. The Court's role, however, is to set aside any personal views it may hold on these matters and to decide only the narrow questions properly before it: do the parties present a dispute over which the Court may exercise jurisdiction and, if so, is the position outlined in the Opinion compelled by the unambiguous text of the 340B statute? For the reasons explained below, the Court concludes that it has jurisdiction and that the Opinion's analysis is not the sole reasonable interpretation of the statute.

Accordingly, the Court will deny the government's motion to dismiss, except with respect to the one claim that AstraZeneca has abandoned. While AstraZeneca has shown that it is

[1] The "340B Program" takes its name from its codification at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

entitled to at least some relief, the Court will provide the parties with an opportunity to offer further input on the precise relief to be awarded, the impact of the Court's conclusions on the cross-motions for summary judgment, and how (if at all) this case should now proceed.

BACKGROUND

About thirty years ago, Congress passed the Veterans Health Care Act ("VHCA"), Pub. L. No. 102-585, 106 Stat. 4943 (1992). One part of the VHCA was the establishment of the 340B Program. The Health Resources and Services Administration ("HRSA"), an agency within HHS, administers the 340B Program.

Under the 340B Program, certain hospitals and clinics ("covered entities") may purchase prescription drugs for their patients at or below maximum prices set by statute ("ceiling prices"). In general, covered entities are "public and not-for-profit hospitals that serve large numbers of patients with low income and/or living in rural areas." (D.I. 54 at 2; *see also* 42 U.S.C. § 256b(a)(4) (defining covered entities to include variety of organizations receiving federal funds, such as federally qualified health centers, sole community hospitals, and rural referral centers))

Congress created a powerful incentive to induce drug manufacturers' participation in the 340B Program: if drug manufacturers wish to receive reimbursements for their drugs under the Medicare Part B and Medicaid programs, the manufacturers must permit covered entities to buy those drugs at the 340B Program's discounted rates. *See* 42 U.S.C. § 1396r-8.

The 340B statute is not especially long nor detailed. The provisions most pertinent to the issues before the Court are reproduced below:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) ***purchased by a covered entity*** on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and ***shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price***.

Id. § 256b(a)(1) (emphasis added). As discussed below, the government relies heavily on the first of these highlighted terms (the "purchased by" provision), while AstraZeneca emphasizes the latter (the "must offer" requirement). (*Compare, e.g.*, D.I. 56 at 23 & n.6 *with* D.I. 65 at 13; *see also* D.I. 43 at 3)

The dispute in this case relates to covered entities' use of third-party pharmacies, referred to by the parties (and the Court) as "contract pharmacies." Neither the "purchased by" provision nor the "must offer" requirement – nor any other part of the 340B statute – addresses whether a covered entity must have an in-house pharmacy for purchasing discounted drugs from manufacturers, or whether the covered entity may or must use an outside, third-party pharmacy to make purchases. The statute is silent on this matter.

According to the administrative record the government has put before the Court,[2] HRSA has issued two relevant guidance documents relating to covered entities' use of contract pharmacy services.

HRSA issued the first relevant guidance document in 1996. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("1996 Guidance"). In the 1996 Guidance, HRSA acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. At the time, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)." *Id.* at 43,550. For covered entities that did not have in-house pharmacies, establishing them would likely have been prohibitively expensive. *See id.* Under the 1996 Guidance, each covered entity was permitted to contract with one (and only one) outside pharmacy to dispense 340B drugs. *Id.* at 43,555 ("Each covered entity [that] purchases its covered outpatients drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The ***limitation of one pharmacy contractor per entity*** does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, ***as long as only one site is used for the contracted services***.") (emphasis added).

HRSA issued the second relevant guidance document 14 years later. *See* Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Guidance"). The 2010 Guidance was similar to the 1996 Guidance in

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[2] The parties agree that the government is solely responsible for preparing the administrative record and providing it to the Court (*see* D.I. 76 at 28, 105), as it has done. (*See generally* D.I. 40, 40-1, 40-2, 40-3, 40-4, 40-5, 40-6, 40-7) The parties further agree that the Court's decision must be based on the administrative record. (*See* D.I. 76 at 21-22, 38, 59)

many respects, but with at least one crucial difference: the 2010 Guidance allowed covered entities to use an unlimited number of contract pharmacies to dispense 340B drugs. *See id.* at 10,277 ("In addition to contracting with a single pharmacy for each clinical site, ***covered entities may pursue more complex arrangements that include multiple pharmacies*** . . . .") (emphasis added).[3]

Since the issuance of the 2010 Guidance, the number of contract pharmacies dispensing 340B drugs has increased dramatically. (*See* D.I. 43 at 4) (citing U.S. Gov't Accountability Off., *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018), https://www.gao.gov/assets/700/692697.pdf (noting increase from about 1,300 contract pharmacies in 2010 to about 20,000 contract pharmacies in 2017)) The five largest U.S. pharmacy chains – CVS, Walgreens, Walmart, Rite-Aid, and Kroger – constitute 60% of all contract pharmacies under the 340B Program. (*Id.*) Some drug manufacturers have suggested that the widespread use of contract pharmacies has increased pharmacies' profits without providing significant benefits for patients. (*See id.* at 4-5; *see also* D.I. 46 at 19-20)

Evidently in response to the proliferation of contract pharmacies, AstraZeneca announced in August 2020 that, effective October 1, 2020, it would begin limiting distribution of 340B drugs to: (i) covered entities with in-house pharmacies, as long as they do not use any contract pharmacy; and (ii) covered entities without in-house pharmacies, as long as they use only a

[3] The 2010 Guidance explicitly states that a covered entity having an in-house pharmacy may also use an unlimited number of contract pharmacies to "supplement" its services. 75 Fed. Reg. at 10,277.

single contract pharmacy. (*See* AR 1107; *see also id.* at 1075-78).[4] AstraZeneca asked HRSA to post a notice about AstraZeneca's policy change on HRSA's website. (*See id.* at 1110-11) HRSA declined that request. (*Id.*)

On December 30, 2020, in light of the policy change by AstraZeneca (and similar changes by other drug manufacturers), and in response to expressions of concern from other stakeholders, including covered entities and contract pharmacies (*see, e.g.*, *id.* at 1065-70, 1084-85, 1090-92), the HHS general counsel issued the Opinion (*see id.* at 1-8). The Opinion concluded: "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price – and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price – even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." (*Id.* at 8) The Opinion added 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." (*Id.* at 1) According to the Opinion, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." (*Id.* at 8) Therefore, the view expressed in the Opinion is that all covered entities – and, implicitly, not just those lacking in-house pharmacies – may use contract pharmacy services without any limit on the number of contract pharmacies per covered entity.

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[4] The Court cites the administrative record using the pagination provided in the bottom righthand corner. For example, "AR 1107" refers to the page marked "ADVOP_001107."

The Opinion asserts that its conclusions are compelled by the "plain meaning" of the 340B statute. (*Id.* at 2-3) Moreover, the Opinion declares that the government's interpretation of the statute has been consistent throughout the past 25 years. (*See id.* at 4-5)

Two weeks after HHS issued the Opinion, AstraZeneca sued the government in this Court. (D.I. 1).[5] AstraZeneca subsequently amended its complaint. (D.I. 13) ("Am. Compl.") The amended complaint contains four claims for declaratory and/or injunctive relief: (i) in promulgating and enforcing the Opinion, the government failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D); (ii) the Opinion exceeds the government's authority under the 340B statute, in violation of § 706(2)(A) & (C); (iii) the Opinion is arbitrary and capricious, in violation of § 706(2)(A); and (iv) in failing to post AstraZeneca's notice to covered entities on HRSA's website, the government exceeded its authority under the 340B statute and unlawfully withheld agency action, in violation of § 706(1). (Am. Compl. ¶¶ 141-65)

AstraZeneca moved for a preliminary injunction and sought to expedite the proceedings. (D.I. 14, 17) After negotiations with the government, the parties agreed to an accelerated briefing schedule for dispositive motions, and AstraZeneca dropped its motion for a preliminary injunction. (D.I. 23, 31)

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[5] Three other drug manufacturers brought similar suits against the government. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.) (filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.) (filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.) (filed Jan. 15, 2021). A trade association representing various brand-name pharmaceutical companies also sued HHS. *See Pharm. Research & Mfrs. of Am. v. Cochran*, No. 8:21-cv-99198-PWG (D. Md.) (filed Jan. 22, 2021).

On May 17, 2021, while briefing was ongoing, HRSA sent AstraZeneca a letter stating that AstraZeneca is "in direct violation of the 340B statute." (D.I. 66-1 at 1) ("Violation Letter") HRSA told AstraZeneca that it "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." (*Id.* at 2) The Violation Letter warned AstraZeneca that it faces civil monetary penalties if it does not comply with its statutory obligations. (*Id.*) HRSA initially requested a response from AstraZeneca by June 1, 2021 (*see id.*), though it subsequently extended that deadline to June 10 (*see* D.I. 77).

In response to the Violation Letter, AstraZeneca filed an emergency motion seeking an "administrative stay" and, in the alternative, expedition of the proceedings. (D.I. 66) The Court declined to enter an administrative stay but agreed to further expedite the already-expedited proceedings, moving up the motions hearing by about two weeks. (D.I. 71)

The Court has carefully considered the administrative record, the parties' briefing, and related materials. (*See generally* D.I. 40, 43, 56, 65, 74).[6] It has also considered the views of several *amici curiae*. (*See generally* D.I. 46, 54, 59, 72) The Court heard extensive oral argument by videoconference on May 27, 2021. (*See* D.I. 76) ("Tr.").[7]

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[6] The government's surreply brief is laden with unfair characterizations of AstraZeneca's positions. (*See, e.g.*, D.I. 74 at 1 (accusing AstraZeneca of making "blatant misstatements" and "spurious" contentions), *id.* at 4 ("preposterous," "nonsensical," "gallingly"), *id.* at 5 ("lengthy diatribe," "invective"), *id.* at 7 ("disingenuous," "bizarrely contends")) While these attacks have not affected the Court's decision, litigants should understand that this type of rhetoric is rarely justified and, more commonly, undermines confidence in the position of the party employing such language.

[7] During the hearing, the government lodged an objection to AstraZeneca's slide

LEGAL STANDARDS

I. Motion To Dismiss

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true . . . .'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant . . . has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court is not obligated to accept "bald assertions" as true. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted). Nor is it obligated to credit "unsupported conclusions and unwarranted inferences." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

II. Administrative Procedure Act

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). In that posture, "[t]he entire case on review is a question of law." *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Accordingly, the "customary summary judgment standard" under Federal Rule of Civil Procedure 56 "does not apply." *Bintz v. Fed. Emergency Mgmt. Agency*, 413 F. Supp. 3d 349, 360 (D. Del. 2019) (citing *Am. Bioscience*, 269 F.3d at 1083). Rather, the APA provides the applicable standard for the reviewing court. *See*

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presentation for purportedly containing evidence outside the administrative record. (*See* Tr. 21-22) Because the Court's decision does not depend on any information that is contained only in the slide presentation, that objection is overruled.

id. According to the APA, the Court shall "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C) & (D).

DISCUSSION

I. The Court May Review The Opinion

The parties dispute whether the Opinion is final and reviewable, as well as whether AstraZeneca's challenge to the Opinion is timely. The Court concludes that the Opinion is final and reviewable and that AstraZeneca promptly challenged it.

A. The Opinion Is Materially Different From The 1996 And 2010 Guidance

The government's arguments regarding unreviewability and untimeliness largely rest on its repeated contention that the Opinion merely restates a position that the government has held throughout the entirety of the 340B Program. (*See. e.g.*, D.I. 56 at 1, 16, 18, 24, 28; D.I. 74 at 1-2, 6-8, 10) The Court rejects this contention.

Importantly, the Opinion's analysis is based (at least in part) on the "must offer" requirement. (*See* AR 2) ("[T]he core requirement of the 340B statute . . . is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities.") Congress did not codify the "must offer" requirement until March 23, 2010, ***after*** HRSA issued the 2010 Guidance on March 5. It was impossible, therefore, for either the 1996 or 2010 Guidance to have addressed the then-nonexistent provision. To the extent that the Opinion interprets manufacturers' obligations in accordance with the "must offer" requirement, it treads "new ground." *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004).

Furthermore, the focus of the Opinion is different from the focus of the 1996 and 2010 Guidance. Both guidance documents were directed toward covered entities, explaining how they could take full advantage of the 340B Program. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,555 ("Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy."); 2010 Guidance, 75 Fed. Reg. at 10,277 ("This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate 'in-house' pharmacy services . . . ."). On the other hand, the Opinion is directed toward drug manufacturers. (*See, e.g.*, AR 1) ("[W]e conclude that . . . a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies . . . .")

AstraZeneca also persuasively argues that the mode of analysis in the Opinion is different from the mode of analysis employed in the 1996 and 2010 Guidance. (*See, e.g.*, D.I. 65 at 6-7) The 1996 Guidance acknowledged there were "many gaps" in the 340B statute. *See* 61 Fed. Reg. at 43,550..[8] The 2010 Guidance similarly recognized that HRSA sought to "create a working framework" to fill in statutory gaps. *See* 75 Fed. Reg. at 10,273. Neither guidance document cited specific provisions in the 340B statute. (*See* Tr. 71-72) That is, neither the

[8] The government tries to explain away the 1996 Guidance's reference to "gaps" by insisting that it was referring solely to the "approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal Programs affected by this legislation," all of whom were "seeking guidance on how the Department intend[ed] to administer the 340B Program." (D.I. 56 at 27 n.9) (citing 61 Fed. Reg. at 43,550; internal quotation marks omitted) This explanation is unpersuasive. In context, HRSA was acknowledging a statutory "gap" as to the proper treatment of pharmacies.

1996 Guidance nor the 2010 Guidance cites § 256b nor discusses its particular provisions. The Opinion, by contrast, is explicitly an exercise in statutory interpretation. (*See* AR 2) ("[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous.") (quoting *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004)) Statutory interpretation is a fundamentally different approach from programmatic gap-filling. (*See generally* Tr. 71) (government conceding that, in guidance documents, "the agency didn't engage in this sort of longer form of statutory interpretation that it did in the advisory opinion")

Based on the administrative record, the Court concludes that the Opinion is the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies..[9] Indeed, as noted above, the 1996 Guidance limited covered entities to using no more than a single contract pharmacy. *See* 61 Fed. Reg. at 43,555 (acknowledging "limitation of one pharmacy contractor per entity"). Strikingly, AstraZeneca's new policy, as announced in August 2020, would not have run afoul of the 1996 Guidance – yet it directly contradicts the Opinion..[10] This reality demonstrates that the

[9] During the hearing, the government insisted that HHS had articulated this position before 2020, but it could not cite anything in the administrative record to support this assertion. (*See* Tr. 72-73)

[10] The government now suggests that the 1996 Guidance was wrong in limiting covered entities to a single contract pharmacy. (*See* Tr. 67; *see also id.* at 94 (same for *amici*)) Regardless of whether the 1996 Guidance was correct, the important point is that the government's interpretation of the statute has not been consistent.

government's interpretation of manufacturers' obligations under the 340B Program has not remained constant but has, instead, evolved over time..[11]

The following table summarizes some of the key differences between the guidance documents and the Opinion:

Document	Directed to:	Number of Contract Pharmacies Permitted	Mode of Analysis	Interprets "Must Offer" Requirement?	Does AZ's 2020 Policy Comply?
1996 Guidance	Covered entities	One	Programmatic Gap Filling	No (did not exist)	Yes
2010 Guidance	Covered entities	Unlimited	Programmatic Gap Filling	No (did not exist)	No
2020 Opinion	Drug manufacturers	Unlimited	Statutory Interpretation	Yes	No

For at least the reasons already explained, and especially in combination, these differences establish that the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted.

To be sure, since 1996, the government has maintained that the 340B statute broadly requires pharmaceutical manufacturers to provide discounts to covered entities. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,549 ("It has been the Department'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."); *id.* at

[11] As AstraZeneca points out, "the Opinion does not acknowledge (much less explain) a change in approach from prior agency guidance." (D.I. 65 at 1) The failure to accept this reality does not, of course, change the fact that the government's interpretation of the statutory obligations of drug manufacturers has actually changed. *See generally Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) ("[T]he agency must at least display awareness that it is changing position and show that there are good reasons for the new policy.") (internal quotation marks omitted).

43,555 ("Under section 340B, we believe 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."); 2010 Guidance, 75 Fed. Reg. at 10,278 (similar). But the government's position overlooks that, throughout the past 25 years, the government has dramatically expanded how covered entities may purchase 340B drugs. The agency's interpretation of manufacturers' obligations with respect to covered entities necessarily shifts every time that HHS changes its guidance with respect to covered entities' rights. In this context, it is inaccurate to insist that manufacturers' duties have never changed, solely on the grounds that the government has always required manufacturers to accommodate all contract pharmacy arrangements that the government has permitted. Again, because the government has changed what covered entities ***may*** do, it has consequently changed what drug manufacturers ***must*** do.

B. The Opinion Constitutes Final Agency Action

There are two requirements for agency action to be final. First, "the action must mark the consummation of the agency's decisionmaking process." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotation marks omitted). That is, the action cannot be "merely tentative or interlocutory." *Id.* at 178. Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* (internal quotation marks omitted). Both requirements are satisfied here.

The Opinion is the "consummation" of HHS's decisionmaking process. The Court agrees with AstraZeneca that the Opinion is not "tentative": it "was issued by the agency's General Counsel," "announces unqualified conclusions," and "anticipates no further

reconsideration of the issue." (D.I. 65 at 2) The government's only argument to the contrary, raised in a footnote, rests on the premise that the Opinion merely restates the position that HHS has held since 1996. (*See* D.I. 56 at 13 n.4) For the reasons explained above, that premise is faulty.

The Opinion also has legal consequences for AstraZeneca. It repeatedly states that pharmaceutical manufacturers are "obligated" and cannot "refuse" to provide 340B drugs to multiple pharmacies who contract with covered entities. (AR 1, 8) That language is mandatory and conveys at least the impression that HHS expects "immediate compliance." *Univ. of Med. & Dentistry of N.J. v. Corrigan*, 347 F.3d 57, 69 (3d Cir. 2003) (internal quotation marks omitted). The Opinion, then, is fairly characterized as "the agency's definitive position." *Id.* (internal quotation marks omitted). HHS has not offered only preliminary thoughts on the matter while launching a more thorough assessment; instead, it has offered its unequivocal answer to a legal question.

The availability of administrative dispute resolution ("ADR") proceedings does not render AstraZeneca's challenge to the Opinion unreviewable by this Court. ADR proceedings permit drug manufacturers to pursue claims against ***covered entities*** for alleged drug diversion and duplicate discounts. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,645 (Dec. 14, 2020) (the "ADR Rule"). ADR proceedings do not provide a venue for manufacturers to challenge ***agency*** action, as AstraZeneca does in this

litigation. If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained. (*See* D.I. 43 at 18-19).[12]

Accordingly, the Opinion is final and reviewable.

C. AstraZeneca's Challenge Is Not Time-Barred

The parties agree that, to be timely, this lawsuit must have been filed "within six years after the right of action first accrue[d]." 28 U.S.C. § 2401(a). The government contends that AstraZeneca waited too long to challenge the Opinion, even though AstraZeneca initiated this lawsuit only a couple of weeks after HHS issued the Opinion. (*See* D.I. 56 at 13-18) In the government's view, AstraZeneca's right of action accrued approximately 25 years ago with the issuance of the 1996 Guidance. (*Id.* at 14) This argument is unavailing. It is predicated, once again, on the false premise (*see supra* Section I.A) that the government's position has been consistent throughout the history of the 340B Program.

In arguing that AstraZeneca should have brought a version of this lawsuit 25 years ago, the government points to (i) a challenge by the trade association PhRMA to a precursor of the 1996 Guidance and (ii) a contemporaneous letter from the HRSA Administrator. (*See* D.I. 56 at 17-18) This evidence does not alter the Court's conclusions. AstraZeneca did not exist in its current form at the time of the PhRMA litigation (*see* Tr. 51), so the plaintiff before the Court

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[12] AstraZeneca also raises serious concerns about its inability to conduct effective audits of covered entities, which is a prerequisite for manufacturers to engage in the ADR process. *See* 42 U.S.C. § 256b(d)(3); ADR Rule, 85 Fed. Reg. at 80,645; *see also* D.I. 43 at 16; D.I. 65 at 19; Tr. 59-61. The administrative record contains no indication that the government ever grappled with these practical problems with the ADR process. *See generally Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *7-10, 12 (S.D. Ind. Mar. 16, 2021) (preliminarily enjoining government from enforcing ADR Rule against drug manufacturer given likelihood that ADR Rule is procedurally defective).

cannot fairly be faulted for not filing suit at that time. Moreover, the PhRMA litigation did not challenge the final 1996 Guidance, and it did not (and could not) challenge the Opinion. Once again, the fact that the government has not consistently taken the same position with respect to manufacturers' obligations under the statute defeats the government's suggestion that a challenge to an earlier iteration of its policy (in 1996) would also essentially be a challenge to the government's current policy (as expressed in the Opinion).

Hence, AstraZeneca's challenge is timely..[13] As the Court has jurisdiction to review the Opinion, it must deny the government's motion to dismiss.

II. The Opinion's Analysis Is Not The Only Permissible Interpretation Of The Statute

Turning to the merits of AstraZeneca's declaratory judgment claims, the Court concludes that there is more than one permissible interpretation of the 340B statute..[14] Because the Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies, the Opinion is legally flawed.

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[13] The government emphasizes that AstraZeneca and other pharmaceutical manufacturers have historically complied with the government's rules for the 340B Program. (*See, e.g.*, D.I. 56 at 17, 25) While that acquiescence may provide a basis for some skepticism regarding the motivation behind manufacturers' recent efforts to push back against the program, AstraZeneca has neither waived nor forfeited any rights to pursue its legal challenges.

[14] During the hearing, counsel for *amici* American Hospital Association and other organizations suggested a helpful way to characterize the two parties' positions: if AstraZeneca is right, then drug manufacturers participating in the 340B Program do not have to provide discounted pricing for ***any*** drugs delivered to contract pharmacies, while if the government is right, then those same manufacturers must give discounted pricing for ***all*** drugs prescribed by covered entities, including drugs delivered to an unlimited number of contract pharmacies or through any other system for obtaining drugs. (*See* Tr. 91) In the Court's view, the statute does not compel either interpretation, yet both are plausible.

The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs. Pharmacies are not mentioned anywhere in the statutory text – neither in § 256b(a)(1), which (as both parties agree) contains the relevant command, nor in § 256b(a)(4), which provides the definition of "covered entity." When a statute does not include even a single reference to the pertinent word (e.g., "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word. Here, the absence of any reference to "pharmacies" is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.

Instead of addressing pharmacies, the first part of the statute – the "purchased by" provision relied on by the government – is directed to the Secretary of HHS, requiring him 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 . . . ***purchased by*** a covered entity . . . does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). This provision does not directly act on covered entities and, in any event, says nothing of the permissible role (if any) of contract pharmacies. The next sentence contains the "must offer" requirement, providing that each agreement between the Secretary and a manufacturer "***shall require that the manufacturer offer*** each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* (emphasis added). This provision, too, says nothing about the permissible role (if any) of contract pharmacies. Again, the statute is simply silent on this point.

The statute's total omission of contract pharmacies renders it ambiguous with respect to the central issue in this case.

Still, the Opinion asserts that the "***plain meaning***" of the statute "requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." (AR 2) (emphasis added; capitalization modified) In particular, the government contends that the "purchased by" provision of § 256b(a)(1) imposes this obligation on manufacturers participating in the 340B Program. (*See, e.g.*, Tr. at 64-65) (arguing that "there is . . . no . . . plausible reading of 'purchased by' that would exclude drugs that are purchased by the covered entity but distributed by a contract pharmacy") This is unpersuasive. The "purchased by" language directly imposes an obligation on the Secretary (and only indirectly imposes obligations on manufacturers), and it refers to "covered outpatient drugs . . . purchased by a covered entity" without any reference to the amount of such drugs purchased or the model by which the drugs are distributed. That language simply cannot bear the weight that the government places on it. It is, instead, ambiguous on the points in dispute between the parties.

The Opinion goes on to add: "It is difficult to envision a less ambiguous phrase[,] and no amount of linguistic gymnastics can ordain otherwise." (AR 2; *see also id.* at 3 ("Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive.")) The Court disagrees. The government may now also disagree, for it acknowledged at the hearing that "Congress could have been more specific that . . . the drugs purchased by a covered entity had to be dispensed in an in-house pharmacy or had to be dispensed through a contract pharmacy or any number of . . . limited arrangements[,] but the fact is it was not specific . . . ." (Tr. 65; *see also*

1996 Guidance, 61 Fed. Reg. at 43,549 ("The statute is silent as to permissible drug distribution systems.")) In any event, it is not at all difficult to imagine a less ambiguous phrase that Congress could have included in § 256b(a)(1). Congress could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Instead, Congress was silent on the issue, and the statute is ambiguous.

If the statute offers any clues on the issue, they militate against the view set out in the Opinion. The Opinion expressly relies on the assumption that contract pharmacies act as agents of covered entities. (*See* AR 6) (noting that "covered entity and contract pharmacy are not distinct, but function as principal-agent").[15] Neither the operative provision in § 256b(a)(1) nor the definition of "covered entity" in § 256b(a)(4) speaks about covered entities' agents – although other provisions in the 340B statute do speak about covered entities' affiliates. For example, § 256b(d)(3)(B)(vi) refers to "associations or organizations representing the interests of" covered entities. If Congress intended to include agents within the definition of "covered entity," it evidently knew how to do so. It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.

Other statutory provisions also cut against HHS's position. For example, another part of the VHCA (which established the 340B Program) refers specifically to "drugs procured by an agency of the Federal Government" that are "received[,] stored, and delivered" by "a commercial

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[15] During the hearing, the government argued that agency relationships between covered entities and contract pharmacies are merely exemplary. (Tr. 34-35) The Court cannot square that contention with the text of the Opinion, which states that it applies "***to the extent*** contract pharmacies are acting as agents of a covered entity." (AR 1) (emphasis added)

entity ***operating under contract*** with such agency." 38 U.S.C. § 8126(h)(3) (emphasis added). Likewise, a provision in a different health care statute explicitly covers "a person authorized to act as a purchasing ***agent*** for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(C) (emphasis added). Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute.

The legislative history is of no greater assistance to the government. When Congress added the "must offer" requirement to the statute in 2010, it specifically contemplated including language referring to drugs "purchased and dispensed by, or ***under a contract entered into for on-site pharmacy services*** with" covered entities. *See* S. Rep. No. 102-259 at 2 (1992) (emphasis added). Congress chose not to include pharmacy services in the version of the bill that it ultimately passed. That omission suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies..[16]

Both parties agree that only Congress may add requirements to the 340B statute. (*See* Tr. 22, 36, 41-42) Yet both parties' interpretations of the statute effectively, and impermissibly, add requirements to it. Under the government's interpretation, pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies. Under AstraZeneca's interpretation, covered entities are required to purchase their 340B drugs through

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[16] The House Report on the 340B Program states: "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(II) at 12 (1992). While that general goal informs the Court's reading of the statute, it does not transform ambiguous statutory language into an unambiguous congressional command.

in-house pharmacies..[17] Neither requirement is contained in the statute, nor (therefore) compelled by it..[18] Thus, on the parties' own views, the Court is not permitted to read either of these requirements into the statute.

In the Court's view, given the ambiguous statutory language, HHS could reasonably choose to opine that manufacturers are not required to deliver 340B drugs to an unlimited number of contract pharmacies when the covered entities themselves never possess the drugs. The Secretary might be motivated to interpret the statute in that manner to deter waste and fraud. (*See generally* D.I. 43 at 5) ("The promise of outsized profits, combined with lax federal oversight, has created a perfect storm for abuse.").[19] Of course, the statutory language does not compel this view, just as it does not compel the view articulated in the Opinion. The point is, once more, that Congress simply has not spoken on the issue.

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[17] Even though AstraZeneca's new policy permits each covered entity that lacks an in-house pharmacy to use a single contract pharmacy, AstraZeneca contends that its agreement to work with any contract pharmacies is voluntary. (*See, e.g.*, Tr. 57-58) Under AstraZeneca's interpretation of the statute, a drug manufacturer participating in the 340B Program is only required to sell covered drugs directly to covered entities.

[18] In reaching this conclusion, the Court necessarily rejects AstraZeneca's "first line position" that the Opinion is "objectively wrong" and "contrary" to the plain language of the 340B statute. (Tr. 43; *see also* D.I. 65 at 12)

[19] Under the now-prevalent "replenishment model," pharmaceutical manufacturers ship prescription drugs to pharmacies for dispensing to all patients. At the time of dispensing, the pharmacies do not know whether the prescriptions were written by medical providers at covered entities and qualify for 340B discounts. After 340B eligibility is later determined (typically using an algorithm), the manufacturers process chargebacks to account for the 340B drugs' discounted prices. The covered entities never physically possess the drugs. (*See* D.I. 65 at 11; D.I. 46 at 12-14; *see also* AR 6 n.6 (extending Opinion's reasoning to replenishment model))

If the Opinion had endorsed AstraZeneca's view of its obligations under the 340B statute, it is possible that covered entities would have brought their own suit against HHS to challenge that interpretation. In that hypothetical case, the outcome would have been the same as the one reached here, because the statutory language does not speak to covered entities' use of contract pharmacies. The text no more compels AstraZeneca's interpretation than the government's alternative interpretation.

While HHS's current interpretation of the statute is permissible, the Opinion is based on the "unjustified assumption" that Congress imposed this interpretation as a statutory requirement. *See Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021). "[D]eference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation marks omitted). Thus, AstraZeneca is entitled to some relief. *See, e.g.*, *Am. Lung Ass'n*, 985 F.3d at 944 (vacating regulation and remanding for further consideration). Before determining the precise relief to be granted – be it setting aside the Opinion, vacating it with respect to AstraZeneca, remanding to HHS, and/or something else – the Court will benefit from obtaining the parties' views on what is most appropriate given the Court's conclusions.

III. AstraZeneca Has Abandoned Its Fourth Claim For Relief

AstraZeneca originally asked the Court to direct the government to post AstraZeneca's notice to covered entities on HRSA's website. (Am. Compl. at 55) In the government's view, the Court lacks jurisdiction to compel such agency action because it is not required by statute. (D.I. 56 at 30) (citing *Massie v. U.S. Dep't of Hous. & Urb. Dev.*, 620 F.3d 340, 347 (3d Cir.

2010)) AstraZeneca's briefs do not address this claim, and the Court understands that AstraZeneca no longer intends to pursue it. (Tr. 58) Accordingly, the Court will dismiss AstraZeneca's fourth claim.

CONCLUSION

The Court concludes by stressing what it is ***not*** deciding today. The government, *amici*, and others have warned that repudiating the government's interpretation of the 340B statute may make it more difficult for covered entities to serve uninsured or underinsured patients, many of whom live in low-income or rural communities. (*See, e.g.*, AR 3-4; D.I. 59 at 8-19) These concerns are amplified by the fact that the world is still recovering from the worst pandemic in a century. The Court does not take these concerns lightly and hopes that the fears prove unfounded.[20] Congress may very well want pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies as a condition for manufacturers' participation in the Medicare Part B and Medicaid programs. But that kind of policymaking is for Congress, not this Court. The only issue before the Court is whether Congress has spoken clearly and unambiguously on this arrangement. It has not.

Therefore, and for all the reasons explained above, the Court will deny the government's motion to dismiss, except with respect to AstraZeneca's abandoned fourth claim for relief. To

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[20] The government's suggestion that the Court's ruling may entirely eviscerate the benefits of the 340B Program is not convincing. As far as the record reveals, permitting drug manufacturers to implement policies like the one AstraZeneca intends to follow would likely result in benefits to covered entities roughly equal to the benefits that they derived from the program between 1996 and 2010. The government admitted at the hearing that nothing in the record would support a contrary conclusion. (*See* Tr. 83) Whether "turning back the clock" in this manner is good or bad policy is not a matter for this Court to decide.

the extent that the government's motion seeks summary judgment, that portion of the motion remains pending. AstraZeneca's motion for summary judgment also remains pending until the Court receives further input from the parties. Thereafter, the Court will determine the precise relief to be awarded to AstraZeneca.

An appropriate Order follows.