UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

CONCISE SUMMARY OF THE CASE

Pursuant to 3rd Cir. LAR 33.3, counsel are required to file a concise summary of the case within **14** days of the date of docketing of the Notice of Appeal. Total statement is limited to no more than 2 pages, single-spaced. Counsel may utilize this form or attach a 2 page statement encompassing the information required by this form.

SHORT CAPTION: AstraZeneca Pharmaceuticals LP v. Secretary of U.S. Dep't of HHS

USCA NO.: 22-1676

LOWER COURT or AGENCY and DOCKET NUMBER:
21-27 (D. Del.)

NAME OF JUDGE: Hon. Leonard P. Stark

Specify who is suing whom, for what, and the subject of this action. Identify (1) the nature of the action; (2) the parties to this appeal; (3) the amount in controversy or other relief involved; and (4) the judgment or other action in the lower court or agency from which this action is taken:

Plaintiff AstraZeneca sued the Department of Health and Human Services and other federal defendants, seeking to set aside an HHS enforcement letter that plaintiff had adopted certain policies in violation of 42 U.S.C. 256b. Under that statute, plaintiff--as a participating drug manufacturer--must provide certain drugs to covered entities at established prices. The violation letter determined that plaintiff's policies resulted in overcharges under the statute by not allowing covered entities to dispense the drugs at multiple locations through third-party pharmacies. The district court vacated the letter as contrary to the Administrative Procedure Act.

LIST and **ATTACH** a copy of each order, judgment, decision or opinion which is involved in this appeal. If the order(s) or opinion(s) being appealed adopt, affirm, or otherwise refer to the report and recommendation of a magistrate judge or the decision of a bankruptcy judge, the report and recommendation or decision shall also be attached.

1. March 11, 2022 Order and Final Judgment
2. February 16, 2022 Order
3. February 16, 2022 Summary Judgment Opinion
4. June 16, 2021 Motion to Dismiss Opinion (reasoning referenced in the summary judgment opinion)

Provide a short statement of the factual and procedural background, which you consider important to this appeal:

Congress created the 340B program in 42 U.S.C. 256b, which requires participating drug manufacturers to provide covered entities with covered outpatient drugs at an applicable price, known as the ceiling price. HHS has consistently explained that covered entities may dispense these drugs to their patients using either in-house pharmacies or though third party contract pharmacies. Plaintiff has adopted a policy by which it "limit[s] distribution of 340B drugs to" covered entities who do not use any contract pharmacies, and those use a single contract pharmacy. Dkt. 78 at 5-6. HHS concluded that this policy was in violation of the statutory requirements and sent plaintiff a violation letter. The district court held that the violation letter violated the requirements of the Administrative Procedure Act, concluding that the letter was based on a "flawed statutory interpretation" and that HHS's position had changed over time. Dkt. 112 at 12, 18.

Identify the issues to be raised on appeal:

1. Whether HHS's violation letter was arbitrary and capricious or otherwise unlawful.

This is to certify that this Concise Summary of the Case was electronically filed with the Clerk of the U.S. Court of Appeals for the Third Circuit and a copy hereof served to each party or their counsel of record

this 27 day of April ,20 22 .

/s/ Daniel Aguilar

Signature of Counsel

Rev. 07/2015

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

ORDER AND FINAL JUDGMENT

For the reasons set forth in the Court's Memorandum Opinion and Order issued on June 16, 2021 (D.I. 78, 79) and the Court's Memorandum Opinion and Order issued on February 16, 2022 (D.I. 112, 113),

IT IS HEREBY ORDERED that:

1. With respect to AstraZeneca's first and second claims in the Second Amended Complaint (D.I. 86 ¶¶ 152-65), AstraZeneca's first motion for summary judgment (D.I. 42) is **DENIED WITHOUT PREJUDICE**, and the government's first motion for summary judgment (D.I. 55) is **DENIED WITHOUT PREJUDICE**. (*See* D.I. 83 ¶ 3)

2. With respect to AstraZeneca's third claim in the Second Amended Complaint (D.I. 86 ¶¶ 166-73), AstraZeneca's first motion for summary judgment (D.I. 42) is **GRANTED**, and the government's first motion for summary judgment (D.I. 55) is **DENIED**. (*See* D.I. 83 ¶ 2)

3. Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (D.I. 40-3 at 1-8), issued by the general counsel of HHS on December 30, 2020, is **SET ASIDE** and **VACATED**. (*See* D.I. 83 ¶ 4)

4. With respect to AstraZeneca's fourth claim in the Second Amended Complaint (D.I. 86 ¶¶ 174-80), AstraZeneca's second motion for summary judgment (D.I. 90) is **DENIED WITHOUT PREJUDICE**, and the government's second motion for summary judgment (D.I. 92) is **DENIED WITHOUT PREJUDICE**.

5. With respect to AstraZeneca's fifth and sixth claims in the Second Amended Complaint (D.I. 86 ¶¶ 181-93), AstraZeneca's second motion for summary judgment (D.I. 90) is **GRANTED**, and the government's second motion for summary judgment (D.I. 92) is **DENIED**.

6. The May 17, 2021 letter from HRSA to AstraZeneca (D.I. 66-1 Ex. 1) is **VACATED** and **SET ASIDE**, and the letter is **REMANDED** to the agency for further consideration in light of the Court's February 16, 2022 Memorandum Opinion. (*See* D.I. 113)

7. Any other requests for relief are **DENIED AS MOOT**.

8. The Clerk of the Court is directed to enter this Order and Final Judgment and to close this case forthwith.

March 11, 2022
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE

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

ORDER

At Wilmington, this **16th** day of **February, 2022**, consistent with and for the reasons stated in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that the May 17, 2021 letter from HRSA to Plaintiff (*see* D.I. 66-1 Ex. 1) is **VACATED** and **SET ASIDE**. The letter is **REMANDED** to the agency for further consideration in light of the Court's Memorandum Opinion.

IT IS FURTHER ORDERED that the parties shall meet and confer and, no later than **February 23, 2022**, submit a joint status report, setting out their proposal(s) for: (i) what relief the Court should grant Plaintiff on the claims for relief in Plaintiff's second amended complaint, based on the analysis provided in the Memorandum Opinion; and (ii) how, if at all, this case should now proceed.

UNITED STATES DISTRICT JUDGE

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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MEMORANDUM OPINION

February 16, 2022
Wilmington, Delaware

STARK, U.S. District Judge:

On May 17, 2021, the Acting Administrator of the Health Resources and Services Administration ("HRSA") within the U.S. Department of Health and Human Services ("HHS") sent a letter to AstraZeneca Pharmaceuticals LP ("AstraZeneca" or "AZ"). In the letter, HRSA notified AstraZeneca of HRSA's conclusion that AstraZeneca has violated its obligations under the federal 340B Program. In this Court, AstraZeneca challenges this "Violation Letter," arguing that the agency did not comply with the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. AstraZeneca and the government have both moved for summary judgment on the administrative record.

As the Court previously acknowledged (*see* D.I. 78 at 1), this case implicates a number of important issues of public policy, including funding for healthcare facilities across the country and access to care – especially for low-income individuals – at those facilities. As before, the Court must set aside any personal views it may have on these matters and decide only the narrow question properly before it, which is now: did HRSA comply with the APA when it issued the Violation Letter? For the reasons explained below, the Court concludes that HRSA did not.

Accordingly, the Court will vacate and set aside the Violation Letter and remand to the agency for further consideration in light of the Court's opinion. The Court will also solicit the parties' views on the impact of the Court's conclusions on the claims for relief in AstraZeneca's second amended complaint and whether (and, if so, how) this case should now proceed.

BACKGROUND[1]

In August 2020, AstraZeneca announced that, effective October 1 of that same year, it would limit 340B pricing for covered outpatient drugs to drugs delivered to: (i) each covered entity's in-house pharmacy; or (ii) a single contract pharmacy chosen by each covered entity, provided that the covered entity does not have an in-house pharmacy. (*See* AR 7608-11)[2]

In response to AstraZeneca's policy change, as well as similar policy changes by other drug manufacturers and complaints from covered entities, on December 30, 2020 the general counsel of HHS issued "Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program." (AR 8048-55) ("Opinion") In the Opinion, HHS mandated that drug manufacturers facilitate sales of 340B drugs regardless of how covered entities distribute those drugs, writing: "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 8048) In particular, HHS took the view that all covered entities may use an unlimited number of contract pharmacies for dispensing 340B drugs. (*See id.* at 8055)

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[1] In a prior memorandum opinion, the Court provided general background information regarding the 340B Program. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 50-53 (D. Del. 2021). The Court incorporates that background information by reference.

[2] As is typical in APA cases, the government was solely responsible for assembling and providing the administrative record ("AR"). Given the size of this administrative record, the Court permitted the government to file it manually. (*See* D.I. 88, 88-1, 89) The Court cites the administrative record using the pagination provided in the bottom righthand corner of each page. For example, "AR 7608" refers to the page marked "VLTR_007608."

According to the Opinion, these conclusions were mandated by the plain and unambiguous language of the statute establishing the 340B Program. (*See id.* at 8049-50)

Shortly after HHS issued the Opinion, AstraZeneca filed suit in this Court. (D.I. 1)[3] AstraZeneca then moved for summary judgment. (D.I. 42) In response, the government filed a combined motion to dismiss and cross-motion for summary judgment. (D.I. 55) After expedited proceedings, the Court issued a memorandum opinion regarding HHS's Opinion and the 340B statute. First, the Court explained how the Opinion differed in material ways from two guidance documents HRSA had issued in 1996 and 2010. *See AstraZeneca*, 543 F. Supp. 3d at 54-57. Next, the Court held that the Opinion constituted final and reviewable agency action. *See id.* at 57-58. For related reasons, the Court also held that AstraZeneca's challenge to the Opinion was timely. *See id.* at 58. Accordingly, the Court denied the government's motion to dismiss, except with respect to one claim for relief AstraZeneca had abandoned. *See id.* at 58, 62.

On the merits of AstraZeneca's claims, the Court concluded that the interpretation of the 340B statute in the Opinion was not compelled by the unambiguous text of the statute, as HHS had reasoned. *See id.* at 58-62. Rather, the 340B statute is "silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *Id.* at 59.

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[3] Other drug manufacturers filed similar suits in other district courts. *See Eli Lilly & Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-14979-DLF (D.D.C.); *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686-DLF (D.D.C.). A trade association representing multiple drug manufacturers, including AstraZeneca, brought another own suit against the government. *See Pharm. Research & Mfrs. of Am. v. Cochran*, No. 8:21-cv-99198-PWG (D. Md.).

Analyzing the text and structure of the 340B statute and similar statutory provisions, the Court explained that textual clues do not support the government's reading of the 340B statute. *See id.* at 60. Moreover, the legislative history cuts against the government's position because Congress specifically did not enact statutory language referring to contract pharmacies. *See id.* at 60-61. Ultimately, the Court concluded that both sides' interpretations are permissible readings of the 340B statute but that neither interpretation is compelled by the plain text of the statute. *See id.* at 61.

Because the Opinion was based on an "'unjustified assumption'" about the statute, AstraZeneca was entitled to relief. *Id.* at 61-62 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). Before disposing of the cross-motions for summary judgment, the Court opted to provide the parties with an opportunity to submit additional views. *See id.* at 62.

Two days later, and before the Court was able to grant AstraZeneca appropriate relief, the acting general counsel of HHS withdrew the Opinion. (D.I. 81-1) In a joint status report filed shortly thereafter, the government argued that the withdrawal of the Opinion mooted AstraZeneca's claims. (D.I. 82) The Court disagreed, observing that the record demonstrated the government's intent to "act in accordance with the withdrawn Opinion." (D.I. 83 at 2) In light of the parties' additional views, the Court granted AstraZeneca's summary judgment motion with respect to one of its claims – that the Opinion was arbitrary and capricious – and denied the corresponding portion of the government's motion. (*See id.* at 2-3) The Court denied without prejudice AstraZeneca's summary judgment motion with respect to the remaining claims and the

corresponding portions of the government's cross-motion for summary judgment. (*See id.* at 3) The Court also vacated and set aside the Opinion. (*See id.*)[4]

In the meantime, while the parties were briefing the issues regarding the Opinion, HRSA sent AstraZeneca the Violation Letter. (AR 1-2) In it, HRSA states that, after a review of AstraZeneca's new policy regarding 340B drugs and "an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." (AR 1) The Violation Letter points specifically to the statute's "shall offer" requirement, which provides that drug manufacturers "'shall . . . 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.*) (quoting 42 U.S.C. § 256b(a)(1)) According to HRSA, "[n]othing in the 340B statute grants a [drug] manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." (*Id.*)

The Violation Letter goes on to state that the agency's interpretation of the 340B statute has been consistent for over 25 years: "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor . . .

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[4] After the Court vacated and set aside the Opinion, another district court endorsed this Court's reasoning and similarly concluded that the Opinion was arbitrary and capricious. *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, 2021 WL 5039566, at *14 (S.D. Ind. Oct. 29, 2021). In light of this Court's decision and the *Eli Lilly* decision, a third district court determined that another drug manufacturer's claims regarding the Opinion were moot. *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, --- F. Supp. 3d. ---, 2021 WL 5150464, at *55 (D.N.J. Nov. 5, 2021).

purchases [of 340B drugs] regardless of the dispensing mechanism." (*Id.*) The Violation Letter instructs 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) In the next sentence, the agency tells AstraZeneca it "must comply with its 340B statutory obligations" and "refund all covered entities for overcharges that have resulted from AstraZeneca's policy." (*Id.*) Otherwise, the Violation Letter warns, AstraZeneca may face civil monetary penalties of up to $5,883 per overcharge. (*Id.* at 2 & n.3) Ultimately, a decision on whether to impose civil monetary penalties will be made by HHS's Office of the Inspector General. (*See* D.I. 100-1 Ex. A)

After the Court vacated and set aside the Opinion, AstraZeneca filed a second amended complaint. (D.I. 86) ("2d Am. Compl.") The revised pleading includes the first three claims from the previous version of the complaint, on which the Court has already ruled. (*Id.* ¶¶ 152-73) It also adds three new claims regarding the Violation Letter:

- In its fourth claim, AstraZeneca seeks declaratory/injunctive relief that, in issuing and enforcing the Violation Letter, Defendants failed to observe notice-and-comment procedures, in violation of 5 U.S.C. § 706(2)(D). (2d Am. Compl. ¶¶ 174-80)

- In its fifth claim, AstraZeneca seeks declaratory/injunctive relief that the Violation Letter exceeds Defendants' statutory authority under 42 U.S.C. § 256(b), in violation of 5 U.S.C. § 706(2)(A), (C). (2d Am. Compl. ¶¶ 181-86)

- In its sixth claim, AstraZeneca seeks declaratory/injunctive relief that the Violation Letter is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A). (2d Am. Compl. ¶¶ 187-93)

The parties agreed on a schedule for the filing of the administrative record and briefing on AstraZeneca's new claims regarding the Violation Letter, which the Court approved. (D.I. 84, 85)

The Court has carefully considered the administrative record and the briefing, as well as various letters, a notice of supplemental authority, and multiple joint status reports submitted by the parties. (*See generally* D.I. 88-1, 91, 93, 94, 95, 100, 102, 104, 106, 107, 108, 110, 111) The Court heard oral argument by videoconference on October 18, 2021. (*See* D.I. 103) ("Tr.")

LEGAL STANDARDS

"[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 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 Violation Letter Is Based On Essentially The Same Interpretation Of The 340B Statute As The Vacated Opinion

AstraZeneca principally argues that the Violation Letter is "based on the same 'legally flawed' reading" of the 340B statute that plagued the Opinion. (D.I. 91 at 9 (capitalization modified); *see also* Tr. at 6) The Court agrees.

A comparison of the Violation Letter and the Opinion reveals multiple parallels between the documents:

- Both the Violation Letter and the Opinion emphasize the "shall offer" language in 42 U.S.C. § 256b(a)(1), i.e., Section 340B(a)(1).
  (*Compare* AR 1 ("Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers 'shall . . . 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.'") *with* AR 8049 ("[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."))

- Both the Violation Letter and the Opinion state that the 340B statute establishes an unqualified requirement.
  (*Compare* AR 1 ("This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.") *with* AR 8049 ("This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs."))

- Both the Violation Letter and the Opinion suggest that a drug manufacturer's refusal to facilitate sales of covered outpatient drugs for dispensing by an unlimited number of contract pharmacies directly contravenes the 340B statute.
  (*Compare* AR 1 ("HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.") *with* AR 8049 ("The plain meaning of Section 340B 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.") (capitalization modified))

- Both the Violation Letter and the Opinion underscore that drug manufacturers may not place conditions on their offers of 340B drugs. (*Compare* AR 1 ("Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities.") *with* AR 8052 ("'[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.'") (quoting 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017)))

- Both the Violation Letter and the Opinion insist that HRSA's interpretation of the 340B statute has remained constant. (*Compare* AR 1 ("HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.") *with* AR 8051 ("The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used.") (citing 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"); Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010) ("2010 Guidance")))

One difference between the documents is that the Opinion leans heavily on the "purchased by" language in 42 U.S.C. § 256b(a)(1), whereas the Violation Letter focuses exclusively on the "shall offer" requirement, which is also in § 256b(a)(1). (*Compare* AR 8049-50 *with* AR 1)[5] That difference is not particularly relevant here because both documents still

[5] The government argues that the Violation Letter does not rely exclusively, or perhaps even at all, on the "shall offer" requirement. (Tr. at 43) In the government's view, the Violation Letter relies additionally on the statute's "purchased by" language, reasoning "these commands are found in the same statutory subsection, and the Violation Letter repeatedly discusses the '340B statute' throughout its text." (D.I. 94 at 6) That argument is unpersuasive. The paragraph of the Violation Letter that quotes the "shall offer" requirement goes on to discuss

insist that drug manufacturers' obligations with respect to contract pharmacies flow directly from the text of § 256b(a)(1). Indeed, the government admits that the Violation Letter "relies directly on statutory text." (D.I. 93 at 11)

It is not surprising that the Violation Letter takes essentially the same legal position as the one espoused in the Opinion. The Opinion was issued by HHS' general counsel, who "[s]upervises all legal activities of the Department and its operating agencies," such as HRSA. Statement of Organization, Functions, and Delegations of Authority, 86 Fed. Reg. 6349, 6351 (Jan. 21, 2021). When HRSA sent AstraZeneca the Violation Letter, the Opinion was still in effect.[6] Accordingly, HRSA, when it sent AstraZeneca the Violation Letter, was bound to follow the Opinion. Moreover, as even the government acknowledges, the Opinion is in the administrative record supporting the Violation Letter precisely because HRSA relied on it in issuing the Violation Letter. (*See* D.I. 93 at 3) ("[T]he administrative record demonstrates that the agency considered that advice [in the Opinion] alongside other statutory interpretations . . . .")

Because the Violation Letter advances essentially the same statutory interpretation as the one contained in the Opinion, the Court's previous analysis of the 340B statute applies here with equal force. *See generally AstraZeneca*, 543 F. Supp. 3d at 58-62; *see also* D.I. 93 at 25-26 (government acknowledging that, in Violation Letter, agency "grounded its determination in the

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drug manufacturers' obligations with respect to that specific requirement. (*See* AR 1) The Violation Letter says nothing about the "purchased by" language.

[6] This Court did not vacate and set aside the Opinion until the end of the following month. (*See* D.I. 83 at 3)

340B statute's text"); Tr. at 48 (government acknowledging that "agencies can't base an enforcement action [on] guidance," but must "base an enforcement action on the statute").[7] The Court will not repeat all that analysis here but will, instead, highlight some of the key points.

Most importantly, the text of 42 U.S.C. § 256b(a) never mentions pharmacies, which is a "strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *AstraZeneca*, 543 F. Supp. 3d at 59. That omission is notable because another provision in § 256b explicitly refers to certain affiliates of covered entities. *See id.* at 60. It is difficult to imagine that "Congress enumerated 15 types of covered entities with a high degree of precision" and then intended to impliedly sweep in sales implicating contract pharmacies. *Id.*

Moreover, the "legislative history is of no greater assistance to the government." *Id.* In 1996, Congress considered but ultimately rejected 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).[8] The exclusion of that language indicates that

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[7] In the latest round of briefing, the government offers additional arguments in favor of its preferred statutory interpretation. (*E.g.*, D.I. 93 at 13 (explaining history of "shall offer" requirement); *id.* at 14-15 (discussing *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)) The government does not convincingly explain why it did not make its additional arguments earlier in this case. The Court has not been persuaded that it should reconsider its interpretation of the 340B statute. *See generally ACLU v. Mukasey*, 534 F.3d 181, 187 (3d Cir. 2008) ("Under the law-of-the-case doctrine, 'when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.'") (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)).

[8] The government seizes on a typographical error in the Court's previous memorandum opinion, where the Court mistakenly referred to congressional action occurring in 2010, even though the Court correctly cited the pertinent Senate Report with the correct date: 1992. (D.I.

Congress did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies. *See AstraZeneca*, 543 F. Supp. 3d at 60-61.[9]

Because the Violation Letter rests on essentially the same flawed statutory interpretation that the Court already rejected, the Violation Letter cannot stand. *See generally Am. Lung Ass'n*, 985 F.3d at 944; *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("[D]eference to an agency's interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress.") (internal quotation marks omitted). It does not matter that the Violation Letter does not describe the statute as "unambiguous" because the Violation Letter still evinces an understanding that its conclusion is driven by a clear statutory command with respect to drug manufacturers' obligations. (*See* Tr. at 21) Accordingly, the Court will vacate and set aside the Violation Letter, just as it vacated and set aside the Opinion.

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93 at 19; Tr. at 57; *see also AstraZeneca*, 543 F. Supp. 3d at 60) That error does not provide a basis for "this Court to reconsider its assessment of the legislative history." (D.I. 93 at 19) Without the error, the Court's analysis still would have been the same.

[9] The government maintains that the legislative history contradicts the Court's interpretation. According to the government, Congress' omission of the reference to drugs "dispensed by" pharmacies located "on-site" was intended to remove a restriction on possible dispensing mechanisms for covered entities. (D.I. 93 at 19) The Court agrees with AstraZeneca that the government's reading focuses too much on selected words in the omitted phrase rather than on the omission of the entire phrase. As AstraZeneca explains, "once Congress had dropped the (far longer and more specific) contract pharmacy language – thereby limiting 340B discounts to sales made to covered entities themselves – there was no need to specify that the covered entity who 'purchased' the drug also 'dispensed' it." (D.I. 95 at 7; *see also* Tr. at 19-20)

II. The Violation Letter Rests On The Faulty Assumption That HRSA's Position Has Not Shifted Over Time

The Violation Letter states that "HRSA has made plain, ***consistently since the issuance of its 1996 contract pharmacy guidance***, that the 340B statute requires manufacturers to honor . . . purchases [of covered outpatient drugs] regardless of the dispensing mechanism." (AR 1) (emphasis added) The Court's previous memorandum opinion explained, however, that the agency's position has not been consistent over the past 25 years. *See generally AstraZeneca*, 543 F. Supp. 3d at 54-57. Again, the Court need not rehash that entire discussion here, though a few points are worth emphasizing.

To start, the Violation Letter focuses on the "shall offer" requirement (*see* AR 1), which Congress did not add to the 340B statute until 2010. Because the 1996 and 2010 Guidance documents were issued before the "shall offer" requirement was enacted, the Violation Letter treads at least some "new ground." *See Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004). Additionally, the 1996 and 2010 Guidance documents were directed to covered entities, *see AstraZeneca*, 543 F. Supp. 3d at 55, whereas the Violation Letter is directed to a specific drug manufacturer.[10] Moreover, the 1996 and 2010 Guidance documents attempted to fill statutory gaps, *see id.*, but the Violation Letter seeks to enforce a requirement allegedly contained in the statute. Notably, AstraZeneca's new policy regarding 340B drugs would have ***complied*** with the parameters set out in the 1996 Guidance, *see id.* at 56, while the Violation

[10] HRSA issued additional violation letters to other drug manufacturers. (*See* AR 3-12) Those letters were substantially the same as the letter addressed to AstraZeneca.

Letter determines that AstraZeneca's new policy does ***not*** comport with the agency's current understanding of the 340B statute.[11]

To summarize, the Court provides the following updated table of differences among all the relevant documents:

Document	**Directed to:**	**Number of Contract Pharmacies Permitted**	**Mode of Analysis**	**Based on "Shall 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 (in part)	No
2021 Violation Letter	AstraZeneca	Unlimited	Enforcement	Yes	No

As this Court has explained, the Opinion was "the first document in which HHS explicitly concluded that drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." *Id.* at 55-56 (emphasis omitted). Now that the Opinion has been vacated and set aside, the Violation Letter (and the similar letters sent to other drug manufacturers) are the only documents concluding that the 340B statute requires drug manufacturers to facilitate sales of covered outpatient drugs for dispensing by an unlimited number of contract pharmacies.

[11] Another district court that considered the 1996 and 2010 Guidance documents agreed with this Court that the agency's "position has in fact shifted over time." *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021). Yet another district court agreed that the agency has changed its views but also concluded that the agency sufficiently explained its changes. *See Sanofi-Aventis*, 2021 WL 5150464, at *50-53. This Court respectfully disagrees with that conclusion.

Despite the logical application of the reasoning in the Court's previous memorandum opinion to the Violation Letter, the government maintains that the Violation Letter is consistent with the view the agency has held all along. It states, for example, "HRSA respectfully contends that its interpretation of manufacturers' obligations does not shift every time that HHS changes its guidance with respect to covered entities' rights." (D.I. 94 at 8) (internal quotation marks and brackets omitted) That contention directly contradicts the Court's previous memorandum opinion. *See AstraZeneca*, 453 F. Supp. 3d at 57.[12] So the government asks the Court to "reconsider its conclusion" in light of the latest round of briefing (D.I. 93 at 26), but the Court has been provided no meritorious basis to do so. *See* D. Del. LR 7.1.5 (noting that motions for reconsideration should be granted "sparingly"); *see also Smith v. Meyers*, 2009 WL 5195928, at *1 (D. Del. Dec. 30, 2009) ("A motion for reconsideration is not properly grounded on a request that a court rethink a decision already made.").

Notably, the government points to a guidance document that was not cited during the previous round of briefing on the parties' earlier motions. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994) ("1994 Guidance"); *see also* D.I. 93 at 22 (government acknowledging that "the previous

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[12] As the Court previously explained:

> 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.

AstraZeneca, 543 F. Supp. 3d at 57.

briefing before this Court did not include the 1994 guidance"). In that document, HRSA announced "final program guidelines regarding eligible covered entities." *Id.* at 25,110. The agency noted in the 1994 Guidance that "issues deal[ing] with manufacturer guidelines" were "beyond the scope" of that document. *Id.* In explaining the covered entity guidelines, the 1994 Guidance refers to a comment in which a stakeholder asked the agency not to require manufacturers "to sell directly to . . . a contract pharmacy," but only to "covered entities and their wholesalers." *Id.* at 25,111. HRSA rejected that proposal because covered entities "often use . . . contract pharmacies," and the agency did not want covered entities to be discouraged from participating in the 340B Program. *See id.*

The Court agrees with AstraZeneca that the government's reliance on the 1994 Guidance is faulty in a few ways. (*See* D.I. 95 at 10) First, the Violation Letter says that HRSA's position has been "consistent[] since the issuance of its ***1996*** contract pharmacy guidance" (AR 1) (emphasis added), a statement which plainly does not encompass the 1994 Guidance. It is a fundamental principle of administrative law that "a reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *see also* Tr. at 52. Courts do not accept counsel's "*post hoc* rationalizations." *Burlington Truck Lines, Inc. v. United States,* 371 U.S. 156, 168 (1962). Second, and consistent with the Court's analysis above, the government previously told the Court expressly that the ***1996 Guidance*** was the first relevant guidance document. (D.I. 76 at 65-66)[13] Thus, the Court should not even consider the 1994 Guidance.

[13] While the government made this statement in connection with the Court's review of

In any event, the 1994 Guidance does not save the government, as it is inconsistent regarding its implications for drug manufacturers. On one hand, it suggests that drug manufacturers should be required to facilitate sales of 340B drugs dispensed by contract pharmacies. *See* 1996 Guidance, 59 Fed. Reg. at 25,111. On the other hand, it acknowledges that it is not providing any guidelines for manufacturers. *Id.* at 25,110 (explaining that "manufacturer guidelines" are "beyond the scope of this notice"). The Court hesitates to read too much into a single paragraph on drug manufacturers' duties with respect to contract pharmacies when the whole document was never intended to impose any duties on drug manufacturers.

Another reason for hesitancy in according any weight to the 1994 Guidance is that it (somewhat confusingly) refers to sales from drug manufacturers "***to*** intermediaries," such as contract pharmacies. *Id.* at 25,111 (emphasis added). In the instant litigation, however, the government acknowledges that drug manufacturers are not required to sell covered drugs ***to*** pharmacies but, instead, insists that manufacturers must facilitate arrangements in which sales are made ***to*** covered entities ***through*** contract pharmacies. (*See* D.I. 93 at 23-25; D.I. 94 at 5 n.1) That is, on the government's current view, drug manufacturers sell to covered entities – and not to contract pharmacies – even when covered entities never physically possess the covered outpatient drugs. The 1994 Guidance appears to have assumed the materially different view that manufacturers would sell covered drugs directly "to intermediaries," including pharmacies.

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the Opinion, it is fair to conclude that the government's statement also applies to the Court's review of the Violation Letter. (*See* D.I. 76 at 65-66) (Court asking if 1996 Guidance was "first relevant guidance" in context of authorization for covered entities to work with contract pharmacies)

The 1994 Guidance is even more confusing when considered alongside the 1996 and 2010 Guidance documents. If the 1994 Guidance is read as having approved arrangements involving multiple contract pharmacies, then the government would have to explain how and why it took a narrower view in the 1996 Guidance, when it limited covered entities to using only a ***single*** contract pharmacy. Later, in 2010, it similarly would have to explain how and why it was returning to a broader view. The administrative record does not reveal any credible explanation, and the government has not offered one in the arguments before this Court.

The Violation Letter's failure to acknowledge that the agency's position has shifted over time provides an independent basis for the Court to award AstraZeneca relief. *See generally Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (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); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."). Accordingly, the Court will vacate and set aside the Violation Letter.[14]

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[14] All district courts that have considered similar violation letters addressed to other drug manufacturers have at least partially vacated and/or set aside those letters, although they have done so for different reasons. *See Eli Lilly*, 2021 WL 5039566, at *22-25 (holding that violation letter was arbitrary and capricious because HRSA failed to explain its "change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements"); *Sanofi-Aventis*, 2021 WL 5150464, at *34-36, 42-45 (concluding that 340B statute is ambiguous on contract pharmacy arrangement but also holding that statute does not permit manufacturers to place conditions on offers; vacating violation letters and agency's determination that manufacturers owe refunds to covered entities for further consideration of how many contract pharmacies are permitted under statute); *Novartis*, 2021 WL 5161783, at *8-9 (concluding that agency's guidance "shifted over time" and setting aside violation letters

CONCLUSION

As the Court did previously (*see* D.I. 78 at 24), the Court concludes today by emphasizing what it is ***not*** deciding. The government spends much of its opening brief stressing that a ruling against it will make it harder, or even impossible, for some patients of covered entities to obtain their medications. (*See* D.I. 93 at 3-10) The Court takes these concerns seriously and hopes that all patients of covered entities receive appropriate medical treatment. But the only issue now before this Court is whether HRSA complied with its obligations under the APA when it issued the Violation Letter. It did not.[15]

For all the reasons explained above, the Court will vacate and set aside the Violation Letter and remand to the agency for further consideration. The Court will give the parties an opportunity to provide further input on how to dispose of the claims for relief in AstraZeneca's second amended complaint and how (if at all) this case should now proceed.

An appropriate order follows.

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without declaring manufacturers' policies permissible or impermissible).

[15] Given the Court's analysis, the Court does not reach other issues presented by the parties, including whether the Violation Letter is interpretive or legislative (*see* D.I. 91 at 15-20; D.I. 94 at 10-12), whether HRSA's threatened imposition of civil monetary penalties is improper (*see* D.I. 91 at 24-26; D.I. 94 at 7), or whether the evidence in the administrative record would support the imposition of such penalties (*see* D.I. 91 at 22-24; D.I. 94 at 3-5). On the last point, the government emphasizes that it assembled a "voluminous" administrative record of over 8,000 pages, including myriad instances of AstraZeneca allegedly overcharging covered entities. (*See* D.I. 93 at 1, 3, 25; D.I. 94 at 2; Tr. at 28) Given the Court's analysis of the legal questions presented here, the bulk of the administrative record is largely immaterial to the government's case. (*See* Tr. at 75-76) ("[I]f the government is right about the statutory interpretation, then [AstraZeneca's policy] would be a problem. But if we [AstraZeneca] are right about the statutory interpretation, then it's not a problem. And all of the government's evidence points to that same central fact.")

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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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

[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

[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.