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.")