IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, et al., *Defendants*.	C.A. No. 21-27-LPS

JOINT STATUS REPORT

Undersigned counsel respectfully submit this joint status report pursuant to the Court's Memorandum Opinion and Order of February 16, 2022 (D.I. 112 and 113). The Court's Order vacated and set aside the letter from HRSA to AstraZeneca issued on May 17, 2021. It also directed the Parties to meet and confer and to set out proposals 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." Based on those discussions, the Parties' respective views are set forth below:

i. What Relief Should the Court Grant AstraZeneca Based on the Analysis Provided in the Memorandum Opinion?

A. AstraZeneca: Based on its conclusion that the May 17 Letter rests on a "flawed statutory interpretation," D.I. 112 at 12, this Court issued an Order vacating the letter and setting it aside, D.I. 113. AstraZeneca believes that the Court's Order—both as a matter of logic and out of respect for the judgment of an Article III court—forecloses the agency from proceeding against AstraZeneca administratively based on the interpretation that this Court has now twice rejected. If Defendants were willing to represent that they will refrain from such action, no further relief would be necessary.

But to date, Defendants have *not* been willing to make such a representation. To the contrary, throughout this litigation, Defendants have never wavered from their position that Section 340B itself authorizes them to charge AstraZeneca with overcharging covered entities and to impose civil monetary penalties against AstraZeneca. After this Court issued its memorandum opinion of June 16, 2021, in which the Court concluded that Defendants' position was "legally flawed," D.I. 78 at 17, there is no indication that Defendants altered their conduct as a consequence of this Court's ruling. Indeed, Defendants told the Court that their efforts "would not be impeded by [the] vacatur" and that HRSA "intends to continue enforcement proceedings against AstraZeneca pursuant to the 340B statute"—that is, pursuant to the agency's flawed reading of the 340B Statute. D.I. 82 at 4 (quotation marks omitted). And on February 14, 2022, a HRSA panel that oversees administrative dispute resolution claims against AstraZeneca expressly rejected AstraZeneca's argument that the panel should stay those proceedings pending the decision in this case, stating only that the panel "respects the role of Article III courts in our constitutional system and will abide by any orders issued by such courts." D.I. 111.

Under these circumstances, AstraZeneca respectfully submits that merely setting the May 17 Letter aside is not sufficient to grant AstraZeneca full relief commensurate with the analysis in the Memorandum Opinion. If the Court merely vacates the letter, there is every indication that Defendants will brush that vacatur aside, much as they did to the Court's vacatur of the Advisory Opinion. AstraZeneca accordingly asks the Court to enjoin Defendants from proceeding against AstraZeneca administratively based on the interpretation of Section 340B rejected by this Court—namely, that Section 340B requires AstraZeneca to provide statutory discounts for contract pharmacy sales. In the alternative, AstraZeneca asks the Court to declare that the 340B Statute does not contain a "statutory command" requiring AstraZeneca to provide

discounts for contract pharmacy sales. D.I. 112 at 12; *see* D.I. 78 at 22 (no such obligation is "contained in the statute"). Such relief is appropriate here, for several reasons.

First, the requested relief flows logically from the Court's Memorandum Opinion. Throughout this case, both sides have agreed that insofar as AstraZeneca has any obligation to provide discounts for contract pharmacy sales, it must be "a pre-existing obligation sounding in the 340B statute itself." D.I. 93 (Defs.' Br.) at 28. That is because, as counsel for Defendants agreed at oral argument, HRSA has no authority to "impos[e] a requirement besides requirements that are already contained in the statute itself." D.I. 103 (Tr.) at 51; *see id.* ("The Court: Because you agree that HRSA can't add to the statutory obligation; is that right, too? Ms. Talmor: Yes, Your Honor."). Therefore, the Court's conclusion that Section 340B does *not* contain a "statutory command" requiring discounts for contract pharmacy sales, D.I. 112 at 12, necessarily means that Defendants cannot take administrative action against AstraZeneca predicated on the view that such a command exists. In other words, Defendants may only enforce statutory obligations, and no such obligation is "contained in the statute." D.I. 78 at 22.

For the same reason, both sides have taken the position that vacating the May 17 Letter means that Defendants cannot proceed against AstraZeneca based on the view that its policy is forbidden by the 340B Statute. For instance, at oral argument, counsel for Defendants stated: "[Even] if Your Honor thought that this letter somehow conveyed the idea that its decision was compelled by Congress, Your Honor still can't set aside the letter without affirmatively finding that Astra's policies [were] permissible under the statute." D.I. 103 at 45. And later: "[T]he only grounds to set aside the violation letter would be a finding that [Defendants] interpreted the statute wrongly and that Astra's policy is permissible." *Id.* at 46. AstraZeneca agreed with that assessment. *See id.* at 9-10.

The need for further relief is also a necessary implication of this Court's prior remedial Order, D.I. 83. There, the Court rejected Defendants' mootness argument on the ground that "HHS and its sub-agency, HRSA, intend to act in accordance with the withdrawn [Advisory] Opinion." *Id.* at 2. In so ruling, the Court recognized that Defendants' continued intention to proceed against AstraZeneca based on their reading of Section 340B—*i.e.*, their intention "to act in accordance with" that erroneous interpretation—meant that there was still a live controversy between the parties. The same is true now: The Court will not have fully resolved the parties' dispute so long as Defendants remain free to "act in accordance with" the interpretation of Section 340B that the Court has rejected (twice).

Second, injunctive and declaratory relief are appropriate remedies under the circumstances. The Administrative Procedure Act gives a district court "authority" to enter injunctions and declaratory judgments as necessary "to grant the [plaintiff] complete relief." *Bowen v. Massachusetts*, 487 U.S. 879, 911 (1988). "This means that the district court has substantial ability to order that relief which is necessary to cure the [agency's] legal transgressions." *Cobell v. Norton*, 240 F.3d 1081, 1108 (D.C. Cir. 2001).

Here, an injunction or declaration is necessary to grant AstraZeneca complete relief. As the D.C. district court recently observed:

> [I]n the context of a request for an injunction, … "once a violation is demonstrated, all that need be shown to obtain an injunction" is "some reasonable likelihood of future violations," and past unlawful conduct is "highly suggestive of the likelihood of future violations."

Ramirez v. U.S. Immigration & Customs Enforcement, --- F. Supp. 3d ----, No. 18-cv-508, 2021 WL 4284530, at *11 (D.D.C. Sept. 21, 2021) (quoting *U.S. Dep't of Justice v. Daniel Chapter One*, 89 F. Supp. 3d 132, 143 (D.D.C. 2015)) (brackets omitted). Absent Defendants' willingness to represent that they will cease taking action against AstraZeneca for its contract pharmacy

policy—and particularly given Defendants' past failure to alter their behavior as a result of this Court's first summary judgment ruling—the "likelihood of future violations" is high. Indeed, unless this Court orders Defendants to stop, "it is hard to see how we don't end up back in front of Your Honor yet again at some point in the future when the government takes yet another step predicated on the same erroneous view of what the statute requires." D.I. 103 at 10.

Defendants argue that an injunction is a drastic remedy that requires an extraordinary showing. But none of the relied-upon decisions share the key feature that makes this case more analogous to *Ramirez* (and other cases in that line): The agency's insistence that, notwithstanding the Court's adverse ruling, the agency *will* continue to take action against the plaintiff based on its legally erroneous position. Nor do Defendants suggest any less-drastic remedy that would be adequate to preclude Defendants from continuing to harm AstraZeneca based on their flawed reading of Section 340B. Harm from continuation of the ongoing agency proceedings—to assess overcharges and civil monetary penalties against AstraZeneca—is neither undefined nor unspecified; preventing this harm is the precise remedy sought in AstraZeneca's complaint, *see* D.I. 86 at 66-67, and the reason that AstraZeneca has sought expedition from the outset of this case, *see* D.I. 66, 104, 108, 110, 111.

Although issuing an injunction would be the most direct way to ensure that Defendants give full effect to this Court's ruling, a declaration that the 340B Statute does not contain a statutory command requiring AstraZeneca to provide discounts for contract pharmacy sales would offer substantial (albeit lesser) protection. Where an agency takes action based on an "interpretation of a statutory provision that has a direct effect on the day-to-day business of" a regulated entity, the agency "puts [the regulated entity] in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Abbott Laboratories v. Gardner*, 387 U.S. 136,

152 (1967). A declaration along the lines requested would relieve AstraZeneca of the "dilemma" that Defendants created by repeatedly (and incorrectly) asserting that the 340B Statute obliges manufacturers to provide discounts for contract pharmacy sales, and by repeatedly threatening to impose severe penalties against AstraZeneca based on that (incorrect) view. Defendants assert that the requested declaration is insufficiently specific because it does not define "contract pharmacy sales," but the Court's discussion of such sales in its opinions (D.I. 78 and 112)—which any declaration could incorporate by reference—is not subject to misinterpretation.

Third, an injunction or declaration along the lines requested would not "place unnecessary burdens on Defendants [or] improperly vitiate Defendants' discretion." *Ramirez*, 2021 WL 4284530, at *3 (brackets and quotation marks omitted). Defendants do not have—and do not claim to have—discretion to "impos[e] a requirement besides requirements that are already contained in the statute itself." D.I. 103 at 51. So by enjoining Defendants from proceeding against AstraZeneca based on an erroneous interpretation of Section 340B, the Court would not be withdrawing from the agency any decision properly within its discretion. And granting the requested relief would not place *any* burdens on Defendants: It would not force them to take any action, only to refrain from taking further impermissible action. Notably, although Defendants object to further injunctive and declaratory relief, they identify *no* respect in which granting such relief would harm them.

In light of the foregoing, AstraZeneca proposes a Form of Order as follows (see the attached Proposed Order and Final Judgment):

(a) GRANTING AstraZeneca's Second Motion for Summary Judgment (D.I. 90) with respect to Claim Five (that the May 17 Letter exceeds Defendants' statutory authority) and

Claim Six (that the May 17 Letter is arbitrary and capricious for failure to acknowledge the agency's change of position).

(b) DECLARING that the 340B Statute does not contain a statutory command requiring AstraZeneca to provide discounts for contract pharmacy sales.

(c) ENJOINING Defendants from proceeding against AstraZeneca administratively based on the interpretation of Section 340B rejected by this Court—namely, that Section 340B requires AstraZeneca to provide discounts for contract pharmacy sales.

(d) DENYING AstraZeneca's Second Motion for Summary Judgment (D.I. 90) with respect to Claim Four (that the May 17 Letter was issued without notice and comment required by law), without prejudice to renewal should the Court's Judgment be reversed on appeal.

(e) DENYING Defendants' Motion for Summary Judgment (D.I. 92).

(f) GRANTING such other relief as the Court deems appropriate.

Finally, AstraZeneca respectfully submits that there is no cause for this Court to remand this matter to the agency. As noted, both sides agree that the agency lacks discretion to engage in substantive rulemaking under Section 340B with respect to contract pharmacy sales or to "impos[e] a requirement besides requirements that are already contained in the statute itself." D.I. 103 at 51. The normal function of a remand—affording the agency a chance to exercise "discretion to reconsider [its] policies"—has no application where the agency lacks policymaking authority relevant to the issue in dispute. *SKF USA Inc. v. United States*, 254 F.3d 1022, 1030 (Fed. Cir. 2001). That is the case here. *See PhRMA v. HHS* (*Orphan Drug II*), 138 F. Supp. 3d 31, 48 (D.D.C. 2015) (HRSA "was not delegated authority to make binding rules that carry the force of law related to section 340B"); *PhRMA v. HHS* (*Orphan Drug I*), 43 F. Supp.

3d 28, 42 (D.D.C. 2014); *see also* D.I. 91 at 19-20 (citing statements by HRSA officials regarding the agency's lack of substantive rulemaking authority).

Defendants insist that a remand is typical in APA litigation, and that this Court's opinions have recognized Defendants' interpretation of Section 340B is permissible. But as noted above, this case is exceptional for the agency's insistence that it will *not* rethink its legal position, depriving a remand of any function. Defendants also do not identify any instance in which a case was remanded where, as here: (1) the agency conceded that it lacked authority to enforce obligations other than those contained in the statute, *see* D.I. 103 at 51, and (2) the Court ruled that the relevant obligation was not "contained in the statute," D.I. 78 at 22. In sum, the fundamental question in this litigation has been whether the 340B Statute contains a requirement that AstraZeneca must provide discounts for contract pharmacy sales; the Court has answered that question (twice), leaving no room for the agency to arrive at a different answer on remand—even if, contrary to fact, the agency were willing to genuinely rethink its approach.

B. Defendants: Defendants recognize that this Court disagreed with HRSA's statutory interpretation set forth in the May 17, 2021 letter from HRSA to Astra and vacated that letter. *See* ECF No. 113. Defendants respectfully contend that this Court's February 16, 2022 order already has granted Astra all of the relief to which it is entitled on the claims pleaded in Astra's second amended complaint and that no further relief is warranted. Final judgment should therefore be entered to facilitate any appellate review.[1]

[1] Defendants note that the government has filed notices of appeal as to the district court decisions in other cases challenging similar HRSA violation letters, including one in which appeal has been taken to the U.S. Court of Appeals for the Third Circuit. *See* Notice of Appeal, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. 3:21-cv-634-FLW (D.N.J. Dec. 28, 2021), ECF No. 113; Notice of Appeal, *Novo Nordisk, Inc. v. Dep't of Health & Hum. Servs.*, No. 3:21-cv-806 (D.N.J. Dec. 28, 2021), ECF No. 73; Notice of Appeal, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81-SEB-MJD (S.D. Ind. Dec. 28, 2021), ECF No. 151; Notice of Appeal,

Astra's requests for further injunctive and declaratory relief should be denied. As an initial matter, they are inconsistent with the Court's opinion. While the Court found that HRSA's May 17, 2021 letter to Astra was predicated on HRSA's erroneous view that the 340B statute contains a "clear" statutory mandate regarding contract pharmacies, the Court specifically "remand[ed]" the matter to HRSA "for further consideration." D.I. 112 at 12, 19. Astra's position relies on the premise that, based on the Court's opinion, the agency could not arrive at a different answer on remand or that administrative proceedings cannot continue. That premise is wrong; indeed, the Court has not repudiated its prior conclusion that "HHS's current interpretation of the statute is permissible." ECF No. 78 at 23.

Moreover, the APA instructs reviewing courts to "hold unlawful and set aside agency action, findings, and conclusions," 5 U.S.C. § 706(2), and thus empowers courts to vacate or invalidate the agency action at issue, which here the Court already has done. "Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *PPG Inds., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995). Vacatur is the standard remedy in APA cases, leaving the agency free to decide how, if at all, it should proceed in light of an adverse ruling.[2] 5 U.S.C. § 706(2)(A); *accord Sierra Club v. Van Antwerp*, 719 F. Supp. 2d 77, 78–79 (D.C.C. 2010)

Novartis Pharmaceuticals Corp. v. Espinosa, No. 1:21-cv-1479 (D.D.C. Dec. 28, 2021), ECF No. 33; Notice of Appeal, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C. Dec. 28, 2021).

[2] Indeed, after rejecting HRSA's statutory interpretation in *Novartis* and *United Therapeutics*, Judge Dabney L. Friedrich concluded that vacatur of the May 17, 2021 letters and a narrowly tailored declaration was the only relief to which the plaintiffs were entitled, and thus denied their requests for further injunctive relief. *See* Order & Memorandum Opinion, *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C. Dec. 28, 2021), ECF Nos. 31, 32.

(collecting cases for the proposition that "both the Supreme Court and the D.C. Circuit Court have held that remand, along with vacatur, is the presumptively appropriate remedy for a violation of the APA"); *Se. Alaska Conserv. Council v. U.S. Army Corps of Eng'rs*, 486 F.3d 638, 654 (9th Cir. 2007), *rev'd on other grounds sub nom. Coeur Alaska v. Se. Alaska Conserv. Council*, 557 U.S. 261 (2009); *New York v. Wolf*, No. 20-cv-1127, 2021 WL 185190, at *1 (S.D.N.Y. Jan. 19, 2021) ("By the APA's plain terms the normal remedy in a successful APA challenge is to set aside—that is, vacate—the final agency action at issue." (cleaned up with citation omitted)).

A permanent injunction of the type sought by Astra here is an exception to the rule and requires a specific showing not made or briefed by Astra in this litigation. In fact, "[t]he Supreme Court has cautioned that a district court vacating an agency action under the APA should not issue an injunction"—"a drastic and extraordinary remedy"—"where 'a less drastic remedy is sufficient to redress' the plaintiffs' injury." *O.A. v. Trump*, 404 F. Supp. 3d 109, 153–54 (D.D.C. 2019) (alterations adopted) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010)); *accord Klamath–Siskiyou Wildlands Ctr. v. Nat'l Oceanic & Atmospheric Admin. Nat'l Marine Fisheries Serv.*, 109 F. Supp. 3d 1238, 1247 (N.D. Cal. 2015) ("A court's decision to issue an injunction constitutes an unwarranted 'extraordinary remedy' if a less drastic remedy, such as vacatur, could sufficiently redress plaintiff's injury." (quoting *Monsanto*, 561 U.S. at 165–66)); *see also N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) ("It was quite anomalous [for the district court] to issue an injunction. When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal."). Accordingly, "[s]uccess on an APA claim

does not automatically entitle the prevailing party to a permanent injunction." *In re Federal Bureau of Prisons' Execution Protocol Cases*, 980 F.3d 123, 137 (D.C. Cir. 2020) (declining to enter permanent injunction); *Sierra Club*, 719 F. Supp. 2d at 78 ("[T]he U.S. Supreme Court made clear in *Monsanto* that there is no presumption to other injunctive relief."). Nor is it "enough for a court considering a request for injunctive relief to ask whether there is a good reason why an injunction should *not* issue." *Monsanto*, 561 U.S. at 158. "Instead, the party" seeking an injunction "must demonstrate that (i) 'it has suffered an irreparable injury,' (ii) 'remedies available at law … are inadequate to compensate for that injury,' (iii) the balance of hardships weighs in favor of an injunction, and (iv) 'the public interest would not be disserved by a permanent injunction.'" *In re Federal Bureau of Prisons' Execution Protocol Cases*, 980 F.3d at 137 (quoting *Monsanto*, 561 U.S. at 156–57). Here, however, Astra has failed to satisfy (or even address) this traditional four-factor test, thus precluding this Court from issuing injunctive relief. *Monsanto*, 561 U.S. at 158.

Astra contends above that the agency "insist[s] that, notwithstanding the Court's adverse ruling, the agency *will* continue to take action against the plaintiff based on its legally erroneous position." Astra misstates the government's position; HRSA has no intention to flout this Court's ruling. Similarly, Astra charges HRSA with failing to "suggest any less-drastic remedy that would be adequate to preclude Defendants from continuing to harm AstraZeneca based on their flawed reading of Section 340B." Astra's claims of continuing harms are based on speculation that the government will take some undefined and unspecified adverse actions in the future and do not support its request for further relief; moreover, Astra's approach attempts to flip its burden to the government. HRSA has no obligation to propose any "less-drastic remedy" over and above the vacatur and remand authorized by the APA and already granted by the Court. *See*

Monsanto, 561 U.S. at 158. Astra also contends that HRSA has "identif[ied] *no* respect in which granting such [declaratory and injunctive] relief would harm" the government. That is not the law: It is Astra's burden to brief and support its entitlement to an extraordinary remedy, *see id.*, something it has not attempted to do, and that oversight cannot be excused by reframing the inquiry as a purported lack of harm to the government. Moreover, in the event the Third Circuit agrees with HRSA's interpretation of the 340B statute in any appeal, an injunction ordering the immediate cessation of ADR proceedings against Astra would result in a considerable waste of resources for the third-party covered entities that are currently exercising their statutory right to an adjudication of their ADR claims.

Furthermore, even if injunctive relief were appropriate, Astra's proposed injunction—preventing "Defendants from proceeding against AstraZeneca administratively based on the interpretation of Section 340B rejected by this Court"—lacks the requisite specificity mandated under Federal Rule of Civil Procedure 65(d). For example, it is unclear whether Astra's proposed injunction is intended to require that ADR panels immediately abandon all proceedings brought against Astra by covered entities, to enjoin ADR panels from issuing decisions adjudicating claims brought by non-parties to this action against Astra, both, neither, or something else. It is also unclear whether the proposed injunction seeks to prohibit any investigation or potential action being considered by the Inspector General with respect to Astra. Regardless, such injunctive relief is not warranted, as Astra has not (and cannot) establish irreparable injury or the inadequacy of other remedies absent injunctive relief because (i) any such relief would rest on the speculative assumption that the ADR proceedings and the Inspector General's process (neither of which are challenged in this case) would result in an adverse decision against Astra, or that any type of adverse administrative action would occur during the pendency of any appeal

to the Third Circuit; and (ii) any adverse decision by an ADR panel and any decision to pursue civil monetary penalties by the Inspector General are subject to federal-court review, thus demonstrating the absence of irreparable harm and the adequacy of an alternative remedy should any harm allegedly occur. *See* 42 C.F.R. § 10.24(d); 42 C.F.R. § 1005.21(k).

Additionally, granting Astra's proposed declaration would be inappropriate. *First*, declaratory relief is proper only when it "will serve a useful purpose in clarifying and settling the legal relations" at issue in a case and "will terminate and afford relief from the … controversy giving rise to the proceeding." *See Guerra v. Sutton*, 783 F.2d 1371, 1376 (9th Cir. 1986); *accord White Marlin Open, Inc. v. Heasley*, No. RDB-16-3105, 2017 WL 467733, at *4 (D. Md. Feb. 3, 2017). This Court's disposition of Astra's APA challenges and vacatur of the Advisory Opinion and May 17, 2021 letter resolved the legal disputes between the parties and terminates any effect of the challenged actions. Any additional declaratory judgment would thus be superfluous and would serve no useful purpose in settling the specific legal disputes at issue in this case. *See Guerra*, 783 F.2d at 1376; *accord White Marlin Open, Inc.*, 2017 WL 467733, at *4. *Second*, Astra asks this Court to declare that the 340B statute never requires it "to provide discounts for contract pharmacy sales" without ever defining, precisely, what a "contract pharmacy sale" is. A declaration announcing such a legal conclusion "imprecise in definition and uncertain in dimension" would be improper and would create unnecessary confusion. *See United States v. Washington*, 759 F.2d 1353, 1357 (9th Cir. 1985). And as Defendants have repeatedly explained, HRSA is not requiring Astra to sell any drugs to any pharmacies, contrary to what Astra's proposed declaration might be understood to suggest. *See* ECF No. 93 at 17, 25; ECF No. 94 at 5 n.1. Astra's proposed declaration thus continues to misstate HRSA's understanding of the statute and position set forth in this and other, related litigation.

Finally, Astra's contention that remand is unnecessary or improper because HRSA lacks an explicit grant of rulemaking authority and because HRSA has not changed its legal position are baseless. As noted above, the government has filed notices of appeal in related litigation, so HRSA's statutory interpretation will presumably be reviewed by several circuit courts of appeal. And HRSA remains the government agency charged with oversight and administration of the 340B Program; Astra's suggestion that it should not be denied the flexibility to reconsider and reevaluate its position on remand is unwarranted.

For these reasons, this Court should enter final judgment consistent with its Memorandum Opinion without granting the additional relief requested by Astra in this Joint Status Report. Specifically, consistent with the Court's decisions in this case, the final judgment should:

(1) With respect to Astra's first and second claims of the second amended complaint, deny without prejudice Astra's first motion for summary judgment and the government's first motion for summary judgment, in accordance with the Court's previous order, *see* ECF No. 83.

(2) With respect to Astra's third claim in the second amended complaint, grant Astra's first motion for summary judgment and deny the government's first motion for summary judgment, in accordance with the Court's previous order, *see* ECF No. 83;

(3) Set aside and Vacate the Opinion issued by the general counsel of HHS on December 30, 2020, in accordance with the Court's previous order, *see* ECF No. 83.

(4) With respect to Astra's fourth claim in the second amended complaint (that the May 17 Letter was issued without notice and comment required by law), deny without

prejudice Astra's second motion for summary judgment and the government's second motion for summary judgment.

(5) With respect to Astra's fifth claim (that the May 17 Letter exceeds Defendants' statutory authority) and sixth claim (that the May 17 Letter is arbitrary and capricious for failure to acknowledge the agency's change of position) in the second amended complaint, grant Astra's second motion for summary judgment and deny the government's second motion for summary judgment.

(6) Set aside and vacate the May 17, 2021 letter from HRSA to Astra (see D.I. 66-1 Ex. 1), and remand the letter to the agency for further consideration in light of the Court's Memorandum Opinion (D.I. 112)

(ii) How, If at All, Should This Case Should Proceed

A. AstraZeneca: This Court's Memorandum Opinion adjudicated or expressly declined to adjudicate all remaining claims in this case. Once the Court issues its remedial Order, therefore, the case will be fully resolved. The Court should enter final judgment and close the case. *See SecurityPoint Holdings, Inc. v. TSA*, 836 F.3d 32, 38 (D.C. Cir. 2016).

B. Defendants: Defendants agree that the Court should enter final judgment and close the case, to facilitate any appellate review, although Defendants respectfully contend that no additional relief is warranted.

Dated: February 23, 2022

McCarter & English, LLP

/s/ Daniel M. Silver
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King St., 8th Floor
Wilmington, DE 19801
Tel.: (302) 984-6300
Fax: (302) 984-6399
dsilver@mccarter.com
ajoyce@mccarter.com

Of Counsel:

Allon Kedem
Jeffrey L. Handwerker
Sally L. Pei
Stephen K. Wirth
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW
Washington, DC 20001-3743
Tel.: (202)942-5000
Fax: (202) 942-5999
allon.kedem@arnoldporter.com
jeffrey.handwerker@arnoldporter.com
sally.pei@arnoldporter.com
stephen.wirth@arnoldporter.com

Attorneys for Plaintiff AstraZeneca Pharmaceuticals LP

United States Department of Justice

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE BENNETT
Assistant Branch Director

/s/ Kate Talmor
Kate Talmor
Jody Lowenstein
United States Department of Justice
Civil Division
Federal Programs Branch
1100 L Street NW
Washington, DC 20005
(202) 305-5267
kate.talmor@usdoj.gov

Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, et al., *Defendants*.	C.A. No. 21-27-LPS

[PROPOSED] ORDER AND FINAL JUDGMENT

For the reasons set forth in the Court's Memorandum Opinion and Order of February 16, 2022 (D.I. 112 and 113),[1] and parties' Joint Status Report of February 23, 2022 (D.I. __),

IT IS HEREBY ORDERED, this _____ day of _____, 2022, that:

1. With respect to Claim Five and Claim Six of the second amended complaint, AstraZeneca's Second Motion for Summary Judgment (D.I. 90) is GRANTED.

2. The Court DECLARES that the 340B statute does not contain a statutory command requiring AstraZeneca to provide discounts for contract pharmacy sales.

3. The Court finds that it is necessary to afford AstraZeneca injunctive relief to prevent Defendants from initiating and/or maintaining further proceedings against AstraZeneca inconsistent with this Court's rulings. Accordingly, Defendants are hereby ENJOINED from proceeding against AstraZeneca administratively based on the interpretation of Section 340B rejected by this Court—namely, that Section 340B requires AstraZeneca to provide discounts for contract pharmacy sales.

[1] Any terms not defined herein shall have the same meaning ascribed to them in this Court's Memorandum Opinions (D.I. 78 and 112), which are incorporated herein by reference.

4. The Violation Letter issued to AstraZeneca by Defendants on May 17, 2021, is SET ASIDE and VACATED.

5. With respect to Claim Four of the second amended complaint, AstraZeneca's Second Motion for Summary Judgment (D.I. 90) is DISMISSED AS MOOT without prejudice to renewal should this Judgment be reversed on appeal.

6. Defendants' Motion for Summary Judgment (D.I. 92) is DENIED.

7. All other requests for relief are DISMISSED AS MOOT.

8. The Court hereby directs that this Final Judgment be entered forthwith.

UNITED STATES DISTRICT JUDGE