IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

JOINT STATUS REPORT

The undersigned counsel respectfully submit this joint status report pursuant to the Court's Memorandum Opinion and Order of June 16, 2021 (D.I. Nos. 78 and 79) requesting that the Parties meet and confer and report on "the precise relief to be granted—be it setting aside the Opinion, vacating it with respect to AstraZeneca, remanding to HHS, or something else." Mem. Op. at 23 (D.I. No. 78). The Court's Order specifically requests the Parties' views with respect to: (i) what relief the Court should grant AstraZeneca in light of the analysis provided in the Memorandum Opinion; (ii) what form of Order should the Court enter; and (iii) how, if at all, should this case now proceed. (D.I. No. 79.)

Subsequent to the Court's Order, Defendants filed a Notice (D.I. No. 81) informing the Court that, "in an effort to avoid confusion and unnecessary litigation," HHS has withdrawn the Advisory Opinion of December 30, 2020, and that "it is Defendants' position that such withdrawal renders claims challenging the Advisory Opinion moot." The Parties have met and conferred about the Court's Order and HHS's subsequent withdrawal of the Advisory Opinion.

Based on those discussions, the Parties respective views are set forth below:

i. What Relief Should The Court Grant AstraZeneca in Light of the Analysis Provided in the Memorandum Opinion?

A. AstraZeneca: Defendants' withdrawal of the Advisory Opinion after this Court issued its Memorandum Opinion did not moot this action or affect in any way the relief that the Court should issue. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Buckhannon Bd. & Care Home, Inc. v. W.V. Dep't of Health & Human Res.*, 532 U.S. 598 (2001) (quotation marks omitted). For that reason, even a litigant's "announcement" that it has fully abandoned the challenged action "does not moot th[e] case." *Trinity Lutheran Church v. Comer*, 137 S. Ct. 2012, 2019 n.1 (2017).

It thus follows that the Government may not moot litigation by ceasing a challenged action, yet nonetheless continue to maintain the same legal position with respect to enforcement. In *Solar Turbines, Inc. v. Seif, et al.*, 879 F.2d 1073 (3d Cir. 1989), for example, the Third Circuit rejected the EPA's contention that its withdrawal of an administrative order rendered a challenge to that order moot even though the "EPA has not altered its position on the merits, and indeed has instituted an action in the district court seeking injunctive relief to prevent further violation of the Clean Air Act on the same grounds as contained in the administrative order." *Id.* at 1079. In rejecting EPA's position, the Court explained that "we cannot allow the agency to control the timing and venue of judicial review by its own procedural maneuvers." *Id.* (citing *Hooker Chemicals Co. v. EPA*, 642 F.2d 48 (3d Cir. 1981)).

This line of precedent controls here. Defendants' withdrawal notice makes clear the Government's view that the "withdrawal of the Opinion does not impact the ongoing efforts of the

Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements. HRSA's enforcement process operated independently from the issuance of the Opinion, and operates independently from the Opinion's withdrawal." (D.I. No. 81.) Defendants may not escape the implications of this Court's Memorandum Opinion by withdrawing the Advisory Opinion only after this Court rejected the statutory interpretation adopted in that Opinion, but before the Court issued judgment. Nor does AstraZeneca believe that Defendants should be permitted to use this Court's Order (D.I. No. 79)—which attempted to accommodate the parties by affording them a chance to discuss the appropriate judgment and related issues—as an opportunity to nullify the Court's merits ruling.

With respect to the merits, AstraZeneca believes the Court should issue an Order vacating and setting aside the Advisory Opinion, and providing further relief as described in response to question (ii) below, given the Court's conclusions that: (a) the Advisory Opinion is a "final and reviewable" agency action, Op. at 16; (b) AstraZeneca's challenge to the Advisory Opinion was timely made, Op. at 17; (c) the Advisory 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," Op. at 12 (emphasis in original); and, most critically, (d) the Advisory Opinion was "legally flawed," Op. at 17, including because it was based on the "unjustified assumption that Congress imposed [the Opinion's] interpretation as a statutory requirement," Op. at 23. The appropriate remedy in these circumstances is to vacate the arbitrary and capricious agency action. *See Sierra Club v. U.S. EPA*, 972 F.3d 290, 309 (3d Cir. 2020). Because of HHS OGC's post-Memorandum Opinion withdrawal of the Advisory Opinion, AstraZeneca agrees with Defendants that no remand to the agency is necessary at this time.

B. HHS: Although HHS respectfully disagrees with the Court's ruling, HHS's OGC has withdrawn the Advisory Opinion in light of the Court's decision, to avoid further confusion and unnecessary litigation regarding its intended scope. *See* D.I. No. 81. Thus the claims challenging the Advisory Opinion are moot, and should be dismissed. *See Marcavage v. National Park Service*, 666 F.3d 856, 861-62 (3d. Cir. 2012). As HHS has made clear in the course of this litigation, the Health Resources and Services Administration's ("HRSA") enforcement proceedings, including the May 17, 2021 Violation Letter, do "not rely on the Advisory Opinion, and HRSA's actions to enforce the 340B statute [itself] would not be impeded by vacatur of the legal advice." ECF No. 69 at 3. HRSA intends to continue enforcement proceedings against AstraZeneca pursuant to the 340B statute, as outlined in the Violation Letter. HHS does not understand the Court's conclusions in the Memorandum Opinion to be inconsistent with this action. As the Court noted, "HHS's current interpretation of the statute is permissible" and the Court determined only that the Advisory Opinion is unlawful because it was "based on the unjustified assumption that Congress imposed this interpretation as a statutory requirement." Mem. Op. at 23. Moreover, the parties have not yet briefed claims regarding HRSA's Violation Letter or the basis for its finding, so any relief on that new agency action would be premature. The Parties also agree that the litigation should continue and that the Court should decide the legality of the HRSA Violation Letter, which militates against Astra's voluntary cessation argument, as HHS acknowledges that the Court will decide the ultimate question of the legality of Astra's policy in this case.

Below, AstraZeneca also seeks a declaration that the Advisory Opinion was adopted without observance of procedures required by law, and a declaration seeking to define the metes and bounds of the 340B statute, neither of which is supported by the Court's Memorandum

Opinion. The Court's Memorandum Opinion did not address AstraZeneca's claim that the Advisory Opinion was issued without observance of procedures required by law, and thus no relief is warranted based on the Court's Memorandum Opinion. The Court's Memorandum Opinion similarly did not address the definitive meaning of the 340B statute, interpreting the statute only in the context of determining that the Advisory Opinion was arbitrary and capricious. If the Court awards Astra relief at all, it should be limited to vacatur of the Advisory Opinion.

ii. What Form of Order Should the Court Enter

A. AstraZeneca: In light of the Court's findings in the Memorandum Opinion, and in view of section (iii) below, AstraZeneca proposes a Form of Order as follows:

(a) DENYING Defendants' Motion to Dismiss as to AstraZeneca's First Claim for Relief (that Defendants failed to observe notice and comment procedures), Second Claim for Relief (that Defendants acted in excess of their authority), and Third Claim for Relief (that the Advisory Opinion is arbitrary and capricious);

(b) GRANTING Defendants' Motion to Dismiss as to AstraZeneca's Fourth Claim for Relief (that Defendants were arbitrary and capricious in not posting AstraZeneca's notice on the HRSA website);

(c) DECLARING that HHS OGC's post-Memorandum Opinion withdrawal of the Advisory Opinion does not moot this litigation;

(d) GRANTING AstraZeneca's motion for summary judgment with respect to AstraZeneca's Third Claim for Relief, and DENYING the Government's motion for summary judgment with respect to AstraZeneca's Third Claim for Relief;

(e) STAYING further proceedings on AstraZeneca's and Defendants' cross motions for summary judgment with respect to AstraZeneca's First and Second Claims for Relief;

(f) DECLARING that the Advisory Opinion was adopted without observance of procedure required by law because "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," Op. at 12 (emphasis omitted);

(g) DECLARING that the 340B Statute "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs," Op. at 18; that a "requirement" for pharmaceutical manufacturers "to deliver 340B drugs to an unlimited number of contract pharmacies" is not "contained in the statute," Op. at 21-22; and that the legal position expressed in the Advisory Opinion (*i.e.*, the 340B statute unambiguously requires manufacturers to offer 340B discounts for unlimited contract pharmacy sales) thus is not in accordance with law and is invalid;

(h) SETTING ASIDE and VACATING the Advisory Opinion;

(i) DIRECTING the Parties to meet and confer with respect to a Second Amended Complaint and ORDERING AstraZeneca to file a status report and/or motion for leave with respect to such Second Amended Complaint by [DATE]; and

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

B. HHS: Because the Advisory Opinion has been withdrawn, AstraZeneca's claims are moot and should be dismissed. If the Court disagrees, the Court should grant HHS's motion to dismiss with respect to AstraZeneca's Fourth Claim for Relief, grant AstraZeneca's motion for summary judgment with respect to AstraZeneca's Third Claim for Relief, deny HHS's motion for summary judgment with respect to AstraZeneca's Third Claim for Relief, and deny the remainder of both motions for summary judgment as moot in light of the Court's order and the withdrawal of the Advisory Opinion.

(iii) How, if at all, Should This Case Proceed

A. AstraZeneca: AstraZeneca believes that the Court's conclusion that the 340B statute is silent with respect to a manufacturer's obligation to deliver 340B drugs to an unlimited number of contract pharmacies, coupled with the Court's finding that the government has taken inconsistent positions on the proper meaning and interpretation of the 340B statute, forecloses HRSA from following through on the threats made in its May 17 letter and also prohibits entry of civil monetary penalties based on AstraZeneca's contract pharmacy policy. If Defendants were willing to represent that they will not follow through on the threats contained in the May 17 letter, or to amend the May 17 letter to reflect the Court's ruling, then AstraZeneca's position would be that no further proceedings to address the May 17 letter are necessary at this time.

However, because Defendants' withdrawal notice expresses HRSA's intent to pursue enforcement against AstraZeneca notwithstanding this Court's Memorandum Opinion and Order, AstraZeneca's position is that this case should now proceed as the Parties proposed at the May 27 oral argument: AstraZeneca would promptly amend its complaint to add claims regarding the May 17 letter. *See* Oral Arg. Tr. at 58-59. AstraZeneca is prepared to do so immediately after this Court's Order and upon leave of Court. The Parties would then promptly submit "short supplemental brief[s]" of up to 10 pages each "that would allow the Court to decide th[e] claim[s]." *Id.* at 111; *see id.* at 85 (government counsel asking for "both sides . . . to submit a short supplemental brief, seven to ten pages at most"). AstraZeneca does not believe at this time that the further proceedings would require a temporary restraining order or preliminary injunction; but if Defendants were to initiate civil monetary penalty or administrative dispute resolution proceedings in the interim, AstraZeneca reserves its right to seek emergency relief in those circumstances.

B. HHS: As explained above, HRSA does not consider the Court's Memorandum Opinion to prevent its enforcement actions under the 340B statute with respect to AstraZeneca, and those enforcement proceedings will continue. HHS does not oppose AstraZeneca's request to supplement its Complaint to challenge the Violation Letter. HHS has compiled an administrative record of more than 8,000 pages supporting the conclusions of the Violation Letter, and asks that any schedule imposed by the Court for briefing claims challenging the Violation Letter allow for service of the record before submission of any briefing. Additionally, because of the size of the record, 10 pages will not permit adequate space to explain the record evidence and adequately address any new claims. HHS now asks the Court to allow each side 35 pages total to brief cross-motions for summary judgment on the additional claims to be divided between two briefs per side.

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