**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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

**JOINT STATUS REPORT**

The undersigned counsel respectfully submit this joint status report pursuant to the Court's oral order that the parties update the Court "regarding any case developments." (D.I. 105). This status report supplements, and incorporates by reference, the parties' report of October 25, 2021 (D.I. 104), as well as Defendants' notice of supplemental authority, filed November 2 (D.I. 105), and Plaintiff's response to that notice, filed on November 3 (D.I. 107).

On November 5, two courts issued opinions addressing HRSA violation letters to other manufacturers that are materially identical to the May 17 letter at issue in this case:

- The U.S. District Court for the District of New Jersey, *see Sanofi-Aventis U.S., LLC v. HHS*, No. 21-cv-00634-FLW (D.N.J. Nov. 5, 2021); *Novo Nordisk Inc. v. HHS*, No. 21-cv-00806-FLW (D.N.J. Nov. 5, 2021) ("Ex. A"); and
- The U.S. District Court for the District of Columbia, *see Novartis Pharma. Corp. v. Espinosa*¸ No. 21-cv-1479-DLF (D.D.C. Nov. 5, 2021); *United Therapeutics Corp v. Espinosa*, No. 21-cv-1686-DLF (D.D.C. Nov. 5, 2021) ("Ex. B").

These opinions are attached as exhibits to this filing. The parties' respective statements regarding the opinions and other developments relevant to this case are set forth below.

**1. Plaintiff**

Notwithstanding this Court's prior opinion (D.I. 78), the government has pressed forward with a contrary interpretation of the 340B statute on at least three fronts: (a) through litigation against other manufacturers; (b) through the ADR process; and (c) through a referral of AstraZeneca for civil monetary penalties (CMPs).

**A. District Court Opinions**

The DC and NJ opinions vacated (at least in part) May 17 violation letters from HRSA materially identical to the letter to AstraZeneca at issue here, but they adopted conflicting rationales for doing so. To the extent this Court looks to those rulings for guidance, AstraZeneca respectfully suggests it should follow the DC court's well-reasoned analysis.

Both decisions accept this Court's conclusion that the 340B statute "is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." DC Op. 9; *see* NJ Op. 78 ("By its terms, §340B is silent on what role (if any) contract pharmacies play in Congress' discount drug scheme."). Both decisions also reject HRSA's argument that an obligation to provide discounts for contract-pharmacy purchases is contained in the "purchased by" language or "shall offer" provision. DC Op. 13 ("HRSA's interpretation stretches the 'Shall Offer' provision beyond its plain meaning."); NJ Op. 78 ("§256b(a)(1) cannot bear the weight HHS places on it."). The decisions diverge, however, in their conclusions regarding what the absence of such an obligation in the text means for the legality of manufacturers' policies. In this respect, AstraZeneca submits that the DC court got it right, for several reasons.

***First***, only the DC court asked the correct legal question: whether the 340B statute *requires* manufacturers to recognize contract pharmacies without limitation. Unlike HRSA,

which is a governmental entity constrained in its regulatory power by the authority expressly delegated to it by Congress, manufacturers are private entities that may freely engage in commercial activity—including setting market prices for their products—so long as their actions are not prohibited by law. *See* D.C. Op. 14 ("[No] language in Section 340B *prohibit*[*s*] manufacturers from placing *any* conditions on covered entities."). Absent such a statutory requirement, there can be no basis for HRSA to accuse manufactures of acting "in direct violation of the 340B statute." Administrative Record at 1 (May 17 letter). The NJ court flipped this basic principle on its head, deeming the manufacturers' policies "[i]mpermissible" because no statutory text provides affirmative "authority for Plaintiffs' policies." NJ Op. 92-93. Illustrative is the NJ court's statement (at 94) that "Plaintiffs' policies are … *ultra vires*," which treats manufacturers as if they were governmental agencies.

***Second***, only the DC court grounded its ruling in the statute's text. *See* DC Op. 13 ("[T]his Court starts, as always, with the text."). Relying heavily on this Court's Memorandum Opinion, the DC court analyzed the operative language of §256(a)(1) and concluded that it "does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.* at 13 (quoting D.I. 78). The DC court also explained that manufacturers' policies comply fully with the plain meaning of the "shall offer" requirement. *Id.* at 13-14 ("[E]ven with the added conditions imposed by the drug manufacturers' new policies, both manufacturers continue to present their drugs to covered entities, as the 'Shall Offer' provision requires."); *id.* at 13 (relying on dictionary definition of "offer"). The court also rejected HRSA's attempt to excuse the absence of "a clear textual hook for its interpretation" with an appeal to "the statute's purpose." *Id.* at 16. "'[N]o legislation pursues its purposes at all costs,'" the court explained; and here, the

statutory "structure suggests that Congress did not intend Section 340B's purpose to be pursued at all costs." *Id.* at 16-17 (quoting *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014)).

The NJ court, by contrast, "start[ed] with the legislative history," NJ Op. 81, and never identified a textual basis for the obligation that manufacturers are supposedly violating. Even with respect to the legislative history, the court drew inferences about Congress's intentions that directly conflict with this Court's reading of that same legislative history. *Compare id.* (inferring, from Congress's decision not to adopt language authorizing on-site contract pharmacies, that Congress "likely did not intend *to prohibit* them altogether"), *with* D.I. 78 at 21 (the "omission suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies"). The NJ court also relied on "§340B's post-enactment history," NJ Op. 85, contrary to the principle that post-enactment history—often disparaged as "legislative future"—is of "marginal, if any, value." *US v. SCS Bus. & Tech. Inst., Inc.*, 173 F.3d 870, 878 (D.C. Cir. 1999).

***Third***, although both courts acknowledged that HRSA's position depends on filling the textual "gap," NJ Op. 78 ("HHS attempts to fill in these gaps"); DC Op. 19 ("the agency's shifting guidance illustrates that is it attempting to fill a gap in this statute"), only the DC court properly recognized that gap-filling is an act of *legislative* rulemaking. *See* DC Op. 19 ("Any such gap-filling must be accomplished by a legislative rather than an interpretive rule."). That blackletter APA principle dooms HRSA's attempts to fill the "gap" in §256b(a)(1): "HRSA lacks the authority to issue a legislative rule." *Id.* (HRSA "acknowledge[s] that it lacks an explicit grant of comprehensive rulemaking authority"). As the D.C. Circuit has explained, "[w]here Congress prescribes the form in which an agency may exercise its authority, … [a court] cannot elevate the goals of an agency's action, however reasonable, over that prescribed form."

*Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (1990); *see PhRMA v. HHS*, 43 F. Supp. 3d 28, 46 (D.D.C. 2014) (HRSA lacks authority to fill gaps under the 340B Statute).

The NJ court asserted that the May 17 letter "contain features that are hallmarks of interpretive rules." NJ Op. 119 n.66. But the court did not reconcile that statement with its earlier conclusion that §256b(a)(1), which contains the "sum total of the statute's language regarding manufacturers' obligations," is "silent." *Id.* at 78. Nor did the court explain how HRSA could use an interpretive rule to create binding requirements not contained in the statute itself. *See Am. Min. Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110 (D.C. Cir. 1993).

**B. ADR Proceedings**

As this Court is aware, four separate ADR petitions have been filed against AstraZeneca, which HRSA has now assigned to panels for formal proceedings. D.I. 104 at 2. At the time of the parties' October 25 status report, only one panel had issued a scheduling order. That order required AstraZeneca to respond to the petition, move to dismiss, or seek a stay by November 21. It also indicated that the parties would be granted, as a matter of right, one 30-day extension of the deadline. *Id.* at 2-3. On November 1, the three remaining ADR panels issued similar scheduling orders, requiring AstraZeneca to file a response, move to dismiss, or seek a stay of proceedings by December 1. Those orders likewise provide that the parties will be granted one 30-day extension as a matter of right, which could extend AstraZeneca's deadline to respond to December 31. Although AstraZeneca has not made a final decision with respect to requesting such an extension, AstraZeneca is likely to do so.

**C. Civil Monetary Penalties**

On November 8, 2021, counsel for AstraZeneca spoke with two officials from the Office of the Inspector General, which is evaluating HRSA's decision to refer AstraZeneca for CMP

proceedings for purported "overcharges" resulting from AstraZeneca's decision to stop recognizing unlimited contract pharmacies. The officials stated that they could not provide any details about the anticipated schedule, but that AstraZeneca would be afforded notice and an opportunity to respond prior to any final decision.

**2. Defendants**

**A. Recent Rulings**

Two more judicial decisions opining on the central issues in this case have been issued. First, in a lengthy, well-reasoned opinion, Chief Judge Wolfson agreed with HRSA's determination and squarely rejected the same arguments presented in this litigation:

> Based on Congressional silence alone, Plaintiffs ask this Court to *prevent* HHS from requiring *any* contract pharmacy arrangements (though to permit them to do so voluntarily, in their own policies), *create* out of whole cloth a right for Plaintiffs to impose conditions on offers to covered entities who use multiple contract pharmacies, [and] *limit* the definition of overcharge without any indicia of legislative intent … all to dramatically size-down a drug discount scheme that Congress has expanded at least three times since 1992 and has never expressed an intention to abate.

Ex. A ("*Sanofi*") at 106.

In making this determination, the court "beg[a]n with the text" and agreed with this Court that the 340B statute is ambiguous on contract-pharmacy usage (77-79). Because the text is ambiguous, the court undertook *de novo* review and determined that HRSA's interpretation "squares better with Congressional intent than Plaintiffs' position that Congress simply never intended to authorize such a dispensing mechanism," *id.* 81. First, "legislative history … weighs in favor of HHS" "[b]ecause Congress *eliminated* a clear limitation on contract pharmacy arrangements in the drafting process" and thus "likely did not intend *to prohibit* them altogether." *Id.* Second, legislative purpose supports the agency because "[c]ontract pharmacy arrangements are not just commonplace," but "a necessary—perhaps even indispensable—means

of attaining § 340B's ends," and "Plaintiffs' interpretation … would dramatically scale back § 340B," violating the presumption against ineffectiveness. *Id.* 83-84. Of particular note, the court explained why, "based on § 340B's post-enactment history, Congress has seemingly ratified contract pharmacy arrangements," since it twice has acted to *expand* the 340B Program without any suggestion that HRSA's "well-settled 1996 Guidance" did not align with Congressional intent. *Id.* 84-86. The court analyzed extensively why "the overall statutory scheme tends to support HHS' reading," rejecting plaintiffs' arguments that another provision in the VHCA, 38 U.S.C. § 8126(h)(3), and another healthcare statute, 42 U.S.C. § 1320a-7b(b)(3)(C), cut against HHS's position. The court explained in depth why it is "[r]are[]" that "courts draw a negative inference about Congressional intent across different phrasings in different statutes drafted at different times on different subject matter, as with § 340B and § 1320a-7b(3)(C)." *Id.* 86-89 (*contra* D.I. 78 at 20-21).

As to the policies before it, the court did not mince words: "the 340B statute forecloses Plaintiffs' policies" and does not permit manufacturers to "unilaterally create and establish policies—whatever the underlying rationale—wherein they dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Id.* 94-95. (The specifics of plaintiffs' unlawful restrictions vary, but neither purport to restrict contract-pharmacy dispensing as severely as Astra.) The court criticized plaintiffs there for "rest[ing] their entire theory," as does Astra here, "on statutory language providing that a manufacturer '*shall offer*'" 340B discounts to covered entities, explaining that "Plaintiffs take the 'shall offer' provision far afield of its context," since that provision "mostly reiterates that manufacturers cannot prioritize full-priced commercial purchases … which is a separate and distinct requirement" that "has little bearing on the question whether, or to what extent, Plaintiffs can

attach strings to 340B sales." *Id.* 92-93. "Plaintiffs' policies would threaten to undo the statutory scheme by rendering 340B offers hollow." *Id.* 94. Finally, the court agreed with HRSA that a 340B "overcharge" encompasses situations where "purchase orders … are denied due to an *ultra vires* eligibility restriction … to the same extent as" purchases completed above the ceiling price.

Notwithstanding its determination that plaintiffs' policies violate 340B, the court partially remanded for the agency to determine "how many contract pharmacies the 340B statute permits, if there is a ceiling at all," reasoning that determination involves "policy choices and balanc[ing of] competing statutory priorities," such as whether there should be "different benchmarks for determining the appropriate number of contract pharmacy sites for a particular type of covered entity." *Id.* 95-96. That in no way undermines its holding that "Plaintiffs cannot impose restrictions on offers to covered entities" and "their policies must cease." *Id.* 95-97.

Conversely, Judge Friedrich ruled that the statute does "not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies." Ex. B ("*Novartis*") at 20-21. HRSA respectfully disagrees with that decision, and notes its departure from the *Lilly* and *Sanofi* courts' reasoning. The *Novartis* court grounds its analysis entirely in the "shall offer" provision added in 2010, and did not substantively discuss the "purchase[s] by" mandate enacted by Congress in 1992 (or the corresponding obligation in manufacturers' PPAs). *Id.* 13-20. Similarly, the court's analysis omits critical context, relying on the dictionary definition of "offer" in commercial contracts without considering how that term interacts with the *preexisting* requirement that manufacturers ensure "purchase[s] by" covered entities do not exceed the ceiling price—or the differences between 340B and commercial sales. *Id.* 13. And the court wrote that HRSA "is incorrect that the record contains evidence of 340B violations," stating that HRSA could only show a violation through evidence that covered "entities were not

offered 340B pricing upon compliance with the manufacturers' policies." *Id.* 14 n.3. This flips the statutory analysis on its head—by stating that the statute is only violated if manufacturers refuse discounts on orders complying *with their own unilaterally devised restrictions*—and does not account for evidence that Novartis charged covered entities commercial pricing of up to, *e.g.*, $14,716 and $12,912/unit. *See* AR 1468, 1474. The court did not reconcile its determination that direct evidence of Novartis charging many times the ceiling price does not "establish a 340B violation" with the statutory directive that "purchase[s] by" a covered entity not exceed the ceiling (perhaps because its analysis turned only on the "shall offer" provision). Finally, the court did not address many of the arguments and analysis presented in HRSA's briefs.

**B. ADR Proceedings**

HRSA notes that the *Sanofi* court also held that the ADR Rule is both substantively lawful and lawfully promulgated. Specifically, the court rejected arguments that the ADR Rule was improperly promulgated in violation of the APA's notice-and-comment requirements; is arbitrary and capricious and contrary to law; violates Article II's Appointments Clause; and usurps judicial authority in violation of Article III. *See* Ex. A at 26-71.

Dated: November 12, 2021

MCCARTER & ENGLISH, LLP

*/s/ Daniel M. Silver*
Michael P. Kelly (#2295)
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
mkelly@mccarter.com
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
Acting 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*