U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

LITTLE RIVERS HEALTH CARE, INC. Petitioner, v. ASTRAZENECA PHARMACEUTICALS, LP, Respondent.	ADR ID: 210202-5 Opposition to Motion to Stay

PETITIONER LITTLE RIVERS'S OPPOSITION TO RESPONDENT ASTRAZENECA'S MOTION TO STAY PROCEEDINGS

Little Rivers Health Care, Inc. ("Petitioner" or "Little Rivers") opposes the motion filed by AstraZeneca Pharmaceuticals ("Respondent" or "AstraZeneca") requesting that the Administrative Dispute Resolution Panel ("ADR Panel") stay the proceedings in the above-captioned case. Since October 1, 2020, AstraZeneca has violated the 340B statute by refusing to offer covered outpatient drugs at the 340B ceiling price through Little Rivers's contract pharmacy arrangements. A stay of these ADR proceedings, which is Little Rivers's sole venue for directly challenging AstraZeneca's denial of statutorily mandated 340B discounts, would compound the harm that Little Rivers and its patients have suffered for over 15 months as the result of AstraZeneca's actions. AstraZeneca's assertions that these ADR proceedings are impacted by collateral litigation and the possibility of future agency rulemaking do not support a stay, especially given the significant harm a stay will cause Little Rivers. Accordingly, the ADR Panel should deny the motion to stay and direct AstraZeneca to respond substantively to Little Rivers's petition so that the ADR Panel can resolve the longstanding claims at issue.

Factual Background

Almost twelve years ago, the Patient Protection and Affordable Care Act ("ACA") was enacted and mandated that the Department of Health and Human Services ("HHS") issue regulations to implement the 340B ADR process within 180 days. ACA § 7102(a), Pub. L. No. 111-148, 124 Stat. 119, 823 (2010) (codified at 42 U.S.C. § 256b(d)(3)). HHS' 180-day deadline fell on September 19, 2010. On September 20, 2010, HHS published an "advance notice of proposed rulemaking and request for comments" in the Federal Register "to obtain information and public comment on how to efficiently and effectively implement the requirements to create an administrative dispute resolution process for the 340B Program authorized by Section 7102 of the Affordable Care Act." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57233, 57,233-57,235 (Sept. 20, 2010). Comments were due on November 19, 2020.

In the midst of the ADR rulemaking process, the Supreme Court issued a decision holding that 340B covered entities do not have a private right of action against pharmaceutical manufacturers to enforce 340B requirements, including the obligation of manufacturers to charge no more than the 340B ceiling price for covered outpatient drugs. *See Astra USA v. Santa Clara County*, 563 U.S. 110, 121–22 (2011). AstraZeneca was one of the nine manufacturers that petitioned the Supreme Court for this holding. The Court based its holding, in part, on the expectation that HHS would soon implement 340B ADR proceedings as mandated by the ACA:

> Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of "overcharges and other violations of the discounted pricing requirements," *id*., at 823, 42 U.S.C.A. § 256b(d)(1)(A), and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA, *id*., at 827, 42 U.S.C.A. § 256b(d) (3)(C).

Astra USA, 563 U.S. at 121-22. HHS did not promulgate ADR regulations for another nine

years, however, and the lack of an ADR regulation and the holding in *Astra USA* left covered entities with no means to directly enforce their rights to 340B discounts.

Nearly six years after its advanced notice of proposed rulemaking, HHS published proposed ADR regulations. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). On August 1, 2017, the Secretary withdrew the proposed ADR regulations without explanation. Office of Mgmt. & Budget, RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last visited Jan. 17, 2022).

In a series of correspondence between AstraZeneca and the Health Resources and Services Administration ("HRSA"), AstraZeneca informed HRSA of its plan to cease offering 340B discounts on drugs purchased by covered entities and distributed by contract pharmacies and HRSA informed AstraZeneca that it was considering whether those plans violated the 340B statute. Letter from Christie Bloomquist, VP Corporate Affairs, AstraZeneca PLC to Admiral Krista Pedley, Director, Office of Pharmacy Affairs (OPA) (July 24, 2020); letter from Admiral Krista Pedley to Christie Bloomquist (Sept. 2, 2020); letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC to Admiral Krista Pedley (Sept. 15, 2020). Beginning October 1, 2020, AstraZeneca began denying 340B discounts by refusing to sell its drugs through the 340B wholesaler accounts associated with contract pharmacies, including to Little Rivers's contract pharmacies.

On December 30, 2020, the HHS Office of the General Counsel ("OGC") issued an Advisory Opinion stating unequivocally that drug manufacturers must offer covered outpatient drugs to covered entities at or below the 340B ceiling price regardless of how the covered entity distributes those drugs. As the HHS OGC correctly stated:

> [T]he core requirement of the 340B statute, as also reflected in the PPA [Pharmaceutical Pricing Agreement] and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity.

Because Little Rivers had no means to enforce its rights to 340B discounts at its contract pharmacies, it, along with other 340B covered entities and RWC-340B, an organization representing 340B Ryan White clinics, filed a lawsuit against HHS seeking an order that HHS implement the ADR process, as well as take other actions to enforce their rights to 340B discounts at contract pharmacies. Amended Complaint, *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020) (stayed), ECF No. 21.

Shortly after Little Rivers filed its suit against HRSA, HRSA issued final ADR rules in December 2020, which became effective January 13, 2021. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-14/pdf/2020-27440.pdf. These rules were issued over ten years past Congress's September 19, 2010, deadline. On January 13, 2021, the court in *RWC-340B v Azar* granted a joint motion to stay that proceeding so that Little Rivers and other plaintiffs in that lawsuit could pursue their rights to file ADR petitions against manufacturers. Joint Motion for Stay, *RWC-340B*, No. 1:20-cv-02906 (D.D.C. Jan. 13, 2021), ECF No. 58. That case has continued to be stayed while Little Rivers pursues the ADR process.

Around the same time, AstraZeneca filed a lawsuit in the United States District Courts for the District of Delaware challenging HHS' interpretation of the 340B statute to require drug manufacturers to provide 340B discounts on drugs shipped to contract pharmacies. *AstraZeneca Pharmas. L.P. v. Becerra*, No. 1:21-cv-00027 (D. Del. Jan. 12, 2021), ECF No. 1. Briefing and arguments on cross-motions for summary judgment in that case are complete. *AstraZeneca*, No.

1:21-cv-00027 (D. Del. Oct. 22, 2021), ECF No. 103.

Also around that time, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit in the U.S. District Court for the District of Maryland against HHS and HRSA, challenging the validity of the ADR regulations and the appointment process for the ADR Panel. *See Pharmaceutical Research & Manufacturers of America v. Becerra*, No. 8:21-cv-198 (D. Md. Jan. 22, 2021), ECF No. 1. The parties filed dispositive motions on PhRMA's claims, and the motions are currently pending before the court. *See PhRMA*, No. 8:21-cv-198 (D. Md.), ECF Nos. 26, 29, 31, 32.

Little Rivers filed its ADR petition against AstraZeneca on February 4, 2021 and the petition was served on AstraZeneca on that same day. The ADR regulations state that, "[u]pon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in [Federal] Rule [of Civil Procedure] 12 or 56." 42 C.F.R. § 10.21(f). Federal Rule of Civil Procedure ("FRCP") 12 ***requires*** an answer to a complaint within 21 days of service and FRCP 56 ***allows*** submission of a Motion for Summary Judgement within 30 days of the close of discovery. Thus, a response is required within 21 days.[1] AstraZeneca did not respond to Little Rivers's petition within the 21-day deadline.

On May 17, 2021, HHS issued a letter to AstraZeneca informing AstraZeneca that its refusal to offer 340B pricing at contract pharmacies violated the 340B statute. AstraZeneca amended its complaint in federal district court to add a challenge to HHS' position in the May 17 letter. Second Amended Complaint, *AstraZeneca*, No. 1:21-cv-00027 (D. Del. Jan. 12, 2021), ECF No. 86.

Almost eight months after Little Rivers filed its petition to institute these ADR proceedings, AstraZeneca filed a request for an indefinite extension of time to respond to the

[1] FRCP 12 tolls the deadline to respond when a party files a motion under Rule 12 (e.g., a motion to dismiss), which is not applicable here.

petition.[2] Little Rivers promptly submitted an opposition to this request on October 22, 2021. The ADR panel issued a scheduling order on November 1, 2021, in which it directed AstraZeneca to file a response within 30 days and gave AstraZeneca one 30-day extension by right.

In November 2021, HRSA and HHS recently submitted a proposed rule to the Office of Management and Budget ("OMB") for review titled "340B Drug Pricing Program; Administrative Dispute Resolution" to the Office of Management and Budget. Proposed Rule Pending EO 12866 Regulatory Review, 340B Drug Pricing Program; Administrative Dispute Resolution, RIN 0906-AB28 (Nov. 18, 2021). The contents of the proposed rule are not public.

AstraZeneca filed its Motion for Stay of these ADR proceedings on January 3, 2022. AstraZeneca is requesting a stay pending the outcome of three matters: 1) its litigation against HHS pending in the District Court of Delaware; 2) the outcome of the PhRMA lawsuit challenging the legality of the ADR regulations and the process for appointing the ADR Panel; and 3) finalization of the revised ADR rules that HHS announced it plans to adopt.

Argument

The ADR Panel should deny the stay requested by AstraZeneca. The harms that will be incurred by Little Rivers in granting a stay far outweigh any of the harms conjectured by AstraZeneca to support a stay and there is no guarantee that a stay would promote efficiency. The mere prospect that federal court proceedings or administrative actions could impact the current ADR proceedings does not overcome the significant harm caused by AstraZeneca's unchecked denial of lawful 340B discounts, and AstraZeneca has not shown that it will suffer

[2] In its October 20, 2021, filing, AstraZeneca cited to the preamble the final ADR Rule, 85 Fed. Reg. at 80,639, to support its assertion that it has 30 days from the date of appointment of the 340B ADR Panel to file a response. The regulation, 42 C.F.R. § 10.21(f), and the incorporated FRCP 12 plainly states the deadline as 21 days, and AstraZeneca has no basis for relying on commentary in the Federal Register rather than the applicable regulation in determining its deadline a time to respond.

any significant injury if this proceeding, pending for almost one year, moves forward.

When deciding whether to grant a stay, courts must "weigh competing interests and maintain an even balance, between the court's interests in judicial economy and any possible hardship to the parties." *Belize Soc. Dev. Ltd. v. Gov't of Belize*, 668 F.3d 724, 732-33 (D.C. Cir. 2012) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248 (1936)); *see also Ctr. for Biological Diversity*, 419 F. Supp. 3d at 20 ("A court's stay order 'must be supported by a balanced finding that such need overrides the injury to the party being stayed.'") (quoting *Belize Soc. Dev.*, 668 F.3d at 732). These competing interests are: (1) harm to the nonmoving party if a stay is issued; (2) harm to the moving party if a stay is not issued; and (3) whether a stay would promote efficient use of resources*." Ctr. for Biological Diversity*, 419 F. Supp. 3d at 20. In addition, "[t]he proponent of a stay bears the burden of establishing its need." *Id.* (quoting *Clinton v. Jones*, 520 U.S. 681, 708 (1997). AstraZeneca has not met its burden, and its motion should be denied.

I. Little Rivers Will Continue to Suffer Significant Harm if the ADR Panel Grants the Stay

In considering a motion to stay a proceeding, the first factor that should be considered is "the injury to the party being stayed." *Belize Soc. Dev.*, 668 F.3d at 732 (citations omitted). Little Rivers will suffer considerable injury to if this Panel grants a stay. As detailed below, AstraZeneca's unlawful overcharges have has significantly impacted Little Rivers's ability to provide services to patients. Little Rivers should not be forced to endure any further delays to these ADR proceedings, after it and other covered entities have waited for years for an ADR process to be implemented and Little Rivers has waited almost one year for a substantive response to its petition from AstraZeneca. The ADR process is the only formal proceeding in which Little Rivers can make its case for damages and because Little Rivers is not a party to

other court cases that AstraZeneca alleges will impact this proceeding, there is no guarantee that its interests will be fully represented in those proceedings.

First, Little Rivers and its patients have suffered injury since AstraZeneca implemented its contract pharmacy policy in October 2020 and will continue to suffer injuries if these ADR proceedings, initiated in February 2020, are delayed any longer. AstraZeneca's policies deprive Little Rivers of savings that allow it to carry out the purposes of the 340B program, which is to allow covered entities to "stretch scarce Federal resources as far as possible." H.R. Rep. No. 102-384, pt. II (Sept. 22, 1992). AstraZeneca's policies not only impact Little Rivers financially, they also impact Little Rivers's patients. Little Rivers uses savings from 340B drugs to help to pay for the health care and related services that it provides to patients that are not funded in whole or part by grants or insurance, which furthers its mission to provide respectful, comprehensive primary health care for all residents in its region, regardless of their ability to pay. Little Rivers Health Care, About, https://www.littlerivers.org/about (last visited Jan. 24, 2022); Pet. ¶ 11. Additionally, Little Rivers offers a sliding fee scale to patients whose incomes are under 200% of the Federal Poverty Level. Pet. ¶ 16. This discount includes access to prescription drugs through the 340B program when they receive a prescription as the result of health care services provided by Little Rivers. Because the 340B discounted price, however, is significantly lower than non-340B prices, patients that relied on obtaining medications at the 340B cost now have to pay much higher prices for their drugs. As the result of AstraZeneca's refusal to sell drugs through the 340B wholesaler accounts associated with contract pharmacies, Little Rivers and its patients will continue to incur damages as long as AstraZeneca's unlawful policy is in place.

Second, AstraZeneca is requesting an indeterminate stay pending three matters that may take years to resolve. The Supreme Court has held that stays for such lengthy periods are

improper. *See Landis,* 299 U.S. at 257 (finding that a stay pending a parallel appeal could last a year or more and was therefore "immoderate and hence unlawful.") The stay that AstraZeneca has requested is "immoderate" and should be denied.

AstraZeneca asks the ADR Panel to stay these proceedings pending resolution of AstraZeneca's lawsuit against HHS challenging HHS' contract pharmacy policies and PhRMA's lawsuit against HHS challenging the legality of the ADR regulations. It is entirely likely, however, that those lawsuits will not be resolved for several years. In the other lawsuits filed by manufacturers related to the contract pharmacy issue, the district court decisions have already been appealed and cross-appealed.[3] AstraZeneca's lawsuit and PhRMA's lawsuit will undoubtedly follow the same path and it will likely be years before a final decision is reached in the federal courts.

Properly promulgated ADR regulations are in place now, and this proceeding should not be stayed based on hypothetical future actions by courts or HHS. Moreover, there is no guarantee that the revised ADR regulations that HHS plans to issue will be proposed or adopted promptly. The last ADR notice-and-comment period took over ten years to complete. Little Rivers should not be asked to wait until this subsequent rulemaking process, which may not have any bearing on the current ADR proceedings, is completed.

Little Rivers and other 340B covered entities waited years for HHS to adopt ADR regulations and were forced to file a lawsuit to prompt HHS to issue those regulations after AstraZeneca implemented its illegal contract pharmacy policies. Little Rivers has waited since October 2020 for relief from AstraZeneca's refusal to provide statutorily required 340B discounts on drugs shipped to contract pharmacies. Little Rivers filed its petition in these proceedings almost one year ago and waited approximately eight months before AstraZeneca

[3] *See, e.g., Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind. Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-634 (D.N.J. Jan. 12, 2021).

acknowledged service of the petition and even then, AstraZeneca asked for additional time to respond.[4] Little Rivers should not have to continue to wait on the sideline while the parties in other lawsuits pursue years of federal appeals and while HHS proceeds with the notice-and-comment process on revised ADR regulations.

Third, this ADR process is the only proceeding by which Little Rivers can clearly obtain monetary redress from AstraZeneca's contract pharmacy policy. Federal courts have denied stays based on the outcome of other litigation when the relief requested differed between jurisdictions. *See I.J.A., Inc. v. Marine Holdings, Ltd., Inc.,* 524 F.Supp. 197, 199 (E.D. Pa.1981) (stay denied where foreign litigation was in its incipiency and the range of requested relief differed in scope); *Christ v. Cormick*, 2007 WL 2022053, at *8 (risk of inadequate relief warranted denial of stay). AstraZeneca incorrectly implies in its Motion that Little Rivers has *not* requested monetary relief through this proceeding. Astra Mot. at 18 ("Petitioner has asked the ADR panel to issue declaratory and injunctive relief. *See* Pet. p. 23 (Relief Requested).") AstraZeneca's statement is entirely inaccurate. Little Rivers requests, "[a]n order directing Respondent to pay to Petitioner any 340B discounts that Respondent has withheld from Petitioner for covered outpatient drugs distributed through contract pharmacies since October 1, 2020." *See* Pet. p. 23 (Relief Requested, No. 3)). Little Rivers's claim for damages is entirely clear.

Moreover, AstraZeneca alleges in its Motion that "HRSA and HHS have disclaimed any authority to issue judgments for money damages," citing to pleadings filed by HHS in the *Sanofi-Aventis* case. Astra Mot. at 18-19. But, AstraZeneca entirely misconstrues the statements made by HHS in that pleading by neglecting to add that HHS stated that the ADR Panel has the authority to

[4] This delay by AstraZeneca in substantively responding to Little Rivers's petition, effectively prejudices Little Rivers's ability to litigate this matter effectively. *Cf. Cintec Int'l Ltd. v. Parkes,* 468 F. Supp. 2d 77, 79 (D.D.C. 2006) (finding plaintiffs were prejudiced by "willful delays of the defendant").

make recommendations to HHS for appropriate actions, including refunds (citing to 40 C.F.R. § 10.24(e)). *Sanofi-Aventis*, No. 3:21-cv-634 (D.N.J. April 19, 2021), ECF No. 62-1 at 49.

Through the ADR process, therefore, Little Rivers has sought damages resulting from AstraZeneca's refusal to offer the 340B ceiling price for covered outpatient drugs distributed through Little Rivers's contract pharmacies. Pet. ¶ 8. Little Rivers submitted an estimate of the damages caused by AstraZeneca's illegal policy that shows that it is losing approximately $36,070.20 during a representative annualized period. Pet. ¶ 8 (Little Rivers Preliminary Damages Calculation to Establish Jurisdiction). This ADR proceeding is the sole forum in which Little Rivers can directly challenge and remedy AstraZeneca's overcharges. *See Astra USA*, 563 U.S. at 121–22 (2011). The damages sought by Little Rivers cannot be granted in in the collateral federal litigation cited to in AstraZeneca's motion because there is no reasonable possibility that Little Rivers will be granted damages except through these ADR proceedings. *See Landis*, 299 U.S. at 255 ("Some courts have stated broadly that, irrespective of particular conditions, there is no power by a stay to compel an unwilling litigant to wait upon the outcome of a controversy to which he is a stranger. *Dolbeer v. Stout*, 139 N.Y. 486, 489, 34 N.E. 1102; *Rosenberg v. Slotchin*, 181 App.Div. 137, 138, 168 N.Y.S. 101; *cf. Wadleigh v. Veazie*, Fed. Cas. No. 17,031; *Checker Cab Mfg. Co. v. Checker Taxi Co.* (D.C.) 26 F.(2d) 752; *Jefferson Standard Life Ins. Co. v. Keeton* (C.C.A.) 292 F. 53.") Accordingly, AstraZeneca's request for a stay should be denied.

Lastly, Little Rivers would suffer injury from a stay pending the outcome of other litigation because Little Rivers is not a party to that litigation and therefore cannot ensure that its positions will be fully and accurately presented in those actions. *See Landis*, 299 U.S. at 255 ("Only in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both.") Little Rivers should

not have to sit by while AstraZeneca and PhRMA litigate their positions in federal court without an opportunity to present its position.

II. AstraZeneca Has Not Demonstrated Clear Hardship or Inequity to Support Its Request for a Stay

In order to support a stay, the movant must "make out a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255. AstraZeneca has not met its burden to show that it will suffer hardship if the ADR Panel denies the stay. AstraZeneca will not suffer any cognizable harm by having to defend itself in this proceeding, and any harm that would come to AstraZeneca from having to answer the Petition on this case is self-imposed.

AstraZeneca asserts that in an absence of a stay, it will be harmed by a wasteful and costly "duplication of efforts" Astra Mot. at 14; *see also* id. at 15. Being required to defend a suit, without more, does not constitute a "clear case of hardship or inequity." *Lockyer v. Mirant Corp.*, 398 F.3d 1098, 1112 (9th Cir. 2005) (quoting *Landis*, 299 U.S. at 255); *see also Commodity Futures Trading Comm'n v. Chilcott Portfolio Mgmt., Inc.*, 713 F.2d 1477, 1485 (10th Cir. 1983) ("the consideration of judicial economy. . . should rarely if ever lead to such broad curtailment of the access to the courts [by way of stay of proceedings]."); *GFL Advantage Fund, Ltd. v. Colkitt*, 216 F.R.D. 189, 193 (D.D.C. 2003) ("[T]he interests of efficiency and judicial economy . . . [do not] establish a 'clear case of hardship' [under Landis].").

As AstraZeneca states in its Motion, dispositive motions in its lawsuit against HHS have been filed. Astra Mot. at 8, 11. AstraZeneca states that this proceeding addresses "precisely the same legal issue" that is being considered in *AstraZeneca Pharmaceuticals L.P. v. Becerra*, No. 1:21-cv-00027 (D. Del.). Astra Mot. at 19. Accordingly, AstraZeneca has briefed this issue for a federal district court and should be well prepared to respond to the petition filed by Little Rivers almost one year ago. AstraZeneca had more than ample time to draft a substantive response to

Little Rivers's petition. Hence, any harm that would befall AstraZeneca from having to answer the Petition on this case is self-imposed by AstraZeneca's delaying tactics.

The AstraZeneca's arguments regarding its need for a stay do not demonstrate the requisite showing of clear hardship or inequity. Little Rivers's injuries due to lack of access to 340B pricing at contract pharmacies clearly outweigh any purported injury to AstraZeneca in having to participate in these proceedings. AstraZeneca's motion should be denied because its reasons to request a stay do not "override the injury to the party being stayed." *Belize Soc. Dev.*, 668 F.3d at 732 (quoting *Dellinger*, 442 F.2d at 787).

III. AstraZeneca's Claims of Judicial Economy Are Speculative

A stay would not promote efficient use of resources. *Ctr. for Biological Diversity*, 419 F. Supp. 3d at 20. AstraZeneca's arguments for a stay rests almost entirely on the premise that a stay would support interests of economy and efficiency, but AstraZeneca merely speculates that a stay would create any economies or efficiencies and, in some cases, the AstraZeneca's arguments are based on incorrect assumptions.

AstraZeneca argues that an order denying a stay pending the outcome of its case against HHS regarding HHS's contract pharmacy policy "will *likely* lead to needless disruption and duplication of efforts." Astra Mot. at 13 (emphasis added). Significantly, AstraZeneca cannot assure that its requested stay will avoid any disruptions or duplication of efforts.

AstraZeneca also argues that a stay would show that the ADR Panel defers to the federal courts in their area of competency and that "interpretation of the 340B statute is a pure question of statutory construction that falls squarely within the bailiwick of the Judiciary." Astra Mot. at 13. AstraZeneca's assertion is wholly incorrect. Congress mandated 340B ADR proceedings to adjudicate disputes between 340B covered entities and manufacturers, and empowered this Panel to render a "final agency decision" that "shall be binding upon the parties involved, unless

invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C). Congress therefore put this matter within the Panel's "bailiwick" in the first instance with its decision to be reviewed later by a court. The ADR Panel, consisting of representatives of HRSA, the Centers for Medicare and Medicaid Services and the HHS Office of Inspector General, is completely competent to interpret the 340B statute. Indeed, courts generally defer to federal agency interpretations of statutes under the agency's oversight. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). In addition, either party to an ADR proceeding is entitled to judicial review of the ADR decision. 10 C.F.R. § 10.24(d). Assuming, for purposes of argument, that a court has any greater competency than the ADR Panel to interpret the 340B statute, there is an opportunity for a court to review the ADR Panel's interpretation.

AstraZeneca also relies on PhRMA's challenge to the ADR regulations to support its case for a stay (*see* Astra Mot. at 15-17), but even AstraZeneca concedes that the U.S. District Court for the District of New Jersey recently issued an opinion rejecting manufacturer Sanofi's claims that the ADR rule is legally invalid. *Sanofi-Aventis*, No. 3:21-cv-634 (D.N.J. Nov. 5, 2021), ECF No. 110. And while the Southern District of Indiana preliminary granted a motion against any ADR proceedings against Eli Lilly, that court has not issued a final decision on the legality of the ADR regulations. *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind. Oct. 29, 2021), ECF No. 144 ("Accordingly, we do not address the ADR Rule in this entry.") Therefore, the only *final* decision on the legality of the current ADR regulations is that those regulations are valid. AstraZeneca has no basis for its expectation that the regulations might be invalidated in the *PhRMA* lawsuit or in the final ruling in the *Eli Lilly* case. Indeed, AstraZeneca cannot dispute that ADR regulations are in place now, and this Panel has authority to decide this dispute.

AstraZeneca also argues that "it seems unlikely that the Panel even has the authority to rule

on the legality of the ADR Rule or the Panel's own constitutionality." Astra Mot. at 15. Petitioner has not asked the ADR Panel to rule on the legality of the ADR rule or the constitutionality of method by which the panel was appointed. If AstraZeneca plans to ask the ADR Panel to rule on those issues, it will have to file a cross-petition in this case. Notably, AstraZeneca did not include in its lawsuit against HHS a claim that the ADR regulations are illegal.

Lastly, AstraZeneca hypothesizes that the unpublished proposed rule to revise the current ADR regulations might impact the current proceedings. AstraZeneca acknowledges that "the details of the proposal are not yet public" (Astra Mot. at 17), thereby completely undermining the basis for a stay pending adoption of those regulations. The possibility that HRSA might one day adopt a new rule revising the current ADR regulations has no impact on AstraZeneca's responsibility to defend itself in the current proceeding. *See Ctr. for Biological Diversity*, 419 F. Supp. at 23 (denying a motion to stay by the National Marine Fisheries Services pending its promulgation of new conservation measures). Any filings that either Petitioner or AstraZeneca make in the current proceedings will certainly be pertinent under any (again, speculative) new ADR procedures.

Conclusion

For the foregoing reasons, the ADR Panel should deny AstraZeneca's motion to stay these proceedings and should direct AstraZeneca to respond substantively to Little Rivers's petition.

Respectfully submitted,

Barbara Straub Williams
Ronald S. Connelly
POWERS PYLES SUTTER & VERVILLE, PC

1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 872-6733
Fax (202) 785-1756
Barbara.Williams@PowersLaw.com
Ron.Connelly@PowersLaw.com

Attorneys for Petitioner

Dated: January 24, 2022

CERTIFICATE OF SERVICE

I hereby certify that on January 24th, 2022, I uploaded the forgoing motion to HRSA's secure workspace for this matter, and emailed a copy to:

The Office of Pharmacy Affairs
Health Resources and Services Administration
340BADR@hrsa.gov

Allon Kedem
Allon.Kedem@arnoldporter.com
Jeffrey L. Handwerker
Jeffrey.Handwerker@arnoldporter.com
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave, NW
Washington, DC 20001-3743

s/ Barbara Straub Williams
Barbara Straub Williams