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

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| RYAN WHITE CLINICS FOR 340B ACCESS, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>ALEX M. AZAR II, *et al.*,<br><br>Defendants. | No. 20-cv-2906 (KBJ) |

**DEFENDANTS' MOTION TO DISMISS FOR LACK OF JURISDICTION**

For the reasons set forth in the accompanying memorandum of law, Defendants respectfully move the Court to dismiss this action in its entirety for lack of jurisdiction, *see* Federal Rule of Civil Procedure 12(b)(1).

Dated: December 14, 2020

Respectfully submitted,

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**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

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Plaintiffs ask this Court to award final relief under the guise of a temporary restraining order to settle a dispute between private parties that, Plaintiffs readily admit, Congress committed to the Secretary of Health and Human Services for resolution in the first instance. This request is improper for multiple reasons, including that the Secretary has now established the administrative-dispute-resolution process that Plaintiffs sought to compel, and the Court cannot grant any additional relief. This suit must be dismissed.

Several pharmaceutical manufacturers acted in recent months to restrict access to drugs through a program, known as "the 340B program," that provides discounted medications to certain healthcare providers. Plaintiffs are a collection of healthcare providers that claim these changes are unlawful. Yet they admit not only that Congress delegated administration and enforcement of the 340B program to the Secretary of HHS, but also that the Supreme Court unequivocally has held that the statutory scheme prohibits private suits to enforce 340B requirements by intended beneficiaries like Plaintiffs. On the contrary, Congress instructed the Secretary to establish a mechanism to resolve 340B disputes within the agency, subject then to judicial review under the Administrative Procedure Act. Although the Secretary missed a statutory deadline to fulfill that mandate, the dispute-resolution process now has been created and will be operational before briefing on this motion is complete. Rather than avail themselves of this process, Plaintiffs instead ask this Court to resolve in their favor the dispute against drug companies that Plaintiffs admit should be brought before the agency. Their request would effect an end-run around binding precedent establishing the non-justiciability of suits by private parties to enforce 340B requirements, and lacks any basis for subject-matter jurisdiction to boot. Plaintiffs' complaint should be dismissed in its entirety, and their request for emergency relief denied.

# BACKGROUND

## I. STATUTORY AND REGULATORY BACKGROUND

In 1992 Congress created a program, administered by the Secretary of Health and Human Services ("HHS"), through which certain hospitals, community health centers, and other federally funded entities (known as "covered entities") serving low-income patients could receive drug discounts. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992), *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). Those discounted drugs both benefit patients, by helping them to afford costly medications, and covered entities, which use the discounts to stretch scarce federal resources and serve a greater number of uninsured and under-insured patients. Drug manufacturers must participate in this drug-discount scheme, known as the 340B Program, in order to have their drugs covered through Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a).

Congress acted to strengthen and amend the 340B Program as part of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), by, *inter alia*, adding new provisions to "improv[e] … program integrity" related to manufacturer and covered-entity compliance, including the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary issued a regulation allowing the imposition of monetary penalties, including up to $5,000 for each knowing and intentional instance of overcharging by a drug manufacturer. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017), *codified at* 42 C.F.R. § 10.11(a).

Relatedly, the ACA instructs the Secretary to establish a 340B Program administrative dispute-resolution process ("ADR process") for covered entities and manufacturers:

> Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers … of violations [of provisions prohibiting diversion of drugs and duplicate discounts], including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described [in the Act].

42 U.S.C. § 256b(d)(3)(A). The Secretary began to establish that process several months later by issuing an advanced notice of proposed rulemaking to request comments on the development of an ADR process. *See* 75 Fed. Reg. 57,233, Sep. 20, 2010. The agency received only about a dozen comments in response. *See* 81 Fed. Reg. 53,381, 53,382 (Aug. 12, 2016) (noting receipt of 14 comments). That notice was then followed by a Notice of Proposed Rulemaking ("NPRM"), which included proposed ADR regulations establishing a panel within the agency to adjudicate disputes between drug manufacturers and covered entities. *See* 81 Fed. Reg. 53,381 (Aug. 12, 2016). The agency received 31 public comments on that proposal. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (to be codified at 42 C.F.R. pt. 10).

HHS resumed its work on the 340B ADR rule earlier this year, with the goal of expeditiously establishing a comprehensive dispute-resolution process. In drafting the final rule, it considered the comments received on the 2016 NPRM and adjusted its proposal in response to several comments.

The final ADR rule was published in the Federal Register on December 14, 2020. *See* 85 Fed. Reg. 80,632. Once the rule takes effect on January 13, 2021, both covered entities and drug manufacturers will have a mechanism to resolve before the agency disputes arising under the 340B program, including "[c]laims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers." *Id.* at

80,644. Those claims will be heard by a "340B ADR Panel," a decision-making body within the Department that, "acting on an express, written delegation of authority from the Secretary of HHS, reviews and makes a precedential and binding decision." *Id.* ADR panels will consist of members selected by the Secretary from HRSA, the Centers for Medicare and Medicaid Services, and HHS's Office of General Counsel (plus a non-voting member from the Office of Pharmacy Affairs), ensuring that each panel has "relevant expertise and experience in drug pricing or drug distribution" and "in handling complex litigation." *Id.* Importantly, the agency process explicitly is governed by the Federal Rules of Civil Procedure, including the deadlines and procedural mechanisms established therein, and claims may be brought "for monetary damages or equitable relief." *Id*. Panel decisions are subject to judicial review under the APA. *Id.* at 80,641.

## II. *ASTRA USA, INC. V. SANTA CLARA COUNTY, CALIFORNIA*

The Supreme Court addressed the justiciability of federal suits by covered entities seeking to enforce 340B requirements in *Astra USA, Inc. v. Santa Clara County, California*, 563 U.S. 110 (2011). In *Astra*, a collection of covered entities had sued drug manufacturers for purported overcharges on 340B-covered drugs. Both sides "conceded that Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling." 563 U.S. at 113. Unable to sue the drugmakers directly under the 340B statute, the covered entities pursued a different theory: That they, as third-party beneficiaries of contracts between HHS and pharmaceutical companies, could claim a breach of contract.

The Court rejected as "incompatible with the statutory regime" the covered entities' efforts to sue to enforce 340B requirements, regardless of the legal theory on which they based their claim. *Astra*, 563 U.S. at 113. The Court held that "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at

117. Although plaintiffs there focused on the contractual provisions agreed to by drug manufacturers to access the Medicaid and Medicare Part B programs, the Court explained that the legal theory mattered not, in light of the evident "incompatibility of private suits with the statute Congress enacted." *Id.* at 121; *see also id.* at 120 ("Far from assisting HHS, suits by 340B entities would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis," and create a "substantial" "risk of conflicting adjudications").

Finally, the Court noted that Congress had responded to reports of inadequate 340B oversight and enforcement, not by authorizing private suits by covered entities, but instead by providing for the establishment of an ADR process within the agency. *Astra*, 563 U.S. at 121-22, *citing* 42 U.S.C. § 256b(d). "Congress thus opted to strengthen and formalize" the agency's enforcement, the Court found, "to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,'" with the agency's resolution of ADR complaints subject to review under the Administrative Procedure Act ("APA"). *Astra*, 563 U.S. at 121-22.

## III. THIS LAWSUIT

Plaintiffs, several covered entities and an association of the same (hereinafter "Covered Entities"), now sue HHS, its Secretary, the Health Resources and Services Administration ("HRSA," a component of HHS to which implementation of the 340B program has been delegated), and its Administrator (hereinafter collectively "the Agency" or "the Secretary"). The Covered Entities challenge the Secretary's delay in promulgating the 340B ADR rule and claim

imminent, irreparable harm from the fact that the process is not yet operational. *See* Am. Compl., ¶ 125, ECF No. 21 ("Compl.").[1]

The renewed attention on an agency dispute-resolution process was prompted, according to the Covered Entities, by recent changes in several pharmaceutical manufacturers' participation in the 340B program. Many covered entities do not (or cannot, in a cost-effective manner) operate in-house pharmacies, according to the complaint, and thus for decades have participated in the 340B program through "contract pharmacies" which, as agents of the covered entity, receive and dispense discounted drugs to uninsured and under-insured patients. Am. Compl. ¶¶ 39-54. The Covered Entities allege that, despite their longstanding reliance on contract-pharmacy arrangements, four drug manufacturers recently acted in various ways to restrict access to discounted drugs through 340B for healthcare providers utilizing outside dispensers. *Id.* ¶¶ 55-68. And the inability to use contract pharmacies as Congress and the agency envisioned, the Covered Entities allege, will force them to scale back or eliminate healthcare services during the current public-health crisis. *Id.* ¶¶ 1-5.

The Covered Entities seek to "compel agency action unlawfully withheld or unreasonably delayed" under the APA, citing the ACA's directive that the Secretary issue an ADR rule by late 2010. Compl. ¶¶ 127-28 (citing 5 U.S.C. § 706(1) and 42 U.S.C. § 256b(d)(3)). But they also bring several additional claims that seek relief much broader than issuance of an ADR rule. The Covered Entities plead a claim for mandamus seeking "an order from this Court directing the Secretary to order pharmaceutical manufacturers … to sell drugs to the Plaintiff Covered Entities at 340B discounts when purchased through contract pharmacies," and "to establish procedures enabling the Plaintiff[s] [] to secure refunds from manufacturers." *Id.* ¶ 134-35. The Covered Entities also

[1] As noted above, the ADR rule the Covered Entities' complaint seeks to compel was recently finalized, and will become effective on January 13, 2020. 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020).

bring a Declaratory Judgment Act claim seeking a pronouncement from this Court to settle their underlying dispute with the drug companies: "[T]hat they are entitled to purchase and dispense drugs at 340B discounts through arrangements with contract pharmacies." *Id.* ¶ 112. Finally, they allege a procedural-due-process violation premised on the agency's "fail[ure] to implement ADR as Congress mandated … and [] fail[ure] to take action on its own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements." *Id.* ¶ 123.

Forty-five days after commencing suit, the Covered Entities sought emergency relief from this Court. *See* Mem. in Supp. of Mot. for TRO/PI, ECF No. 24-1, ("TRO/PI"). In their request for a temporary restraining order or preliminary injunction, the Covered Entities acknowledge that they "cannot vindicate their rights to contract pharmacy arrangements by an action directly against the Drug Companies because 340B covered entities do not have a private right of action against the Drug Companies." *Id.* 43-44 (citing *Astra*, 563 U.S. at 113-14). And they admit that the contract-pharmacy dispute belongs in the ADR process. *Id.* 43 ("If the Secretary had implemented ADR ten years ago … the Covered Entities could have challenged the Drug Companies' actions as soon as July 1, 2020 … [but due to the Rule's recent issuance] [t]he soonest that the Covered Entities could reasonably expect relief through ADR would be mid-2021."). Because, they claim, "[t]he Covered Entities and their patients simply cannot wait that long," *id.* 43, they urge the Court to resolve their dispute with the drug manufacturers through injunctions directed—not to the manufacturers—but to the Secretary.

To that end, the Covered Entities' request for emergency relief first seeks an order compelling agency action, 5 U.S.C. § 706(1), and a writ of mandamus, 28 U.S.C. § 1361, directing the Secretary to fulfill within 60 days "a clear, nondiscretionary duty to promulgate ADR regulations." TRO/PI 20-22. Their requested relief goes far beyond the institution of an ADR

process, however. The Covered Entities also ask the Court to declare "that 340B covered entities are entitled to purchase covered outpatient drugs at 340B discounts from contract pharmacies" and portray that decree as "uncontroversial because the Secretary *agrees* with the Covered Entities" on the issue. *Id.* 42-44. And the Covered Entities further implore the Court to issue an affirmative injunction instructing the Secretary to exercise his enforcement authority. *Id.* 44-45. Specifically, the Covered Entities insist that, to "ensure that the Covered Entities can purchase 340B discounted drugs through contract pharmacy arrangements," "the Court should order the Secretary to take appropriate steps," such as "order[ing] the Drug Companies to honor contract pharmacy arrangements," "impos[ing] [civil monetary penalties]" upon the Drug Companies," or even "excluding them from participation in Medicaid and Medicare Part B." *Id.* Stated plainly, the Covered Entities ask this Court to decide the ultimate merits of their dispute against several drug manufacturers that, the Covered Entities concede, Congress intended to commit for resolution before the agency ADR process.

## STANDARD OF REVIEW

The Secretary moves to dismiss this case for lack of subject-matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1). Plaintiffs bear the burden to show subject-matter jurisdiction, and the Court must determine whether it has jurisdiction before addressing the merits. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998). In deciding a motion brought under Rule 12(b)(1), the court need not limit itself to the allegations in the complaint. *See Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Rather, the "court may consider such materials outside the pleadings as it deems appropriate to resolve the question

whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000); *see Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987).[2]

The Secretary also opposes the Covered Entities' motion for preliminary injunctive relief. "A preliminary injunction is an extraordinary and drastic remedy." *Munaf v. Geren*, 553 U.S. 674, 689 (2008) (citation omitted). It is "never awarded as of right," *id.* at 690, and "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion," *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted). The movant must satisfy a four-prong test, establishing "that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

## ARGUMENT

As the Covered Entities repeatedly admit, under unmistakable Supreme Court precedent, they "are wholly reliant upon the Secretary to vindicate their rights," TRO at 3, because "Congress [] opted to … make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements." *Astra*, 563 U.S. 121-22; *see also* TRO at 3-4 ("340B covered entities cannot sue drug companies for violating 340B requirements"). That ADR process now has been created and will be operational before briefing on this motion to dismiss is complete. The Covered Entities must bring their claims against the pharmaceutical companies for resolution in the ADR process in the first instance; through that mechanism, a panel of experts appointed by the Secretary will issue a binding decision

[2] Should the Court determine that any of the threshold grounds presented here for dismissal are not jurisdictional, Defendants also move to dismiss under Federal Rule of Civil Procedure 12(b)(6), which authorizes a court to dismiss a claim on the basis of a dispositive issue of law. *Neitzke v. Williams*, 490 U.S. 319, 326 (1989). To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must contain sufficient factual allegations, accepted as true, to state a claim for relief that is "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). While a court must treat the complaint's factual allegations as true, it need not accept as true legal conclusions set forth in a complaint. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

resolving the contract-pharmacy dispute that then may, if necessary, be reviewed by a federal court. There is no jurisdictional basis for the Covered Entities to leapfrog that process and seek ultimate resolution from this Court of their "complain[t] of overcharges and other violations" of 340B requirements, *Astra*, 563 U.S. at 122. At bottom, the Covered Entities' requests for declaratory and injunctive relief all run afoul of *Astra* because they seek to achieve that which the Supreme Court has forbidden—private enforcement of 340B requirements—through a suit nominally against the Secretary but presenting a dispute with drugmakers. As demonstrated below, the Covered Entities' claim to compel creation of an ADR process is moot and this Court lacks jurisdiction to award any other relief. This suit must be dismissed in its entirety.

## I. This Court Lacks Subject-Matter Jurisdiction Over All of the Covered Entities' Claims.

### A. The Covered Entities' claims to compel issuance of an ADR rule are moot.

The Covered Entities assert several claims seeking to compel the issuance of a regulation that recently was finalized and published in the Federal Register and soon will go into effect. *See* TRO/PI at 41-42; Compl. ¶¶ 126-31 (pleading claim for relief under 5 U.S.C. § 706(1)); ¶¶ 119-25 (claiming that failure to timely establish ADR process violates due process); ¶¶ 132-35 (requesting writ of mandamus). Notwithstanding the Covered Entities' complaints that the rule is tardy, they now have received all the relief to which they possibly could be entitled on this claim. The claim therefore is moot.

Under Article III of the Constitution, federal courts are courts of limited jurisdiction that can only decide "actual, ongoing controversies." *Clarke v. United States*, 915 F.2d 699, 700-01 (D.C. Cir. 1990) (en banc) (quoting *Honig v. Doe*, 484 U.S. 305, 317 (1988)). Even if an action poses a live controversy when filed, the mootness doctrine requires "a federal court to refrain from deciding it if events have so transpired that the decision will neither presently affect the parties'

rights nor have a more-than-speculative chance of affecting them in the future." *Id.* at 701 (quotation omitted).

The Covered Entities' requests for "a writ of mandamus and an injunction on [sic] the APA ordering the Secretary to issue ADR regulations within 60 days," TRO/PI at 22, are moot because the Secretary has done so. As detailed above, *supra* Background § I, the Secretary published on December 14, 2020, a final rule establishing the ADR process envisioned in the ACA, *see* 42 U.S.C. § 256b(d)(3), and that process will take effect in 30 days.

The caselaw is clear: A claim seeking to compel agency action is rendered moot when the agency has taken or takes the action requested in the complaint. *See, e.g.*, *Karst Envtl. Educ. & Prot., Inc. v. EPA*, 475 F.3d 1291, 1298-99 (D.C. Cir 2007) (dismissing claim as "moot *when filed*" where agency had completed action before complaint was filed); *Gray v. Office of Personnel Mgmt.*, 771 F.2d 1504, 1514 (D.C. Cir. 1985) (concluding that petition to compel agency decision became moot when agency rendered its decision); *Doe v. Doe Agency*, 608 F. Supp. 2d 68, 71-72 (D.D.C. 2009) (dismissing action to compel agency to complete classification review as moot where agency had completed review); *Boening v. CIA*, 579 F. Supp. 2d 166, 172 (D.D.C. 2008) (concluding that claim to compel agency to adjudicate prepublication request within specified timeframe was mooted by final agency decision); *Stillman v. CIA*, 517 F. Supp. 2d 32, 36 (D.D.C. 2007) (same). Because the Covered Entities have now received the relief they requested—issuance of an ADR rule—and soon will be able to avail themselves of its dispute-resolution procedures, their claim should be dismissed as moot.[3]

[3] The Covered Entities' requests for additional forms of relief do not alter this analysis. As demonstrated *infra* §§ I.B, C, this Court lacks jurisdiction to award the requested injunctive relief, so Covered Entities may not rely on those requests to save their sole potentially viable claim from dismissal on mootness grounds. *See, e.g.*, *Weiner v. Klais & Co., Inc.*, 108 F.3d 86, 91 (6th Cir. 1997) ("With regard to … declaratory relief, plaintiff has merely asserted a form of relief, not a cause of action. Plaintiff is not entitled to this relief in the absence of a viable claim."); *Riley-Jackson v. Ocwen Loan Servicing, LLC*, 2013 WL 5676827, at *5 (E.D. Mich. Oct. 18, 2013) ("To the extent injunctive relief

The Covered Entities' procedural due-process claim also is moot to the extent it is premised on the Secretary's "fail[ure] to implement ADR as Congress mandated." Compl. ¶ 95. The Covered Entities ground this claim on the purported "depriv[ation] … of their property interest in the ADR cause of action." TRO/PI at 33. Because that cause of action—a complaint capable of adjudication before the agency, subject to APA review in federal court—is now available under the ADR, the Covered Entities' claim for violation of due process premised on the delay in issuance of an ADR rule also is moot.

**B. The Covered Entities' Declaratory Judgment Act claim should be dismissed.**

i. The Covered Entities have not pleaded any cause of action to support their request for declaratory relief.

The Covered Entities' complaint purports to plead a freestanding claim for relief under the Declaratory Judgment Act, 28 U.S.C. § 2201, *see* Compl. ¶¶ 111-18, to resolve the contract-pharmacy dispute that, Plaintiffs readily admit, cannot under Supreme Court precedent be decided in an action directly against the drug manufacturers. TRO/PI 3-4 ("The Covered Entities are wholly reliant upon the Secretary to vindicate their rights" because "covered entities cannot sue drug companies for violating 340B requirements"). The Covered Entities nonetheless seek to skirt that limitation by asking this Court to declare—through a supposedly *preliminary* motion—"that 340B covered entities are entitled to purchase covered outpatient drugs at 340B discounts from contract pharmacies." *Id.* 42-43.

Even putting aside the impropriety of granting the ultimate relief Plaintiffs seek through an emergency motion, *but see infra* § II, this Court must dismiss the Declaratory Judgment Act ("Act") claim because that statute does not create a substantive cause of action. Rather, the Act is

is requested as a remedy, as Plaintiff has failed to state a legally cognizable claim … , she has no underlying cause of action upon which a request for injunctive relief may be based.").

a procedural, enabling statute that does not itself confer jurisdiction. *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 199 (2014) (Courts have "long considered the operation of the Declaratory Judgment Act to be only procedural, leaving substantive rights unchanged."). Declaratory relief is thus available only where there exists a judicially remediable right and, to maintain such a suit, a plaintiff must point to a cause of action arising under some other law. *See Schilling v. Rogers*, 363 U.S. 666, 677 (1960); *see also Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950); *Severe Records, LLC v. Rich*, 658 F.3d 571, 580 (6th Cir. 2011) (court must determine "whether, absent the availability of declaratory relief, the instant case could nonetheless have been brought in federal court"). Stated plainly, a declaratory-judgment claim must be premised on some pre-existent right under federal law that itself confers jurisdiction. *Ali v. Rumsfeld*, 649 F.3d 762, 778 (D.C. Cir. 2011).

The Covered Entities make no attempt to ground their request for declaratory relief on a pre-existing, judicially remediable right that would provide either a basis for jurisdiction or a cause of action. On the contrary, the Covered Entities seek to enforce their ability to purchase drugs at discounted prices through the 340B program—a right for which "covered entities do not have a private right of action," TRO/PI 44, and that the Supreme Court explicitly has held is enforceable only by the Secretary. *See Astra*, 563 U.S. at 117 ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities"). In other words, the Covered Entities could not possibly bring this suit directly to enforce their right to discounted drugs, and cannot excuse the absence of a cause of action by purporting to sue under the Declaratory Judgment Act in a suit nominally against the Secretary instead.[4]

[4] In their motion the Covered Entities claim that *Astra*'s "holding that 340B covered entities cannot sue drug companies was based upon the Secretary's assurance that ADR regulations would be forthcoming." TRO/PI 4 (citing 563 U.S. at 116); *see also* TRO/PI 44 ("The Court's holding in *Astra* was premised on the Secretary's promise to issue ADR regulations.") This is a misreading of the precedent. *Astra*'s holding is unequivocal in its basis in the text of the

The Covered Entities cannot identify any other cause of action that would permit the Court to opine on what the 340B statute requires. Although their argument in support of declaratory relief makes passing reference to "the constitutional violation" (without explicit mention of due process), *see* TRO/PI 43, their due-process claim is premised on the belated issuance of an ADR regulation—*i.e.*, the denial of a Congressionally created cause of action, and that issue now has been remedied. Nor can the Covered Entities invoke the APA as either the cause of action or jurisdictional basis for their Declaratory Judgment Act claim. That is because the Declaratory Judgment Act cannot be used to circumvent the normal administrative process by asking a court to opine on a statute's meaning absent a cognizable APA claim. "A judicial declaration telling [the defendant] how to interpret the [statute] would constitute an end-run around Congress's clear intent that the [agency] interpret and enforce the [statute] in the first instance. *Schilling* teaches that the Declaratory Judgment Act does not authorize such a result." *C&E Servs., Inc. v. D.C. Water and Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002). The Covered Entities' sole potentially cognizable APA claim seeks to compel the overdue issuance of an ADR rule (a matter the Secretary now has remedied), and the APA does not permit a general suit asking a court to express its view on a statute, untethered from a final agency action amenable to judicial review. *See id.*; 5 U.S.C. § 706. Indeed, that result would usurp the authority Congress granted to the Secretary.

ii. There is no case or controversy between the parties.

*Even if* the Covered Entities could plead an independent cause of action sufficient to seek relief under the Declaratory Judgment Act, their request still would fail to present an actual controversy. "Article III, § 2, of the [United States] Constitution extends the 'judicial Power' of

ACA, and its only mention of the ADR process recounts that the ACA "directs the Secretary to develop formal procedures for resolving overcharge claims" and, "[u]nder those procedures, which are not yet in place, HRSA will reach an 'administrative resolution' that is subject to judicial review" under the APA. 563 U.S. at 116.

the United States only to 'Cases' and 'Controversies.'" *Steel Co.*, 523 U.S. at 102. "No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006) (citation omitted). "As used in the Constitution, those words do not include every sort of dispute, but only those 'historically viewed as capable of resolution through the judicial process.'" *Hollingsworth v. Perry*, 570 U.S. 693, 700 (2013) (citation omitted). Thus Article III restricts the authority of federal courts to resolve only those disputes that involve the "determin[ation] [of] rights of persons or of property which are actually controverted in the particular case before it." *California v. San Pablo & Tulare R.R. Co.*, 149 U.S. 308, 314 (1893). "This is a 'bedrock requirement."' *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (citation omitted).

Nor is it "enough that the party invoking the power of the court ha[s] a keen interest in the issue." *Hollingsworth*, 570 U.S. at 700; *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Indeed, to review such cases "would be inimical to the Constitution's democratic character" and would weaken "the public's confidence in an unelected but restrained Federal Judiciary." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133 (2011).

Similarly, "[t]he Declaratory Judgment Act provides that, 'in a case of actual controversy within its jurisdiction … any court of the United States may declare the rights and other legal relations of any interested party seeking such declaration[.]'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007) (quoting 28 U.S.C. § 2201(a)). For purposes of a declaratory-judgment action, an "actual controversy" exists only where "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 127 (citation omitted).

It is difficult to imagine a more-quintessential example of an advisory opinion than a declaration confirming a legal principle on which the Covered Entities plead agreement between the parties. The Covered Entities allege that the "Secretary *agrees* with the Covered Entities that the 340B statute entitles covered entities to purchase 340B drugs via contract pharmacy arrangements[.]" TRO/PI 44. In fact, they include copious citations to past statements of the agency's position, *id.* 3, 8-11, and do not allege that the agency has changed its views. The Covered Entities cannot obtain a declaration resolving their contract-pharmacy dispute against the drugmakers via a declaratory-judgment claim against the Secretary because they have not pleaded an actual controversy between the parties regarding the proper interpretation of the 340B program requirements.[5] With no asserted dispute between the parties, there is nothing for this Court to declare. "The declaratory judgment procedure is available in the federal courts only in cases involving an actual case or controversy … and it may not be made the medium for securing an advisory opinion in a controversy which has not arisen" between the parties to the suit. *Coffman v. Breeze Corp.*, 323 U.S. 316, 324 (1945).

### C. This Court lacks jurisdiction to award any other relief requested in the Complaint or preliminary injunction motion.

As explained above, the Secretary's issuance of the ADR rule provides the Covered Entities the full relief to which they could be entitled under their claim to compel unreasonably delayed agency action, 5 U.S.C. § 706(1). Although they urge this Court to grant sweeping additional declaratory and injunctive relief, this Court lacks subject-matter jurisdiction to issue

[5] The fact that at least three of the pharmaceutical manufacturers alleged to have harmed Plaintiffs are seeking to intervene in this action demonstrates that, far from a justiciable suit against HHS and its Secretary, this matter is a dispute between private parties over a question of statutory interpretation that must be resolved, in the first instance, by the agency's ADR process. *See* ECF No. 12, Eli Lilly Mot. to Intervene; ECF No. 13, Sanofi-Aventis Mot. to Intervene; ECF No. 29, Astra-Zeneca Mot. to Intervene. Resolving the contract-pharmacy dispute at this stage would unnecessarily mire this Court in factual and legal disputes that should be resolved, in the first instance, through the ADR process.

either. Because Plaintiffs are not entitled to anything more, the complaint must be dismissed.

i. The requested injunctive relief would invade the presumptively unreviewable realm of prosecutorial discretion.

The Covered Entities press for injunctive relief that would run afoul of Supreme Court precedent constraining a court's ability to proscribe an agency's exercise of enforcement discretion. The Covered Entities urge this Court to direct the Secretary's administration and enforcement of the 340B program, including taking specific "actions to bring the Drug Companies in line," such as instructing the Secretary to "order the Drug Companies to honor contract pharmacy arrangements," "impose [civil monetary penalties] upon" them, or "exclud[e] them from participation in Medicaid and Medicare Part B." TRO/PI 44-45. Whether analyzed under the rubric of procedural due process or the APA, Compl. ¶¶ 119-31, this Court lacks authority to enjoin the Secretary to take specific enforcement actions against pharmaceutical manufacturers. To the extent the Covered Entities' due-process and APA claims seek relief beyond the (now moot) issuance of an ADR rule, they are not redressable and thus must be dismissed.

In another suit—like this one—seeking to compel the Secretary of HHS to take specific enforcement actions, the Supreme Court unequivocally held that exercises of prosecutorial discretion are presumptively unreviewable. *Heckler v. Chaney*, 470 U.S. 821, 832 (1985). Plaintiffs there challenged an agency decision to refuse to enforce alleged violations within HHS's jurisdiction and brought suit seeking—like here—"various investigatory and enforcement actions to prevent these perceived violations," including "statements to the drug manufacturers" regarding usage of certain drugs and "recommend[ing] the prosecution of all those" who knowingly violated the regulatory scheme. *Id.* 823-24. The Supreme Court rejected that attempt to force the agency's hand, ruling that the decision whether to bring an enforcement action is the paradigmatic example of presumptively unreviewable action committed to agency discretion by law, 5 U.S.C.

§ 701(a)(2). *Heckler*, 470 U.S. at 828-33. Indeed, the "Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," "attributable in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement." *Id.* at 831. Absent a command from Congress directing how an agency will exercise its enforcement authority, "an agency refusal to institute proceedings is a decision 'committed to agency discretion by law' within the meaning of [the APA]." *Id.* at 835.

*Heckler* thus obligates courts to decline review of an agency's enforcement efforts. "Choosing whether and how to enforce a statute is the quintessential type of action 'committed to an agency's absolute discretion'"; an agency thus "could have declined to pursue any enforcement action against [a regulated entity], and such a decision would have been wholly unreviewable." *Better Mkts., Inc. v. DOJ*, 83 F. Supp. 3d 250, 256 (D.D.C. 2015) (citation omitted). Fundamentally, enforcement is an obligation for the executive branch to undertake, and is subject to its discretion.

The Covered Entities ignore this black-letter administrative law by urging this Court to usurp the agency's authority, in the first instance, to resolve the contract-pharmacy dispute through the newly created ADR process. An injunction (much less a *preliminary* one) instructing the Secretary to take specific enforcement steps would be particularly unwarranted here, where the agency has *not* refused to act in response to the drug companies' restrictions on 340B program access. On the contrary, the Secretary expeditiously worked to finalize the ADR process intended by Congress to resolve disputes about the 340B program. True, that process was delayed substantially, but that matter now has been remedied and provides no basis to hold that the

Secretary has forfeited his statutory authority to enforce 340B program requirements.[6] If an actual refusal to take enforcement action is "presumed immune from judicial review," *Heckler*, 470 U.S. at 832, there surely exists no ground to order emergency relief forcing the agency to *enforce faster*—particularly when that agency is playing a fundamental role in the government's response to a global pandemic and must determine how best to allocate scarce resources.

The Covered Entities spend pages briefing the contract-pharmacy issue, TRO/PI 22-25, including pronouncements of the Secretary that, they claim, express agreement with their statutory interpretation, and focus the bulk of their brief on the serious harms resulting from restricted access to 340B discounts, *id.* 25-39. Tellingly, however, the Covered Entities wholly ignore the fact that this Court lacks authority under *Heckler* and its progeny to review the Secretary's enforcement of 340B program requirements, much less to enjoin him to take specific enforcement actions. Nowhere in their request for (allegedly) preliminary relief do the Covered Entities provide authority suggesting that this Court may so direct the exercise of an agency's enforcement discretion. On the contrary, Congress established a different process: Covered entities and pharmaceutical manufacturers first must bring any claims relating to the 340B program before the agency, via the new ADR process, and any party dissatisfied with the agency's resolution of a dispute between covered entities and pharmaceutical manufacturers may then seek judicial review of *that* agency action in federal court. The Covered Entities' request to leapfrog that agency process flips convention—and fundamental administrative-law principles—on their heads.

In addition, the Covered Entities' requested injunctive relief improperly seeks wholesale changes to an agency program—*i.e.*, they ask this Court to oversee HHS's administration and

[6] The Covered Entities assert, without citation, that "HRSA has abandoned its responsibility to enforce the 340B statute's requirements for contract pharmacies." TRO/PI 25. But the drug manufacturers' changes only went into effect within the past few months, and the Secretary expeditiously put in place the ADR process where disputes such as this one clearly belong. Any contention that the agency has "abandoned" its enforcement role is unsubstantiated hyperbole.

enforcement of the 340B program, at least with regard to participation through contract pharmacies. The Court cannot do so. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990) (noting that "programmatic improvements" must be sought in Congress or at the agency and not through the courts under the APA). The Covered Entities "cannot seek *wholesale* improvement of this [340B] program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004) (citation omitted). Because "[t]he prospect of pervasive oversight by federal courts" over the enforcement program of HHS and HRSA "is not contemplated by the APA," *i.e.*, the proper vehicle for challenging agency action, *id.* at 67, the Court should decline the Covered Entities' invitation to instruct the Secretary in his exercise of enforcement discretion. The only mandatory duty the Covered Entities have identified, issuance of a rule establishing an ADR process, already has been completed. Absent any other mandatory duty, injunctive relief is unavailable.

ii. The Covered Entities cannot receive any additional relief on their due-process claim.

The Covered Entities' invocation of the Fifth Amendment does not entitle them to any additional relief. Relying on caselaw establishing that a Congressionally created cause of action "is a property interest protected by the Due Process Clause," the Covered Entities contend that the Secretary's delay in establishing the ADR process has denied them access to this cause of action as a vehicle for adjudicating their 340B dispute. TRO 18-20. To remedy that alleged violation, they urge this Court to issue sweeping injunctive relief allowing them to bypass use of the newly created process altogether: "[T]he Secretary has deprived the Covered Entities of their protected property interests under the Due Process Clause … Curing this harm now requires more than ADR. The Court should, therefore, order the Secretary to enforce the Covered Entities' rights[.]" TRO/PI

45.

This argument fails because, even accepting the Covered Entities' claim to a protected property interest in an ADR process, a delay in fulfilling that mandate does not permit the Covered Entities to eschew the agency process altogether and seek final relief from this Court. The Covered Entities cite no caselaw supporting the broad remedy they seek; on the contrary, the remedy for a due-process violation is provision of the process itself. The principle case relied upon by the Covered Entities is instructive. In *Logan v. Zimmerman Brush Co.*, a terminated employee successfully argued that his due-process rights had been violated by the inability to present his claim of discrimination to an employment commission. 455 U.S. 422 (1982) (cited at TRO/PI 19). After first agreeing that "a cause of action is a species of property," *id.* at 428, the Court found a violation, confirming that "the Due Process Clause grants the aggrieved party the opportunity to present his case and have its merits fairly judged." *Id.* at 433. But the Court did *not* proceed to decide for itself the merits of the employment claim for which a hearing had been denied—rather, it remanded to the agency for provision of the process due. *Id.* at 438. The same result must accrue here. Even if the Covered Entities have a protected property interest in the ADR process, the relief for denial of that right is coextensive with their APA claim—establishment of that process. The Fifth Amendment to the U.S. Constitution provides no ground for this Court to sidestep the fact that "Congress authorized no private right of action under § 340B for covered entities," *Astra*, 563 U.S. at 113, by itself adjudicating a matter textually committed to the Secretary for initial resolution.

Plaintiffs' attempt to argue otherwise falls short. No authority in their papers suggests that the remedy for denial of a property interest in a cause of action is to entirely sidestep use of that process by decreeing the outcome of a wholly separate dispute that Congress undoubtedly

committed for resolution through the process it created. Instead, the Covered Entities hang their argument on two words isolated from a Supreme Court opinion, contending that "[a] court may remedy all conditions that 'flow from' the constitutional violation[.]" TRO/PI 43 (citing *Milliken v. Bradley*, 433 U.S. 267, 281-82 (1977)). But that authority actually compels restraint: "The well-settled principle that the nature and scope of the remedy are to be determined by the violation means simply that federal-court decrees must directly address and relate to the constitutional violation itself … federal-court decrees exceed appropriate limits if they are aimed at eliminating a condition that does not violate the Constitution or does not flow from such a violation." *Milliken*, 433 U.S. at 281-82. Violations of 340B program requirements certainly do not violate the Constitution. And, contrary to the Covered Entities' insistence, restrictions on contract-pharmacy access do not "flow from" the delay in establishing ADR, but rather from independent actions of drugmakers.[7]

As demonstrated conclusively above, this Court cannot grant any additional relief that the Covered Entities have not received through the Secretary's actions in establishing an ADR process. Whether styled as violations of due process, the APA, or requests for mandamus and declaratory relief, each of the Covered Entities' requests for relief are dead ends. The ADR process will be available before briefing on this motion is complete; at that time, the Covered Entities may promptly move for relief before the agency through mechanisms available under the Federal Rules of Civil Procedure. And while the Covered Entities may dislike waiting for that process to play out, it is the only process Congress provided to them. Because this Court cannot provide any

[7] Plaintiffs also cite one extra-circuit authority upholding the power of a district court to order pandemic-related reductions in immigration-detention population to remedy unconstitutional conditions of confinement. TRO/PI 43 (citing *Roman v. Wolf*, 977 F.3d 935, 937 (9th Cir. 2020)). That opinion cited well-established authority confirming a district court's ability to fashion injunctive relief to remedy unconstitutional prison conditions. *Roman*, 977 F.3d at 941-45. That case does not support this Court's ability to pluck the contract-pharmacy dispute from the agency adjudication where it belongs (and now can be brought) by instead deciding that dispute in the first instance.

additional relief, the Covered Entities' claims must be dismissed.

## II. The Covered Entities Are Not Entitled to Preliminary Relief.

Putting aside briefly that the Covered Entities' complaint warrants dismissal in its entirety, they cannot establish any entitlement to either a temporary restraining order or a preliminary injunction. Not only did they wait more than four months after the events alleged to have caused harm before filing suit, and forty-five days after commencing suit to seek "emergency" relief, there is nothing preliminary about the relief Plaintiffs seek. On the contrary, the Covered Entities urge the Court to grant the full panoply of relief requested in their complaint under the guise of an extraordinary, emergency motion. *See* TRO 41-44 (requesting "an injunction ordering the Secretary to issue ADR regulations," "a declaration affirming that 340B covered entities are entitled to purchase covered outpatient drugs at 340B discounts from contract pharmacies," and an "order … to take appropriate steps … to bring the Drug Companies in line," up to and including monetary penalties and exclusion *writ large* from Medicaid and Medicare).

*Even if* this Court had authority to order such relief at some stage of the litigation, it clearly would not be appropriate in the form of an emergency motion. The Covered Entities are seeking an improper mandatory injunction that would, in effect, provide the ultimate relief sought on the merits. The D.C. Circuit "has expressly cautioned that '[t]he power to issue a preliminary injunction, especially a mandatory one, should be 'sparingly exercised.'" *Newark Pre-Sch. Council, Inc. v. HHS*, 201 F. Supp. 3d 72, 78 (D.D.C. 2016) (quoting *Dorfmann v. Boozer*, 414 F.2d 1168, 1173 (D.C. Cir. 1969)). The standard is a "demanding" one, *Archdiocese of Wash. v. Wash. Metro Area Transit Auth.*, 897 F.3d 314, 319 (D.C. Cir. 2018), and the movant must "clearly" show that "he or she is entitled to relief or that extreme or very serious damage will result from the denial of the injunction." *Elec. Privacy Info. Ctr. v. DOJ*, 15 F. Supp. 3d 32, 39 (D.D.C.

2014) (citation omitted) (collecting cases). This "significantly heightened" burden is warranted, *Feng Wang v. Pompeo*, 354 F. Supp. 3d 13, 20 (D.D.C. 2018), because, at its core, "[t]he purpose of a preliminary injunction is merely to preserve the relative position of the parties" while the Court decides the merits of a plaintiff's claim. *Newark Pre-Sch. Council, Inc.*, 201 F. Supp. 3d at 78 (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). "[I]t is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits," *University of Texas*, 451 U.S. at 395, and a preliminary injunction that effectively would grant full relief accordingly is improper. *See, e.g.*, *Dorfmann v. Boozer*, 414 F.2d 1168, 1173 n.13 (D.C. Cir. 1969) (*per curiam*) ("[A] preliminary injunction should not work to give a party essentially the full relief he seeks on the merits."); *Senate of State of Cal. v. Mosbacher*, 968 F.2d 974, 978 (9th Cir. 1992) (explaining that granting "judgment on the merits in the guise of preliminary relief" is "highly inappropriate"). The Covered Entities' motion for preliminary relief must fail on this ground alone.

Moreover, the Covered Entities cannot satisfy any of the *Winter* factors. *See* 555 U.S. at 20. Pre-*Winter*, the D.C. Circuit had adopted a sliding scale approach, under which "a strong showing on one factor could make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011). But it since has construed *Winter* "at least to suggest if not to hold that a likelihood of success is an independent, free-standing requirement for a preliminary injunction." *Id.* (citation omitted); *see also Nken v. Holder*, 556 U.S. 418, 438 (2009) (Kennedy, J., concurring) ("When considering success on the merits and irreparable harm, courts cannot dispense with the required showing of one simply because there is a strong likelihood of the other."). Because the Covered Entities not only are unlikely to succeed on the merits, but *cannot*, given the Court's lack of jurisdiction, their request for preliminary relief must be denied on this

additional ground.

Nor can they satisfy the remaining factors. The Covered Entities detail harms flowing from *the pharmaceutical manufacturers'* decisions to restrict 340B access through contract pharmacies. TRO/PI 25-39. But those harms are not remediable through an injunction against the Secretary, for multiple reasons including that the Secretary did not cause those harms and because the Supreme Court squarely has held that covered entities may not sue to enforce 340B requirements, *Astra*, 563 U.S. 110. *See* TRO/PI 39 (admitting that, as a result of *Astra*, Covered Entities "must rely on the Secretary to enforce 340B program requirements"). Stated differently, the harms claimed are not traceable to actions of the Secretary and thus cannot be remediated via an emergency injunction proscribing enforcement actions.

Nor have the Covered Entities established that the balance of the equities or the public interest favor the relief requested. Once more, they focus on the merits of the contract-pharmacy dispute between the Covered Entities and the drugmakers, *not* the dispute this Court is hearing between the Covered Entities and the agency. For example, they focus on the public interest in providing care for "our country's most vulnerable patients" and the burdens imposed on health centers should they be denied long-term access to 340B discounts. TRO/PI 39-40. Access to 340B discounts is undoubtedly important, particularly in the midst of a pandemic, but that fact does not permit this Court to intervene before the Secretary has been able to address the dispute regarding contract-pharmacy participation through the newly established ADR process.

The Covered Entities' assertion that "Defendants … would not suffer any economic or direct harm if the requested injunction to require manufacturers to provide 340B discounts were granted," *id.* at 39, misses the point—as does their reliance on caselaw standing for the uncontroversial proposition that there exists "no public interest in the perpetuation of unlawful

agency action." *Id.* (citing *League of Women Voters*, 838 F.3d 1, 12 (D.C. Cir. 2016)). The public interest here favors regularity and the proper functioning of administrative law. Congress has committed enforcement of 340B to the Secretary, *Astra*, 563 U.S. at 114, and he must be permitted in the first instance to decide this dispute. It matters not whether the agency faces "economic or direct harm"; issuance of an injunction that would usurp the agency's authority to enforce a matter committed to its discretion by law is not in the public interest. And there can be no reliance on "unlawful agency action," given that the only plausible "violation" by the agency—a delay in establishing an ADR process—already has been rectified.

Because the Covered Entities cannot succeed on the merits, have not shown that irreparable harm is resulting from any reviewable action by the Secretary, and request relief that is not in the public interest, their request for emergency relief must be denied.

## CONCLUSION

Defendants thus respectfully request that this Court dismiss all of the Covered Entities' claims and deny their motion for a temporary restraining order and preliminary injunction.

Dated: December 14, 2020

Respectfully submitted,

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