UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMERICAN HOSPITAL ASSOCIATION, ET AL., Plaintiffs, v. **DEPARTMENT OF HEALTH & HUMAN SERVICES, ET AL.,** Defendants.	Case No. 4:20-cv-08806-YGR **ORDER GRANTING MOTION TO DISMISS** Re: Dkt. No. 64

Plaintiffs the American Hospital Association, 340B Health, America's Essential Hospitals, the Association of American Medical Colleges, the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Regional Medical Center, and St. Mary's Medical Center bring this action against defendants the Department of Health & Human Services ("HHS"), and acting Secretary of HHS Norris Cochran.[1] Plaintiffs allege two causes of action based on violations of the Administrative Procedure Act ("APA"), 5 USC section 706: (1) for an unlawful, arbitrary, and capricious agency action; and (2) for an agency action unlawfully withheld or unreasonably delayed.

Now before the Court is defendants' motion to dismiss for lack of subject-matter jurisdiction. (Dkt. No. 64.)[2] Having preliminarily reviewed the motion to dismiss, the Court

[1] This action was initially commenced against then HHS Secretary Alex M. Azar II, who has since resigned on January 20, 2021 because of the incoming administration of President Joseph R. Biden. As of the date of this Order, a successor to Azar has not yet been confirmed.

[2] The Court notes that there are other pending motions on the docket, including a motion for preliminary injunction (Dkt. No. 7), and several motions to intervene filed by various drug companies seeking to intervene in this action. (*See* Dkt. Nos. 28, 35, 38, 62.) The Court stayed consideration of these motions until it addressed the motion to dismiss. (*See* Dkt. Nos. 70, 80.)

issued an Order to Show Cause ("OSC") as to why the matter should not be dismissed for lack of subject-matter jurisdiction. (Dkt. No. 70.) Plaintiffs filed a response to the OSC and the motion to dismiss, and the matter was fully briefed by the parties. (*See* Dkt. Nos. 81, 82.)

Having carefully considered the pleadings and the papers submitted, as well as oral argument from counsel on February 9, 2021 via the Zoom platform, and for the reasons set forth more fully below, the Court **GRANTS** the motion to dismiss. Further, in light of the analysis herein, the remaining pending motions are **DENIED AS MOOT**.

I. BACKGROUND[3]

The Court summarizes the allegations in the operative complaint, as well as those materials and documents that are properly judicially noticeable. Thus:

A. Relevant Statutory Framework

This action concerns a part of the statutory framework forming the backbone of this nation's healthcare system. Specifically, the 340B Program, administered by the Secretary of HHS, through which certain hospitals, community health centers, and other safety-net providers (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). The Health Resources and Services Administration ("HRSA"), a sub-department of HHS, is responsible for administering the 340B Program. Drug manufacturers are required to participate in the 340B Program in order to have their drugs covered through Medicaid and Medicare Part B. *See* 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). The discounted drugs benefit both 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.

This action touches upon a common practice in the 340B Program: contract pharmacies. In 1996, HRSA issued "final guidelines" that acknowledged that "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing

[3] Citations to the record and complaint are omitted to expedite the issuance of this Order.

pharmaceutical care to their patients." 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996). HRSA also made clear that "[u]nder section 340B, . . . if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, *the statute directs the manufacturer to sell the drug at the discounted price*." *Id.* at 43,555 (emphasis supplied).

In 2010, the 340B Program was updated in several substantive ways by the United States Congress through the passage of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). In one update, Congress expanded the categories of covered entities to include critical access hospitals and other hospitals serving patients who live in isolated rural areas. *See* 42 U.S.C. § 256b(a)(4)(M)–(O).

In another update, Congress added 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 has since issued regulations allowing the imposition of monetary penalties, including up to $5,000 (plus adjustments for inflation) for each knowing and intentional instance of overcharging by a drug manufacturer. *See* 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).

Additionally, as relevant here, Congress updated the statute by directing the Secretary to:

> [E]stablish[] procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including . . . [o]versight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in instances of retroactive adjustments to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

42 U.S.C. § 256b(d)(1)(B)(ii). To this end, Congress further directed that:

> 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).

In compliance with the foregoing, the Secretary began to establish the dispute resolution process several months later by issuing an advanced notice of proposed rulemaking to request comments on the development of an administrative dispute resolution ("ADR") process. *See* 75 Fed. Reg. 57,233 (Sept. 20, 2010). 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 final ADR rule was published in the Federal Register on December 14, 2020. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (*codified at* 42 C.F.R. pt. 10).[4]

This final ADR rule took effect on January 13, 2021, and provided that 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 are heard by a "340B ADR Panel," a decision-making body within HHS 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 consist of members appointed by the Secretary from the HRSA, the Centers for Medicare and Medicaid Services, and HHS's Office of General Counsel, and includes 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.* 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 thereafter subject to judicial review under the APA. *Id.* at 80,641.

[4] The record does not reflect any explanation for the six-year delay between the initial proposed rule and the subsequent NPRM, nor the four-delay between the NPRM and the final ADR rule.

B. Relevant Background

Plaintiffs are either covered entities, as defined by the statute, or associations that represent covered entities, all of which benefit from the 340B Program. Specifically, plaintiffs and plaintiffs' association members have entered into agreements with contract pharmacies, generally retail pharmacies, under the 340B Program to provide discounted drug prices to low-income communities. These contract pharmacies are generally utilized where the covered entities do not have access to an in-house pharmacy and must therefore direct its patients to outside third-party pharmacies.

During the summer and fall of 2020, several drug companies[5] notified 340B Program participants, including plaintiffs, that certain drugs would no longer be provided under the 340B Program to covered entities without an in-house pharmacy.[6] Where the covered entity lacked an in-house pharmacy and otherwise participated in a contract pharmacy arrangement, these drug companies required the covered entities to submit additional paperwork and participate in a process to determine the eligibility of these contract pharmacies. For instance, as alleged, some of these drug companies limited the 340B Programs benefits to *one* qualifying contract pharmacy—as opposed to the many contract pharmacies upon which the covered entities had previously relied. Other requirements included the submission of certain claims data from the contract pharmacies, and the limiting of eligible contract pharmacies to within a 40-mile radius of the covered entity.

In response to these actions, plaintiffs sent several letters to the drug companies and the government—HHS and HRSA. In response to one of these letters, HRSA Communications Director Martin Kramer[7] wrote via email on July 8, 2020 that although the agency "strongly

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[5] As alleged in the complaint and reflected on the docket, these drug companies include: Eli Lilly and Company, AstraZeneca LP, Sanofi-Aventis U.S. LLC, Novo Nordisk, Inc., and Novo Nordisk Pharma. United Therapeutics Corporation is also alleged as one of the drug companies which has revised its contract pharmacy rules, but has not sought to intervene in this matter at the time of this Order.

[6] The earliest action of the drug companies was alleged to have occurred in May and June 2020, with an effective date of its new eligibility rules of July 1, 2020.

[7] The Court takes judicial notice that Martin Kramer is the director of HRSA's Office of Communications—which is a public-facing role, not one charged with either statutory

encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements," "HRSA's current authority to enforce certain 340B policies . . . is limited" because Congress has not granted it "comprehensive regulatory authority" "to develop enforceable policy that ensures clarity in program requirements." (*See* Dkt. No. 81 at 8-9.)[8]

As a result of these changes instituted by the drug companies as to the 340B Program, plaintiffs allege that they will be forced to scale back or eliminate healthcare services during the current and ongoing public-health crisis. Thus, plaintiffs allege that the HHS Secretary and HHS unlawfully have refused to take specific enforcement actions to block the manufacturers' changes and that this purported failure to enforce 340B access violates the APA.[9]

II. LEGAL STANDARD

Rule 12(b)(1) provides that an action may be dismissed for lack of subject matter jurisdiction. Federal courts are of "limited jurisdiction" and plaintiff bears the burden to prove the requisite federal subject matter jurisdiction. *Kokkonen v. Guardian Life Ins. Of Am.*, 511 U.S. 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994). A challenge pursuant to Rule 12(b)(1) may be facial or factual. *See White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000). A facial 12(b)(1) motion involves an inquiry confined to the allegations in the complaint, whereas a factual 12(b)(1) motion permits the court to look beyond the complaint to extrinsic evidence. *Wolfe v. Strankman*, 392

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interpretation, program enforcement, or policy formulation.

[8] Notably, plaintiffs characterize these statements as final agency actions under the APA.

[9] The briefing further reflects that on December 30, 2020, HHS's General Counsel issued a detailed advisory opinion setting forth his office's view on the use of contract-pharmacy arrangements in the 340B Program. *See* Advisory Opinion 20-06 On Contract Pharmacies Under the 340B Program ("AO"), Dec. 30, 2020, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last visited Feb. 8, 2021). That opinion analyzes the "plain meaning" of the 340B statute, the evident Congressional intent behind its provisions, the history of manufacturers' and covered entities' actions operating under the pricing scheme, and the agency's longstanding statutory interpretation. Based on these considerations, it emphasizes that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs . . . even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8. The advisory opinion interprets the 340B statutory requirements "in general and does not opine on the legality of any specific contract-pharmacy model." *Id.* at 8 n.9.

F.3d 358, 362 (9th Cir. 2004). Thus, in a factual 12(b)(1) motion, the Court may consider evidence outside the complaint to resolve factual disputes in the process of determining the existence of subject matter jurisdiction. *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988). Courts consequently need not presume the truthfulness of a plaintiff's allegations in such instances. *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (citing *White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000)). "Dismissal for lack of subject matter jurisdiction because of the inadequacy of the federal claim is proper only when the claim is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as to not involve a federal controversy." *Steel Co. v. Citizens for a Better Env.*, 523 U.S. 83, 89 (1998) (quoting *Oneida Indian Nation of N.Y. v. Cty. Of Oneida*, 414 U.S. 661, 666 (1974)).

III. ANALYSIS

Defendants move to dismiss the complaint for lack of subject matter jurisdiction based on three separate grounds for dismissal, namely that: (1) *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), bars a private action against defendants or the drug companies under the statutory framework of the 340B Program, and plaintiffs are required to use the recently adopted ADR process; (2) no final agency action exists to establish an APA violation; and (3) the principles of agency discretion articulated in *Heckler v. Cheney*, 470 U.S. 821 (1985) bar this action which seeks to compel certain discretionary agency enforcement action as to alleged violations of the 340B Program. The Court addresses each in turn.

A. *Astra* and the ADR Process

Defendants aver that *Astra* forecloses plaintiffs' action in this case. Specifically, defendants contend that the United States Supreme Court has held that there is no private right of action for enforcement under the 340B Program, and has reiterated that any alleged violations are subject to initial resolution through the statutorily mandated ADR process administered by HHS. Plaintiffs argue that *Astra* is inapposite, whereby the covered entities there were suing to enforce the 340B Program requirements *directly against* the drug companies themselves. Plaintiffs also point out that *Astra* did not foreclose actions against HHS for violations of the APA.

Plaintiffs do not persuade. As defendants correctly summarize, in *Astra*, a collection of

covered entities had sued drug manufacturers for purported overcharges on 340B Program-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 drug companies directly under the 340B statute, the covered entities pursued a different theory: as third-party beneficiaries of contracts between HHS and drug companies that effectuate 340B discounts, the covered entities could claim a breach of contract.

The Supreme Court was not persuaded by this creative recasting of the *Astra* plaintiffs' claims. The Supreme Court rejected as "incompatible with the statutory regime" the covered entities' efforts to sue to enforce 340B requirements. *Id*. "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 to which the drug manufacturers had agreed in order to access the Medicaid and Medicare Part B programs, the Supreme 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").

In reaching this conclusion, the Supreme Court reiterated that Congress had provided an alternative administrative process in which to resolve disputes under the 340B Program. Specifically, Congress had responded to reports of inadequate 340B Program 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 "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 APA. *Astra*, 563 U.S. at 121-22.

Although plaintiffs here have similarly and creatively recast their claims as an APA action

against HHS and the Secretary of HHS, this action is nothing more than an *indirect action* against the drug manufacturers themselves. Indeed, plaintiffs' claims and the remedy sought are entirely premised on the enforcement of the 340B Program requirements against the various allegedly non-complying drug companies.[10] In other words, plaintiffs here seek precisely that which *Astra* forbids: the *private* enforcement of 340B program requirements.

Plaintiffs' remaining arguments as to the inapplicability of the ADR process do not compel a contrary result. Plaintiffs argue that the ADR process does not control because it "is intended to provide retrospective remedies, while Plaintiffs here seek forward-looking relief." (Dkt. No. 81 at 12.) The ADR rule itself, however, facially disproves this premise. The ADR rule repeatedly discusses the availability of equitable relief and explicitly incorporates the Federal Rules of Civil Procedure and mechanisms allowed thereunder. *See* 42 C.F.R. § 10.21(a) (allowing claim for equitable relief); *id.* § 10.21(b) (granting jurisdiction where equitable relief sought will exceed specified monetary threshold); *id.* § 10.23(b) (incorporating Federal Rules). Plaintiffs' unexplained aversion to pursuing their claims before the agency provides no ground for this suit to deviate from the now established ADR process. Indeed, both of the other two actions by covered entities prompted by the same contract-pharmacy changes now have been stayed *at the joint request of plaintiffs and defendants* in this actions so that the plaintiffs there may pursue these same matters before the agency. *See, e.g.*, ECF No. 25, Mot. to Stay, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906, ECF No. 21, Am. Compl. (D.D.C.); *see also Nat'l Ass'n of Comm. Health Ctrs. v. Azar,* No. 20-cv-3032, ECF No. 12, Mot. to Stay (D.D.C.) (requesting stay of proceedings to allow plaintiff to "rely on that dispute-resolution mechanism—the only process available to them to remedy violations of Section 340B").[11]

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[10] Although, as discussed in the *Heckler* section, plaintiffs concede that they are not seeking to enjoin any specific enforcement action against the drug companies, but rather, a generalized enforcement of the statutory scheme by HHS.

[11] The Court further recognizes that some cases have since been filed by the drug companies and other covered entities concerning either the ADR rule or the drug companies' new position as to contract pharmacies. (*See* Dkt. No. 85.) The Court does not opine on the validity of the ADR rule under the APA, nor the process that was used to enact it. That said, the fact that challenges are being made, also does not weigh into the Court's evaluation of subject-matter

In sum, Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process. This process provides the agency an initial opportunity to develop rules and regulations applicable to the enforcement of the 340B Program requirements. Moreover, the panel consists of decisionmakers with intimate familiarity, technical knowledge, and understanding of the nuances inherent in the 340B Program. The judiciary has a prescribed role in this process, but its role comes *only after* the parties have participated in this ADR process. This Court will not otherwise short-circuit the foundational regime that Congress has enacted in the 340B Program.

Accordingly, the Court **GRANTS** defendants' motion to dismiss on this ground.

B. Final Agency Action

Defendants contend that there is no final agency action which would establish an APA violation. In response, plaintiffs aver that the July 8, 2020 email sent by Kramer qualifies as an agency action upon which an APA violation can be premised, and that defendants have impermissibly withheld agency action by failing to enforce the 340B Program requirements.

Plaintiffs do not persuade. "As a general matter, district courts are empowered to review agency action by the [APA], 5 U.S.C. § 551 . . . [b]ut for a court to hear a case like this pursuant to the APA, there must be '*final agency action* for which there is no other adequate remedy in a court.'" *Mamigonian v. Biggs*, 710 F.3d 936, 941 (9th Cir. 2013) (quoting 5 U.S.C. § 704). Subject-matter jurisdiction is thus lacking where an agency has yet to render any final decision. *Id.* For an agency action to satisfy the finality requirement, "the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citations omitted); *see also, Winnemucca Indian Colony v. Dep't of Interior*, 819 F. App'x 480, 482 (9th Cir. 2020) (dismissal warranted because, at time complaint was filed, agency "had not reached a final decision" on pending matter (quoting *Fairbanks N. Star Borough*

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jurisdiction given precedent and the plain language of the statute.

v. U.S. Army Corps of Eng'rs, 543 F.3d 586, 591 (9th Cir. 2008))).

Here, the purported agency action consists of correspondence sent by Kramer on July 8, 2020. A single email from an agency official with no role in policy formulation or ultimate decision-making authority, stating a legal principle, cannot be characterized as a "decision," much less a final agency action. *See* 5 U.S.C. § 551(13) (limiting agency action to "an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act"). Plaintiffs do not identify any other potential "agency action" which is not surprising given the record reflects that HHS is still contemplating the statutory interpretation of the 340B Program.[12] At this stage, "[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." *C&E Servs., Inc. v. D.C. Water and Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002) (affirming dismissal of declaratory judgment claim on ground that "district court . . . lacked authority to adjudicate [plaintiff's] rights . . . except pursuant to the [APA] *following* a[n] [agency] determination" (emphasis in original)); *see also Gill v. Dep't of Justice*, 913 F.3d 1179, 1184 (9th Cir. 2019).

Plaintiffs further fail to demonstrate that HHS has unlawfully withheld agency action under the APA. The definition of "failure to act" is coextensive with the inquiry under section 706(1) of agency action entitled "unlawfully withheld." Such a claim "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). Here, the plain language of the statute does not include language which mandates the specific contemplated enforcement of the 340B Program.[13] Indeed, "Congress gave HHS a specific delegation of rulemaking authority to

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[12] Indeed, as noted in the briefing and at oral argument, HHS is currently in transition to the new Biden administration, as well as handling the national response to the ongoing coronavirus (COVID-19) pandemic.

[13] To the extent that plaintiffs are arguing that HHS and HRSA is failing to enforce the statutory penalty scheme as contemplated under the 340B Program and has essentially abdicated its statutory responsibilities, the Court discusses this argument under the subsequent section involving *Heckler*.

establish an adjudication procedure to resolve disputes between covered entities and manufacturers" and "has not given HHS [] broad rulemaking authority" under the 340B Program. *Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41-45 (D.D.C. 2014) (setting aside rule on ground that, under 340B, "Congress specifically authorized rulemaking" only for (1) establishment of ADR; (2) drug-pricing methodology; and (3) imposition of monetary sanctions for violations).[14]

In sum, plaintiffs do not challenge a discrete action, nor do they point to any statutory provision that requires HHS to take the actions plaintiffs seek with respect to the 340B Program. Plaintiffs' aversion to the now available ADR process is not grounds for an APA violation at this juncture. To the extent that plaintiffs are dissatisfied with the ADR process, the ADR rule endows plaintiffs the ability to initiate an APA action by appealing a final determination made in the ADR process *at that time*—and no sooner.

Accordingly, the Court alternatively **GRANTS** the' motion to dismiss on this ground.

C. Agency Discretion

Finally, defendants contend that under *Heckler*, plaintiffs are unable to maintain an action requesting enforcement of the 340B Program. Specifically, HHS cannot be ordered to prosecute or enforce certain requirements that are its absolute discretion.

The Court agrees, at least at this juncture. In *Heckler*, the Supreme Court held "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." 470 U.S. at 831. That doctrine makes clear that, absent an unmistakable 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]." *See id.* at 835 (citation omitted).

[14] The calculus would be different if, for instance, plaintiffs were challenging defendants' failure to finalize the ADR resolution process required by Congress under the relevant statute. However, such process has now been established, and plaintiffs point to no other unlawfully withheld agency action.

Here, plaintiffs backtrack from their own requests for emergency relief in which the pending motion for preliminary injunction sought to order HHS "to require the [d]rug [c]ompanies" to honor 340B prices through contract pharmacies, requiring HHS to order refunds from manufacturers, and requiring referral of "the matter" "for assessment of civil money penalties." (Dkt. No. 7 at 36.) Plaintiffs now disavow any request for this Court to order "what the contours of that [enforcement] policy should be, or what specific enforcement actions the Department should take against the [d]rug [c]ompanies." (Dkt. No. 81 at 6-7.)

Even this concession cannot satisfy the principles articulated above in *Heckler*. Plaintiffs cannot simply evade the categorical bar on review of agency enforcement efforts by asking for a sweeping, industry-wide enforcement "policy" rather than specified injunctions directing the agency to take specific enforcement steps or actions. HHS' decision whether to enforce or prosecute violations under the 340B Program are committed to its discretion.

Further, plaintiffs' arguments that this case presents an instance where HHS and HRSA have abdicated their statutory responsibilities are currently without merit. *See Heckler*, 470 U.S. at 833 n.4 (noting that a claim for violation of the APA may be brought in instances where an "agency has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities" or where an agency believes it lacks jurisdiction). Neither the allegations nor the parties' briefing reflect such a scenario. Instead, the record demonstrates that HHS and HRSA continue to contemplate their response to the recent actions by the drug companies. Such continued contemplation, in light of the ongoing presidential transition and pandemic, does not currently rise to the level of an adoption of a general policy that amounts to abdication of any statutory responsibilities, nor have the agencies otherwise determined that they lack jurisdiction to impose any civil penalties against the drug companies. At this stage, given that the drug companies' actions are recent, an action brought against HHS on this ground is premature.

Accordingly, the Court alternatively **GRANTS** the' motion to dismiss on this ground. Because plaintiffs may be able to maintain a narrower action seeking general enforcement of the statute in the future, assuming certain decisions, determinations, or actions by HHS, the Court will

dismiss the action **WITHOUT PREJUDICE**.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** the motion to dismiss and **DISMISSES** this action **WITHOUT PREJUDICE**. Moreover, in light of the ruling on the motion to dismiss, the motion for preliminary injunction and motions to intervene are **DENIED AS MOOT**.

The Clerk of the Court is directed to close this matter.

This Order terminates Docket Numbers 7, 28, 35, 38, 62, and 64.

IT IS SO ORDERED.

Dated: February 17, 2021

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT JUDGE

United States District Court
Northern District of California