

United States District Court
Northern District of California

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**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.)

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

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

8 **I. BACKGROUND³**

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

11 **A. Relevant Statutory Framework**

12 This action concerns a part of the statutory framework forming the backbone of this
 13 nation’s healthcare system. Specifically, the 340B Program, administered by the Secretary of
 14 HHS, through which certain hospitals, community health centers, and other safety-net providers
 15 (known as “covered entities”) serving low-income patients could receive drug discounts. *See*
 16 Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992),
 17 *codified at* § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). The Health Resources
 18 and Services Administration (“HRSA”), a sub-department of HHS, is responsible for
 19 administering the 340B Program. Drug manufacturers are required to participate in the 340B
 20 Program in order to have their drugs covered through Medicaid and Medicare Part B. *See* 42
 21 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a). The discounted drugs benefit both patients, by
 22 helping them to afford costly medications, and covered entities, which use the discounts to stretch
 23 scarce federal resources and serve a greater number of uninsured and under-insured patients.

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

27 ³ Citations to the record and complaint are omitted to expedite the issuance of this Order.
 28

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

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

10 In another update, Congress added new provisions to “improv[e] . . . program integrity”
11 related to manufacturer and covered-entity compliance, including the imposition of civil monetary
12 penalties on manufacturers that knowingly and intentionally overcharge covered entities. *See* 42
13 U.S.C. § 256b(d)(1). Relying on that authority, the Secretary has since issued regulations
14 allowing the imposition of monetary penalties, including up to \$5,000 (plus adjustments for
15 inflation) for each knowing and intentional instance of overcharging by a drug manufacturer. *See*
16 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation,
17 82 Fed. Reg. 1,210 (Jan. 5, 2017), *codified at* 42 C.F.R. § 10.11(a).

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

19 [E]stablish[] procedures for manufacturers to issue refunds to covered
20 entities in the event that there is an overcharge by the manufacturers,
21 including . . . [o]versight by the Secretary to ensure that the refunds
22 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.

23 42 U.S.C. § 256b(d)(1)(B)(ii). To this end, Congress further directed that:

24 Not later than 180 days after March 23, 2010, the Secretary shall
25 promulgate regulations to establish and implement an administrative
26 process for the resolution of claims by covered entities that they have
27 been overcharged for drugs purchased under this section, and claims
28 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].

1 42 U.S.C. § 256b(d)(3)(A).

2 In compliance with the foregoing, the Secretary began to establish the dispute resolution
3 process several months later by issuing an advanced notice of proposed rulemaking to request
4 comments on the development of an administrative dispute resolution (“ADR”) process. *See* 75
5 Fed. Reg. 57,233 (Sept. 20, 2010). That notice was then followed by a Notice of Proposed
6 Rulemaking (“NPRM”), which included proposed ADR regulations establishing a panel within the
7 agency to adjudicate disputes between drug manufacturers and covered entities. *See* 81 Fed. Reg.
8 53,381 (Aug. 12, 2016). The final ADR rule was published in the Federal Register on December
9 14, 2020. *See* 340B Drug Pricing Program: Administrative Dispute Resolution Regulation, 85
10 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) (*codified at* 42 C.F.R. pt. 10).⁴

11 This final ADR rule took effect on January 13, 2021, and provided that both covered
12 entities and drug manufacturers will have a mechanism to resolve before the agency disputes
13 arising under the 340B Program, including “[c]laims by covered entities that may have been
14 overcharged for covered outpatient drugs purchased from manufacturers.” *Id.* at 80,644. Those
15 claims are heard by a “340B ADR Panel,” a decision-making body within HHS that, “acting on an
16 express, written delegation of authority from the Secretary of HHS, reviews and makes a
17 precedential and binding decision.” *Id.* ADR panels consist of members appointed by the
18 Secretary from the HRSA, the Centers for Medicare and Medicaid Services, and HHS’s Office of
19 General Counsel, and includes a non-voting member from the Office of Pharmacy Affairs,
20 ensuring that each panel has “relevant expertise and experience in drug pricing or drug
21 distribution” and “in handling complex litigation.” *Id.* The agency process explicitly is governed
22 by the Federal Rules of Civil Procedure, including the deadlines and procedural mechanisms
23 established therein, and claims may be brought “for monetary damages or equitable relief.” *Id.*
24 Panel decisions are thereafter subject to judicial review under the APA. *Id.* at 80,641.

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

B. Relevant Background

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

9 During the summer and fall of 2020, several drug companies⁵ notified 340B Program
10 participants, including plaintiffs, that certain drugs would no longer be provided under the 340B
11 Program to covered entities without an in-house pharmacy.⁶ Where the covered entity lacked an
12 in-house pharmacy and otherwise participated in a contract pharmacy arrangement, these drug
13 companies required the covered entities to submit additional paperwork and participate in a
14 process to determine the eligibility of these contract pharmacies. For instance, as alleged, some of
15 these drug companies limited the 340B Programs benefits to *one* qualifying contract pharmacy—
16 as opposed to the many contract pharmacies upon which the covered entities had previously relied.
17 Other requirements included the submission of certain claims data from the contract pharmacies,
18 and the limiting of eligible contract pharmacies to within a 40-mile radius of the covered entity.

19 In response to these actions, plaintiffs sent several letters to the drug companies and the
20 government—HHS and HRSA. In response to one of these letters, HRSA Communications
21 Director Martin Kramer⁷ wrote via email on July 8, 2020 that although the agency “strongly
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23 ⁵ As alleged in the complaint and reflected on the docket, these drug companies include:
24 Eli Lilly and Company, AstraZeneca LP, Sanofi-Aventis U.S. LLC, Novo Nordisk, Inc., and Novo
25 Nordisk Pharma. United Therapeutics Corporation is also alleged as one of the drug companies
26 which has revised its contract pharmacy rules, but has not sought to intervene in this matter at the
27 time of this Order.

28 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

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

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

10 II. LEGAL STANDARD

11 Rule 12(b)(1) provides that an action may be dismissed for lack of subject matter
 12 jurisdiction. Federal courts are of “limited jurisdiction” and plaintiff bears the burden to prove the
 13 requisite federal subject matter jurisdiction. *Kokkonen v. Guardian Life Ins. Of Am.*, 511 U.S.
 14 375, 377, 114 S.Ct. 1673, 128 L.Ed.2d 391 (1994). A challenge pursuant to Rule 12(b)(1) may be
 15 facial or factual. *See White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000). A facial 12(b)(1) motion
 16 involves an inquiry confined to the allegations in the complaint, whereas a factual 12(b)(1) motion
 17 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.

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

21 ⁹ The briefing further reflects that on December 30, 2020, HHS’s General Counsel issued
 22 a detailed advisory opinion setting forth his office’s view on the use of contract-pharmacy
 23 arrangements in the 340B Program. *See* Advisory Opinion 20-06 On Contract Pharmacies Under
 24 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,
 25 2021). That opinion analyzes the “plain meaning” of the 340B statute, the evident Congressional
 26 intent behind its provisions, the history of manufacturers’ and covered entities’ actions operating
 27 under the pricing scheme, and the agency’s longstanding statutory interpretation. Based on these
 28 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.

1 F.3d 358, 362 (9th Cir. 2004). Thus, in a factual 12(b)(1) motion, the Court may consider
2 evidence outside the complaint to resolve factual disputes in the process of determining the
3 existence of subject matter jurisdiction. *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir.
4 1988). Courts consequently need not presume the truthfulness of a plaintiff's allegations in such
5 instances. *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (citing *White v.*
6 *Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000)). "Dismissal for lack of subject matter jurisdiction
7 because of the inadequacy of the federal claim is proper only when the claim is 'so insubstantial,
8 implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit
9 as to not involve a federal controversy.'" *Steel Co. v. Citizens for a Better Env.*, 523 U.S. 83, 89
10 (1998) (quoting *Oneida Indian Nation of N.Y. v. Cty. Of Oneida*, 414 U.S. 661, 666 (1974)).

11 **III. ANALYSIS**

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

20 **A. *Astra* and the ADR Process**

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

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

1 covered entities had sued drug manufacturers for purported overcharges on 340B Program-
2 covered drugs. Both sides “conceded that Congress authorized no private right of action under
3 § 340B for covered entities who claim they have been charged prices exceeding the statutory
4 ceiling.” 563 U.S. at 113. Unable to sue the drug companies directly under the 340B statute, the
5 covered entities pursued a different theory: as third-party beneficiaries of contracts between HHS
6 and drug companies that effectuate 340B discounts, the covered entities could claim a breach of
7 contract.

8 The Supreme Court was not persuaded by this creative recasting of the *Astra* plaintiffs’
9 claims. The Supreme Court rejected as “incompatible with the statutory regime” the covered
10 entities’ efforts to sue to enforce 340B requirements. *Id.* “Congress vested authority to oversee
11 compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered
12 entities.” *Id.* at 117. Although plaintiffs there focused on the contractual provisions to which the
13 drug manufacturers had agreed in order to access the Medicaid and Medicare Part B programs, the
14 Supreme Court explained that the legal theory mattered not, in light of the evident
15 “incompatibility of private suits with the statute Congress enacted.” *Id.* at 121; *see also id.* at 120
16 (“Far from assisting HHS, suits by 340B entities would undermine the agency’s efforts to
17 administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis,” and
18 create a “substantial” “risk of conflicting adjudications”).

19 In reaching this conclusion, the Supreme Court reiterated that Congress had provided an
20 alternative administrative process in which to resolve disputes under the 340B Program.
21 Specifically, Congress had responded to reports of inadequate 340B Program oversight and
22 enforcement, not by authorizing private suits by covered entities, but instead by providing for the
23 establishment of an ADR process within the agency. *Astra*, 563 U.S. at 121-22 (citing 42 U.S.C.
24 § 256b(d)). “Congress thus opted to strengthen and formalize” the agency’s enforcement “to
25 make the new adjudicative framework the proper remedy for covered entities complaining of
26 ‘overcharges and other violations of the discounted pricing requirements,’” with the agency’s
27 resolution of ADR complaints subject to review under the APA. *Astra*, 563 U.S. at 121-22.

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

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

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

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

27 ¹¹ The Court further recognizes that some cases have since been filed by the drug
28 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

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

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

10 **B. Final Agency Action**

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

15 Plaintiffs do not persuade. "As a general matter, district courts are empowered to review
16 agency action by the [APA], 5 U.S.C. § 551 . . . [b]ut for a court to hear a case like this pursuant to
17 the APA, there must be '*final agency action* for which there is no other adequate remedy in a
18 court.'" *Mamigonian v. Biggs*, 710 F.3d 936, 941 (9th Cir. 2013) (quoting 5 U.S.C. § 704).

19 Subject-matter jurisdiction is thus lacking where an agency has yet to render any final decision.
20 *Id.* For an agency action to satisfy the finality requirement, "the action must mark the
21 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or
22 interlocutory nature. And second, the action must be one by which 'rights or obligations have
23 been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154,
24 177-78 (1997) (citations omitted); *see also, Winnemucca Indian Colony v. Dep't of Interior*, 819
25 F. App'x 480, 482 (9th Cir. 2020) (dismissal warranted because, at time complaint was filed,
26 agency "had not reached a final decision" on pending matter (quoting *Fairbanks N. Star Borough*

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28 jurisdiction given precedent and the plain language of the statute.

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

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

16 Plaintiffs further fail to demonstrate that HHS has unlawfully withheld agency action
17 under the APA. The definition of “failure to act” is coextensive with the inquiry under section
18 706(1) of agency action entitled “unlawfully withheld.” Such a claim “can proceed only where a
19 plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*.”
20 *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). Here, the plain language of the statute
21 does not include language which mandates the specific contemplated enforcement of the 340B
22 Program.¹³ Indeed, “Congress gave HHS a specific delegation of rulemaking authority to
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24 ¹² Indeed, as noted in the briefing and at oral argument, HHS is currently in transition to
25 the new Biden administration, as well as handling the national response to the ongoing
26 coronavirus (COVID-19) pandemic.

27 ¹³ To the extent that plaintiffs are arguing that HHS and HRSA is failing to enforce the
28 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*.

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

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

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

14 **C. Agency Discretion**

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

18 The Court agrees, at least at this juncture. In *Heckler*, the Supreme Court held “that an
19 agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a
20 decision generally committed to an agency’s absolute discretion.” 470 U.S. at 831. That doctrine
21 makes clear that, absent an unmistakable command from Congress directing how an agency will
22 exercise its enforcement authority, “an agency refusal to institute proceedings is a decision
23 committed to agency discretion by law within the meaning of [the APA].” *See id.* at 835 (citation
24 omitted).

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27 ¹⁴ The calculus would be different if, for instance, plaintiffs were challenging defendants’
28 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.

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

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

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

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

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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