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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE AMERICAN HOSPITAL ASSOCIATION,
800 Tenth Street, NW, Suite 400
Washington, DC 20001, *et al.*,

Plaintiffs,

–v–

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201, *et al.*,

Defendants.

Case No. 4:20-cv-08806-YGR

PLAINTIFFS' RESPONSE TO ORDER TO SHOW CAUSE, OPPOSITION TO DEFENDANTS' MOTION TO DISMISS, AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Hearing date: February 9, 2021
Time: 2:00 pm
Judge: Hon. Yvonne Gonzalez Rogers
Courtroom: Zoom Platform

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INTRODUCTION

Defendants Department of Health and Human Services and Acting Secretary Norris Cochran[1] (collectively, "HHS" or "the Department") contend that the Court must dismiss Plaintiffs' complaint for lack of subject-matter jurisdiction. *See* Defs.' Mot. to Dismiss ("Defs.' Mot."), ECF No. 64, at 10–19. But each of HHS's arguments—that the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County* bars this action, that there is no final agency action, that the Court may not interfere with the Department's enforcement discretion, and that there is no case or controversy because HHS and Plaintiffs agree on what the 340B statute requires of drug manufacturers—fails to address Plaintiffs' actual claims. Indeed, HHS misrepresents Plaintiffs' action as "a dispute between private parties under the guise of an injunction compelling the Secretary of Health and Human Services to take specified enforcement actions against drug companies." *Id.* at 1. In reality, Plaintiffs have brought a valid Administrative Procedure Act (APA) case against HHS for its failure to develop an enforcement policy to bring Eli Lilly and Company, Sanofi-Aventis U.S. LLC, AstraZeneca PLC, Novartis Pharmaceuticals Corporation, United Therapeutics Corporation, and Novo Nordisk, Inc. and Novo Nordisk Pharma (collectively, the "Drug Companies") into compliance with the law, as Congress has instructed.

Plaintiffs challenge a final agency action—HHS's decision that it lacks the authority to develop an enforceable policy with respect to the 340B statute's requirement that drug manufacturers offer 340B drugs at or below the 340B ceiling price to covered entities that dispense those drugs through contract pharmacies—and the Court need not interfere with HHS's enforcement discretion with respect

[1] Plaintiffs' complaint named Alex M. Azar II, in his official capacity as the Secretary of Health and Human Services, as a defendant in this action. *See* ECF No. 1. Acting Secretary Norris Cochran is former Secretary Azar's successor and is automatically substituted as a defendant pursuant to Federal Rule of Civil Procedure 25(d).

to what the contours of that policy should be, or what specific enforcement actions the Department should take against the Drug Companies engaging in unlawful practices. That HHS and Plaintiffs agree as to what the 340B statute requires of the Drug Companies only undergirds Plaintiffs' claim that the decision Plaintiffs challenge is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. HHS's misrepresentations of Plaintiffs' claims, Congress's directives, and Supreme Court precedent should be rejected.

For the reasons set forth below, Plaintiffs respectfully request that this Court deny HHS's motion to dismiss and grant Plaintiffs' motion for a preliminary and permanent injunction.

ARGUMENT

I. The Supreme Court's Decision in *Astra USA, Inc. v. Santa Clara County* Does Not Deprive Plaintiffs of the Right to Bring Their APA Claims Against HHS.

HHS insists that "[t]his suit is barred by unmistakable Supreme Court precedent," Defs.' Mot. at 9, but HHS mistakes that very precedent. Put simply, the Supreme Court held in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), that covered entities, to which the 340B statute does not provide a private right of action against manufacturers for alleged overcharges, may not bring that same private action simply by relying on the theory that they are intended beneficiaries of the manufacturers' form contracts with the government. The plaintiff in *Astra* operated 340B covered entities and brought suit against drug manufacturers for overcharging for 340B drugs under the theory that, although the 340B statute provided no private cause of action, the covered entities were third-party beneficiaries of the Pharmaceutical Pricing Agreements (PPAs) the drug manufacturers had entered into with HHS. *See id.* at 113.

The Supreme Court held that the plaintiff could not bring such a third-party-beneficiary breach-of-contract claim against the drug manufacturers, reasoning that "[i]f 340B entities may not sue [drug

manufacturers] under the statute, it would make scant sense to allow them to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute." *Id.* at 114. Critically, the Court explained that "[t]hough labeled differently, suits to enforce § 340B and suits to enforce PPAs *are in substance one and the same*." *Id.* at 114 (emphasis added). The Court did not go so far as HHS insists and "reject[] as 'incompatible with the statutory regime' the covered entities' efforts to sue [HHS] to enforce 340B requirements, regardless of the legal theory on which they based their claim." Defs.' Mot. at 4 (quoting *Astra*, 563 U.S. at 113). Indeed, if HHS's interpretation of the Supreme Court's opinion were correct, no plaintiff could bring an APA claim against an agency over its implementation of a statute unless the statute also provided a private right of action.

II. This Court Has Jurisdiction to Consider Plaintiffs' Challenge to HHS's Action.

A. HHS's Decision That It Does Not Have the Authority to Develop an Enforceable Policy Is a Reviewable, Final Agency Action.

The final agency action Plaintiffs challenge as a violation of the APA is HHS's decision that "HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute," and that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program." Email from Martin Kramer to Richard Sorian (July 8, 2020), https://www.340bhealth.org/files/HRSA_Response_on_Eli_Lilly_-_07-08-2020.pdf; *see also* Pls.' Mot. for a Prelim. and Permanent Inj. ("Pls.' Mot."), ECF No. 7, at 12; Compl., ECF No. 1, ¶ 58.[2] As to the first part of HHS's decision, the Department has granted the relief Plaintiffs requested by stating that 340B providers are legally entitled to distribute 340B drugs through contract pharmacies

[2] The Health Resources and Services Administration (HRSA) is the agency within HHS responsible for administering the 340B Program.

and that it would be a violation of the 340B statute for drug manufacturers not to offer 340B prices for 340B drugs to those 340B providers. *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* ("AO"), HHS, 1 (Dec. 30, 2020); Compl. ¶¶ 44–45.[3] But HHS has not wavered from the position that "without comprehensive regulatory authority, HRSA is unable to develop enforceable policy." HHS has never revoked that determination, developed an enforcement policy, or indicated that it is in the process of developing one. HHS's contention that there exists no final agency action for the Court to consider should therefore be rejected.

HHS does not contest that HRSA's determination that it lacks authority to develop an enforceable policy with respect to contract pharmacies meets the first prong of the test for whether an agency action is final, *i.e.*, that the decision "mark[ed] the consummation of the agency's decision-making process" and was not merely tentative or interlocutory in nature. *Gill v. Dep't of Justice*, 913 F.3d 1179, 1184 (9th Cir. 2019) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). HHS offers no indication—in its motion or otherwise—that the Department is continuing to consider the specific decision Plaintiffs challenge.

HHS claims that it is "actively investigating the matter," Defs.' Mot. at 11 (citation omitted), but the Department offers no information on what there is to investigate or what exactly it is investigating. After all, the pharmaceutical companies that have adopted the unlawful contract pharmacy practices have hardly concealed their conduct or wavered in their determination to continue the conduct deemed illegal by the HHS General Counsel.[4] HHS also claims in the same sentence to be

[3] Plaintiffs and HHS' agreement on what requirements the 340B statute imposes on drug manufacturers does not, as HHS argues, mean that there is no live case or controversy before the Court. *See* Defs.' Mot. at 17–19. As laid out below, Plaintiffs' challenge to HHS's decision that it lacks authority to develop enforceable policy with respect to the statute's requirements is properly before the Court.

[4] The Drug Companies' only defense is that they disagree with Plaintiffs and HHS's interpretation of the 340B statute. *See, e.g.*, Proposed Intervenor-Def. Eli Lilly & Co.'s Mot. to Dismiss, ECF No. 28-2, at 11–19; AstraZeneca LP's Mot. to Dismiss, ECF No. 35-2, at 16–17; Sanofi-Aventis U.S. LLC's

"working closely with each impacted covered entity," *id.* (citation omitted), but HHS has provided no affidavits supporting this claim nor challenging the assertion in the complaint that the Department "has not notified [the association Plaintiffs'] member hospitals that it has taken any action or intends to take any action to require the Drug Companies to issue refunds to hospitals," Compl. ¶ 61; *see also id.* ¶ 60 (because HHS had taken no action, Plaintiffs "Avera St. Mary's Hospital and [St. Mary's Medical Center] joined a letter to the Secretary signed by more than 1,100 340B hospitals stating that the Drug Companies' collective actions to deny access to 340B pricing are clear violations of the 340B statute and urging the Secretary to use his authority to end these practices"). Moreover, that HHS could, at some point, change its decision regarding the authority it believes HRSA has to develop enforceable policy with respect to the contract pharmacy issue does not change the fact that the Department's current decision is final. *See Ctr. for Biologic Diversity v. U.S. Bureau of Land Mgmt.*, No. CV 17-8587-GW, 2018 WL 3004594, at *10 (C.D. Cal. June 8, 2018) (that agency may later change its decision irrelevant to finality of agency action).

The Department's conclusion that it has no authority to adopt an enforcement policy is particularly indefensible after the HHS General Counsel's recent advisory opinion. As HHS notes, "since this suit has been filed, the General Counsel . . . [has] issu[ed] a strongly worded opinion explaining that 'to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price.'" Defs.' Mot. at 11 (quoting AO at 1). General Counsel Robert Charrow's opinion that "the 340B statute does not permit

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Mot. to Dismiss, ECF No. 38-3, at 10–13; Novo Nordisk Inc.'s Mot. to Dismiss, ECF No. 62-11, at 1–3.

manufacturers unilaterally to refuse discounted drugs to covered entities using contract pharmacies" has now "been set forth conclusively," *id.* at 9, and persuasively.

While the advisory opinion is consistent with HHS's past stance on how the 340B statute should be interpreted, *see* Compl. ¶¶ 44–45; Pls.' Mot. at 8, 17–18, it does nothing to establish the Department's enforcement *policy* with respect to covered entities' use of contract pharmacies and the statutory requirement that drug manufacturers offer those covered entities 340B drugs at 340B prices. In fact, the opinion's "[l]imitation[]" that "it does not have the force or effect of law," AO at 8, reinforces HRSA's earlier determination—which Plaintiffs challenge here—that "HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program," Compl. ¶ 58; Pls.' Mot. at 12.

HHS's determination that it lacks authority to develop enforceable policy also meets the second prong of the *Bennett* test for finality, *i.e.*, that the agency action is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Gill*, 913 F.3d at 1184 (quoting *Bennett*, 520 U.S. at 177–78). As outlined in Plaintiffs' motion for a preliminary and permanent injunction (Plaintiffs' motion), HHS's decision "prevented the agency from bringing actions against the Drug Companies, resulting in Plaintiffs' inability to purchase the Drug Companies' products at or below 340B ceiling prices despite having sought redress from HRSA." Pls.' Mot. at 20. HHS fails to respond to Plaintiffs' arguments and retorts only that "an abstract opinion on the scope of the agency's enforcement authority would not present a cognizable, concrete claim" between the parties "because no rights or obligations would be determined, and no consequences would flow, from the agency's belief regarding its own statutory authority." Defs.' Mot. at 12. But the legal consequences flowing from HHS's action—*i.e.*, the Department's determination that it lacks authority to develop enforceable policy vis-à-vis the statutory requirement that drug manufacturers offer 340B discounts whether or not

covered entities use contract pharmacies—are clear, and they are having an immediate and significant impact on the hospital Plaintiffs and the association Plaintiffs' members.

Every day that the Drug Companies continue to implement their unlawful contract pharmacy practices, Plaintiffs (or their members) are incurring higher expenses than they otherwise would if receiving 340B drug discounts, which is impacting the services they provide to vulnerable populations. *See* Pls.' Mot. at 24–25 (outlining irreparable harm Plaintiffs face due to HHS's action). HHS's determination that it lacks authority to develop an enforceable policy—a policy to enforce the 340B statute, which HHS correctly interprets to require the Drug Companies to offer the 340B drug discounts whether or not covered entities use contract pharmacy arrangements—had the legal consequence of requiring Plaintiffs to lose access to statutory discounts to which they are entitled under law, which is particularly difficult to manage while the pandemic is putting an enormous strain on hospitals' financial resources and accordant ability to care for their patients.

B. The 340B Statute Does Not Require Plaintiffs to Seek Resolution of Their Claims Through HHS's Newly Created Administrative Dispute Resolution Process.

HHS insists that Plaintiffs must seek resolution of their claims against the Department through the Administrative Dispute Resolution (ADR) process prior to seeking judicial review. This argument should be rejected, as the ADR process is intended to provide retrospective remedies, while Plaintiffs here seek forward-looking relief, and because Congress did not create an exhaustion requirement or jurisdictional bar to proceeding in court with a claim challenging a final agency action by HHS when it amended the 340B statute to instruct HHS to establish the ADR process to resolve certain disputes between covered entities and drug manufacturers. *See* 42 U.S.C. § 256b(d)(3); *see also Kerr v. Jewell*, 836 F.3d 1048, 1057–58 (9th Cir. 2016) (noting that "a statutory scheme precludes district court jurisdiction when 'it is "fairly discernible" from the statute that Congress intended [parties] appealing

covered agency actions to proceed exclusively through the statutory review scheme,'" and that "[i]n applying this standard, 'we examine the statute's text, structure, and purpose.'") (alterations omitted) (quoting *Elgin v. Dep't of Treasury*, 567 U.S. 1, 10 (2012)); *Charles Schwab & Co Inc. v. Fin. Indus. Reg. Auth. Inc.*, 861 F. Supp. 2d 1063, 1069 (N.D. Cal. 2012) ("In order to mandate exhaustion, a statute must contain 'sweeping and direct' statutory language indicating that there is no federal jurisdiction prior to exhaustion, or the exhaustion requirement is treated as an element of the underlying claim.") (alteration and citation omitted); *cf. also Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1034 (9th Cir. 2005), *abrogated on other grounds* ("[T]he mere fact that FIFRA recognizes EPA authority to suspend registered pesticides to protect listed species does not mean that FIFRA remedies trump those Congress expressly made available under [the Endangered Species Act], or that FIFRA provides an exclusive or primary remedy.").

Even if the 340B statute could plausibly be interpreted to require exhaustion of Plaintiffs' APA claims through the ADR process, Plaintiffs would be excepted from that requirement because of the significant practical effects that requiring exhaustion would have on Plaintiffs or their members. *See McCarthy v. Madigan*, 503 U.S. 140, 146 (1992), *superseded by statute on other grounds* (noting that "[i]n determining whether exhaustion is required, federal courts must balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion" and that "[a]pplication of this balancing principle is 'intensely practical'") (citation omitted); *see also id.* at 147 (noting that "prejudice may result, for example, from an unreasonable or indefinite timeframe for administrative action"); Pls.' Mot. at 24–25 (demonstrating immediate and irreparable harm to Plaintiffs, which grows daily). One need only look at what happened with Medicare appeals to get a sense of what could and likely would happen if Plaintiffs had to bring the instant claims first through the ADR process. Denied Medicare claims can be appealed through a

four-step administrative process, 42 U.S.C. § 1395ff, the third step of which is statutorily required to be decided within 90 days, *id.* § 1395ff(b)(1)(E)(i), (d)(1)(A). Yet by 2016, appeals at this third stage were taking *935* days, and the backlog of appeals had grown to more than 750,000. *Am. Hosp. Ass'n v. Burwell,* 209 F. Supp. 3d 221, 223 (D.D.C 2016).

Moreover, the ADR process is intended, as relevant here, to provide retrospective relief for drug company overcharges, *see* 42 U.S.C. § 256b(d)(3)(A) (requiring the development of the ADR process "for the resolution of claims by covered entities that they *have been overcharged* for drugs") (emphasis added), and is not an enforcement policy administered by the Department. The statute not only required HHS to take steps to ensure that covered entities received refunds, but it also specifically required HHS to provide for improvements in compliance in order *to prevent* such overcharges. *Id.* § 256b(d)(1)(A). In other words, while the ADR process may resolve how much each individual drug company owes each 340B entity for past overcharges, HHS also has the independent responsibility to bring the pharmaceutical industry into compliance with the law. HHS has a number of tools for accomplishing this duty: the biggest tool in the Department's arsenal is the ability to impose civil money penalties, which does not require the use of the ADR process and which has the potential to impact drug company conduct both through the notice of intent to impose penalties unless conduct conforms to the law, as well as the deterrent effect of the actual imposition of the penalties.

In any event, the ADR process is focused on addressing disputes regarding particular conduct by a particular company vis-à-vis one or more covered entities. *See, e.g.*, *id.* § 256b(d)(3)(B)(iii) (requiring HHS to "establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section"). The ADR process is no substitute for an enforcement policy that would address

and *prevent* illegal conduct by a sizeable segment of the pharmaceutical industry against 340B providers that use contract pharmacies.

C. The Relief Plaintiffs Request Would Not Interfere with HHS's Enforcement Discretion.

HHS argues that because "the APA provides no authority for this Court to enjoin the Secretary to take specific enforcement actions against pharmaceutical manufacturers," the Court must dismiss Plaintiffs' complaint. Defs.' Mot. at 14. But Plaintiffs have requested no such injunction; instead their challenge is to HHS's decision that it cannot develop an enforceable policy for bringing the Drug Companies into compliance with the 340B statute's requirements. On December 30, 2020, HHS's General Counsel correctly interpreted the 340B statute to require drug manufacturers to offer 340B drugs to covered entities at 340B prices regardless of whether they dispense those drugs via contract pharmacies, and HHS has the authority to develop an enforcement policy to bring the Drug Companies into compliance with the statute so interpreted. Plaintiffs have not requested an injunction that would direct HHS as to the content of that enforcement policy or as to how HHS would enforce the 340B statute with respect to individual drug companies, and therefore the relief Plaintiffs have requested would not interfere with HHS's enforcement discretion.

III. HHS's Failure to Develop an Enforcement Policy to Address the Drug Companies' Illegal Refusal to Provide 340B Discounts for Drugs Dispensed at Contract Pharmacies Is Agency Action Unlawfully Withheld or Unreasonably Delayed.

If this Court were to find that there has not been final agency action by HHS, then it should find that the Department's failure to issue a final decision regarding the legality of the Drug Companies' practices violates the APA's prohibition on "unlawfully withheld or unreasonably delayed" agency action. 5 U.S.C. § 706(1).

As originally enacted in 1992 (and to this day), the 340B statute requires in express terms that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs," and "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1); *see also Astra*, 563 U.S. at 118 (noting that these agreements "simply incorporate statutory obligations"). However, prior to passage of the Affordable Care Act (ACA), the HHS Office of Inspector General (OIG) issued multiple reports in which it identified serious problems with HRSA's oversight and enforcement of the 340B statutory requirements. *See* OIG, D. Levinson, Deficiencies in the Oversight of the 340B Drug Pricing Program, p. ii (OEI–05–02–00072, Oct. 2005); OIG, D. Levinson, Review of 340B Prices 11 (OEI–05–02–00073, July 2006).

The drumbeat of failures identified by the OIG led Congress in 2010 to add several important enforcement provisions to the 340B statute as part of the ACA. For example, Congress required the Secretary to "provide for improvements in compliance by manufacturers with the requirements of [section 340B] in order to prevent overcharges and other violations of the discounted pricing requirements specified in [section 340B]." 42 U.S.C. § 256b(d)(1)(A). Congress further directed HHS to adopt a number of measures to improve compliance by manufacturers, *including* measures to improve the accuracy and transparency of ceiling prices, procedures for refunds of overcharges, manufacturer audits, and civil money penalties on drug manufacturers for noncompliance. *Id.* § 256b(d)(1)(B). The amended statute required the Secretary to adopt "standards" for imposing civil monetary penalties, which were required "to be promulgated by the Secretary not later than 180 days after March 23, 2010." *Id.* Congress also directed HHS to, within 180 days, create an ADR process for covered entities and manufacturers, which could resolve claims by covered entities that they have been

overcharged, or claims by manufacturers (after the conduct of audits) that covered entities have violated the prohibition on duplicate discounts or diversion. *Id.* § 256b(d)(3).

HHS flagrantly violated these 180-day statutory deadlines. It missed the deadline for issuing the civil monetary penalty regulations by almost seven years and then delayed making the regulations effective for another two years. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563 (Nov. 30, 2018). Notably, HHS implemented the regulations only when forced to do so pursuant to a lawsuit brought by some of the plaintiffs in this case. *See* Joint Status Rep. & Stip. of Dismissal, ECF No. 36, *Am. Hosp. Ass'n v. HHS*, Case No. 1:18-cv-2112-JDB (D.D.C.). The agency missed the deadline for the ADR regulations by 10 years, a period during which the agency proposed a rule six years after issuing advance notice of proposed rulemaking, then publicly abandoned any effort to issue the final regulation one year later. *See* Office of Information and Regulatory Affairs Public Calendar at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90). HHS published the final regulations, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020), only after some of the Plaintiffs in this lawsuit and others had repeatedly pressed HRSA and HHS officials to address the Drug Companies' clear violations of section 340B with respect to contract pharmacies, *see* Compl. ¶¶ 57–62; Pls.' Mot. at 11–14, and after yet more lawsuits had been filed, *see Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C.); *Nat'l Ass'n of Cmty. Health Centers v. Azar*, 1:20-cv-3032 (D.D.C.).

In implementing the enforcement and compliance provisions mandated by Congress, HHS's consistent course of action has been not to act until forced to do so by a lawsuit. HHS's latest failure, which Plaintiffs seek to have addressed in this lawsuit, is the failure, in the face of violations of the 340B statute by six pharmaceutical companies, to develop an enforcement policy designed to improve

compliance and prevent overcharges, despite the statutory mandate to do so.[5] This violates the APA's prohibition on "unlawfully withheld or unreasonably delayed" agency action. *See* 5 U.S.C. § 706(1) (requiring courts to "compel agency action unlawfully withheld or unreasonably delayed").

Because the statute provided that HHS "shall" take steps "to prevent overcharges and other violations of the discounted pricing requirements" and bring the Drug Companies into compliance with the law, 42 U.S.C. § 256b(d)(1)(A), HHS was unequivocally compelled to take action. *See Vietnam Veterans of Am. v. Cent. Intel. Agency*, 811 F.3d 1068, 1075 (9th Cir. 2016) (citing *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63–64 (2004)); *see also Res. Renewal Inst. v. Nat'l Park Serv.*, No. C 16-688, 2016 WL 11673179, at *4 (N.D. Cal. July 15, 2016) (citing *United States v. Monsanto*, 491 U.S. 600, 607 (1989) (use of the term "shall" conveys that the duty to act is mandatory)). Likewise, HHS's nine- and 10-year delays in issuing and implementing the two statutorily required enforcement and compliance measures identified above provide no basis for confidence that HHS will adopt an enforcement policy with respect to the contract pharmacy violations, even where its General Counsel has recognized the violations. Since HHS's General Counsel has already conducted the necessary legal analysis and announced that the conduct by the pharmaceutical companies violates the law, HHS could adopt an enforcement policy with minimal use of agency resources, and these delays are unreasonable under the six-factor test adopted by the Ninth Circuit. *See Indep. Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997); *see also* Pls.' Mot. at 22–24.

HHS argues that Plaintiffs cannot rely on the APA's prohibition on "unlawfully withheld or unreasonably delayed" agency action because HHS has discretion as to whether to bring enforcement actions with respect to violations of section 340B. Defs.' Mot. at 13. While this principle applies to

[5] To date, HHS also has never used the civil money penalty provision, diluting its effectiveness as a deterrent against illegal conduct by pharmaceutical companies.

individual enforcement decisions, it does not apply here when a significant segment of the pharmaceutical industry is violating the law and HHS has unreasonably delayed acting. *See Soneji v. Dep't of Homeland Sec.*, 525 F. Supp. 2d 1151, 1155 (N.D. Cal. 2007) (rejecting government's argument that because immigration agency has discretion to grant or deny an application for permanent residence, it must therefore also have the discretion not to make a decision); *Adams v. Richardson,* 480 F.2d 1159, 1164 (D.C. Cir. 1973) (Department of Health, Education and Welfare may not neglect its responsibility to enforce school desegregation requirements).

HHS has ample discretion in deciding how its (thus far never-used) enforcement powers will be exercised. It does not have the discretion that it claims here, namely to indefinitely delay adopting any policy to address the egregious conduct of a sizeable segment of the pharmaceutical industry, nor does it have the discretion not to stop a major segment of the pharmaceutical industry from violating the statute in a manner that undermines the 340B program.

A factor making HHS's delay particularly unreasonable is the impact of the illegal conduct on countless 340B providers and the patients they serve. This delay has had and will continue to have serious consequences. As set forth in Plaintiffs' motion, the hospital Plaintiffs and other 340B providers cannot afford to continue to absorb the losses that are growing every day. *See* Pls.' Mot. at 22–23.

The only remedy for the delays caused by the deadlines missed and the Department's unwillingness to develop a comprehensive enforcement policy that "shall provide for improvements in compliance by manufacturers with the requirements of [section 340B] in order to *prevent* overcharges and other violations of the discounted pricing requirements specified in [section 340B]" is for this Court to order the Department to begin its process of developing an enforcement policy and report its progress to the Court. 42 U.S.C. § 256b(d)(1)(A) (emphasis added); *see also* Pls.' Mot. at 29.

IV. The Factors for a Preliminary and Permanent Injunction Are Met.

In opposing Plaintiffs' motion, HHS does not present an argument as to why Plaintiffs are unlikely to succeed on the merits. Moreover, in the General Counsel's advisory opinion, issued after Plaintiffs moved for preliminary relief, HHS essentially conceded half of the merits—*i.e.*, it agreed that the 340B statute requires drug manufacturers to provide 340B drugs at or below the ceiling price when dispensed through a contract pharmacy. AO at 1. The issue left for this Court to decide is whether HHS's decision that it does not have the authority to develop an enforcement policy to implement the 340B statute as interpreted is correct.

As Plaintiffs' motion demonstrates, that decision is arbitrary, capricious, and otherwise not in accordance with law because the Department *does* have the authority to develop an enforcement policy based on the 340B statute. While the General Counsel's advisory opinion that HHS issued after the filing of this lawsuit is a step in the right direction, HHS's claim that it has no authority to develop an overarching enforcement strategy—which could include, for example, directing the companies to comply or referring them to OIG for imposition of civil monetary penalties—is incorrect and has allowed the Drug Companies to avoid both the law and HHS's authority.

The second factor Plaintiffs must demonstrate for a preliminary injunction is irreparable harm. This means that the claimed harm must be "actual and imminent" and one "for which monetary damages cannot adequately compensate." *Conroy's, Inc. v. Hejazi*, No. C 06-1684, 2006 WL 8442694, at *3 (N.D. Cal. July 18, 2006). As demonstrated in Plaintiffs' motion, the Department's failure to act is already causing harm to covered entities, including Plaintiffs, and that harm is irreparable. Pls.' Mot. at 24–25. HHS argues that it is the Drug Companies that are causing the harm, not HHS, but it cites to no authority to support the argument that this is a basis for denying preliminary relief. Defs.' Mot. at 20. If HHS had developed an enforcement policy and if it had implemented the statute as interpreted

by its General Counsel, some or all of the six Drug Companies would likely have ceased or not initiated their unlawful, harmful practices. HHS cites no authority for the proposition that Plaintiffs must show that the government has directly caused the harm for a preliminary injunction to issue. HHS's position that it cannot develop a policy to enforce the statute, unless overturned by this Court, will cause the covered entities to continue to suffer harm.

As to the final factor—that the balance of equities favors Plaintiffs and a preliminary injunction is in the public interest—HHS's argument that the Court may not consider the demonstrated harm to public health and human welfare but instead should consider only "regularity and the proper functioning of administrative law," *id.* at 21, contorts this consideration beyond recognition. In any event, if the "proper functioning of administrative law" were a goal more important than public health, then granting a preliminary injunction would achieve that goal by ensuring that HHS is enforcing the 340B statute as Congress intended.

Additionally, contrary to HHS's assertion, the timing of Plaintiffs' lawsuit does not weigh against a preliminary injunction. Six months ago, there was only one company (Eli Lilly) and one drug (Cialis®) involved. HHS's failure to act emboldened Eli Lilly to expand its policy to all of its drugs, and HHS's continued failure to act emboldened the five other drug companies to jump on board, the most recent on December 1, 2020. Compl. ¶ 55. As each additional company joined Eli Lilly, the harm to covered entities grew and HHS's failure to act precipitated that harm. Throughout this period, Plaintiffs and other covered entities repeatedly petitioned HHS to take action to stop the Drug Companies, as well as reaching out to the Drug Companies directly to try to get them to cease their unlawful practices. *See id.* ¶¶ 52–53, 57–62. It was eminently appropriate for Plaintiffs to file this lawsuit only after their efforts to bring an end to these practices outside of court failed and when the harm HHS's inaction is causing reached a critical level.

Also contrary to HHS's assertion, a preliminary injunction at this stage would not provide the ultimate relief on the merits. The case the government cites to support its argument, *Senate of State of California v. Mosbacher*, 968 F.2d 974 (9th Cir. 1992), is inapposite. In that case, the California State Senate was seeking the release of census data. If the court had granted a preliminary injunction and released the data, there would be no way to undo that action. Here if the Court grants a preliminary injunction for Plaintiffs but ultimately rules for HHS, HHS could later continue its policy of doing nothing beyond the announcement by the General Counsel that the Drug Companies' practices are illegal.

In any event, this action is ready for a decision on the merits. As described above, this Court has jurisdiction over this matter, Plaintiffs meet all of the requirements for a preliminary injunction, and the questions raised by the parties are matters of law. Thus, Plaintiffs are entitled to entry of a permanent injunction pursuant to Federal Rule of Civil Procedure 65(a)(2). *See* Pls.' Mot. at 27–29.

HHS takes the position that there are factual issues to consider because the Drug Companies' practices are not identical. But the differences between those practices—which relate only to the extent to which each policy makes exceptions or imposes conditions pursuant to which covered entities are allowed to buy drugs at or below the 340B ceiling price when the drugs are dispensed through contract pharmacies—are irrelevant to Plaintiffs' claims. The problem with the Drug Companies' practices, as relevant to Plaintiffs' action against HHS, is that the companies are refusing to offer 340B drugs at 340B prices to covered entities that use contract pharmacies, whether the refusal is universal or through the imposition of conditions. And this is the unlawful act that Plaintiffs maintain HHS has the authority and obligation to stop. The scope of that authority and obligation is the legal question that is to be resolved by the Court.

CONCLUSION

For the reasons stated above, Plaintiffs respectfully request that the Court deny HHS's motion to dismiss and grant Plaintiffs' motion for a preliminary and permanent injunction.

Respectfully Submitted,
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