UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– THE DEPARTMENT HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Case No. 1:18-cv-2112

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO STAY

This action challenges Defendants' protracted delays in implementing 2010 amendments to 42 U.S.C. § 256b, which governs the program by which hospitals, community health centers, and other federally funded clinics that disproportionately serve the poor (known as "covered entities) are entitled to discounted prices on prescription drugs (the "340B Program"). On January 5, 2017, HHS promulgated the final rule to implement those amendments, which sought to increase the transparency, accuracy, and enforceability of 340B "ceiling" prices—the maximum rates that drug companies are permitted to charge 340B providers.

Plaintiffs previously consented to Defendants' request for an extension of time to respond to plaintiffs' motion for summary judgment. Instead of filing a response, on the day their opposition was due Defendants moved to stay further proceedings in this case, indefinitely, while HHS prepares a proposed rule that, Defendants state, "will propose that the 340B Drug Pricing Rule take effect January 1, 2019, rather than July 1, 2019." Mem. in Supp. of Defs.' Mot. for a Stay. ECF No. 15 (Oct. 15, 2018) ("Motion" or "Mot."). They argue that their proposed rule "would effectively provide plaintiffs with all of the relief they have sought." *Id.* at 4. But in fact,

as explained below, if the stay is granted there is a significant, and potentially high, risk that plaintiffs will receive *none* of the relief they seek.

In their motion for summary judgment, Plaintiffs have demonstrated that they are entitled to a judicial order requiring that the regulation promulgated in January 2017 be made effective within 30 days. Defendants should be directed to respond to Plaintiffs' motion promptly (Plaintiffs suggest within 7-10 days) so the Court can rule on the merits of this important case.

BACKGROUND

As explained in Plaintiffs' motion for summary judgment, Congress created the 340B Program in 1992 to provide covered entities with outpatient drug discounts comparable to those Congress had made available to state Medicaid agencies. In March 2010, Congress required the Secretary to "develop[] . . . a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers," and specifically directed HHS to issues regulations to implement the new statutory provisions. 42 U.S.C. § 256b(d)(1)(B)(i). On June 17, 2015, HHS issued proposed regulations, and on January 5, 2017, the Department issued a Final Rule. *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (the "Final 340B Rule").

The Final 340B Rule sought to improve the "integrity" of the 340B Program, as required by 42 U.S.C. § 256b(d), by (1) improving the accuracy of ceiling prices by adopting clear methodologies, such as the calculation of ceiling prices that are subject to statutory penalties when drug prices rise faster than inflation; (2) increasing the transparency of ceiling prices by requiring HRSA to publish them online; and (3) improving compliance by imposing civil monetary penalties when drug companies overcharge covered entities. 82 Fed. Reg. at 1,229-30.

The Final 340B Rule set an effective date of March 6, 2017, with enforcement to begin April 1, 2017. *Id.* at 1,210-11.

The effective date of the Final 340B Rule has since been delayed five times, most recently until July 1, 2019. 83 Fed. Reg. 25,943 (June 5, 2018). As set forth in Plaintiffs' Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judgment, ECF No. 2-1 (Sept. 11, 2018) ("Pls.' Mem.") at 9-10, Defendants' delay of the Final 340B Rule is arbitrary and capricious, an abuse of discretion, and is contrary to law, in violation of APA section 706(2)(A), and constitutes unreasonably delay in violation of APA section 706(1).[1]

After Defendants' most recent delay—a full additional year delay, after nearly a year and a half of shorter delays—Plaintiffs filed this action, on September 11, 2018. On September 26, Defendants requested, with Plaintiffs' consent, an extension of time to respond to Plaintiffs' motion for summary judgment, from September 28 to October 15 (ECF No. 14). In their motion, Defendants explained that the parties were already "discussing options for resolving this case that may obviate the need for the parties to finish briefing, and for the Court to decide, the summary judgment motion." ECF No. 14 at 1.

Those discussions failed. But instead of filing their opposition to Plaintiffs' motion for summary judgment, Defendants have moved for a stay or, in the alternative, a retroactive extension of their deadline to respond to Plaintiffs' summary judgment motion. Their stay/extension request is based principally on a commitment to issue a proposed rule that, according to Defendants, will—if approved by the Office of Management and Budget (OMB), if issued in proposed form, and if converted to final form after a proposed comment period with

[1] Defendants correctly note (Mot. at 3) that Plaintiffs have not challenged the four previous delays of the effective date of the Final 340B Rule. This reflects the recognition that those delays have come and gone—not a view that the delays were lawful.

sufficient time for a sufficiently long pre-effective-date compliance period—move the effective date of the Final 340B Rule to January 1, 2019. Mot. at 4. (Defendants state that the proposed rule "currently appears" on OMB's website, *id.* at 3 n.2, but the website contains only a note that the proposed rule has been submitted to OMB.)

ARGUMENT

I. Defendants' Motion to Stay Should Be Denied.

In 2010, Congress enacted vital improvements to the 340B Program, and directed HHS to issue regulations to implement those changes. Almost seven years later, in January 2017, HHS promulgated the final rule required by Congress, which was the culmination of years of policy and economic analysis and consideration of comments. As noted above, the Final 340B Rule (1) set forth a methodology for calculating ceiling prices; (2) required the publication of ceiling prices; and (3) set forth detailed standards for the assessment and imposition of civil monetary penalties for manufactures that overcharge covered entities. 82 Fed. Reg. 1,210.

Having declined to defend their unreasonable delay, Defendants offer as grounds for a stay a proposed rule, submitted this past Friday to OMB, to advance by six months the effective date of the Final 340B Rule, from July 1 to January 1, 2019. The submission of the proposed rule to OMB, however, is no basis for a stay—or for any delay of this litigation—for two reasons:

First, Defendants are not committing to issuing a final rule that moves the effective date up to January. Even if they were, there is no assurance that Defendants will succeed in their goal of issuing a final rule with an effective date of January 1, 2019, and it is unlikely that Defendants will reach this goal. Executive Order 12866 gives OMB 90 days to review a proposed rule, 58 Fed. Reg. 51,735 and 51,742 (Oct. 4, 1993), but even if OMB approves issuance of a notice of proposed rulemaking (NPRM) promptly, the agency will likely allow the standard minimum 30-

day comment period. (It has not indicated otherwise.) Thus, even if the NPRM were issued within a week of being submitted to OMB (October 22, 2018), the comment period would close November 21, 2018, leaving 12 days for preparation of the final rule, clearance through HHS, submission to OMB, and clearance by OMB, in order to allow a 30-day effective date. Defendants might be able to slightly shorten the comment period or the effective date (which would require a demonstration of "good cause," 5 U.S.C. § 553(d)(3)), but this timeline strongly suggests that it is unlikely that Defendants will be able to issue a final rule that is effective January 1, 2019.

A further complication is that, as Defendants point out, the 340B Program is organized principally on a quarterly basis. *See* Mot. at 2. Defendants have represented that if the effective date of the Final 340B Rule slips even a day past January 1, 2019, *none* of the Rule's changes to the program could be implemented until the beginning of the next quarter, which begins April 1, 2019. While Plaintiffs do not fully understand the basis of this claim and therefore do not agree to its validity, Defendants' position further supports Plaintiffs' request for an order directing that the rule be made effective within 30 days (or on January 1, 2019 if Defendants demonstrate that an earlier effective date is not feasible).

Second, no rulemaking is necessary in these circumstances. The Court can and should simply adjudicate Plaintiffs' claims and order Defendants to make the Final 340B Rule effective within 30 days.

II. The Court Also Should Deny Defendants' Alternative Request for an Extension of Time to Respond to Plaintiffs' Summary Judgment Motion.

In the alternative, Defendants argue that even if OMB's consideration of a proposed rule does not justify a stay, the Court should extend Defendants' time to respond to Plaintiffs' summary judgment motion pending resolution of Defendants' "planned" motion to dismiss,

which Defendants state is not due until November 13. Mot. at 1, 4. They do not, however, explain any of the grounds they intend to rely on in their "planned" motion. This alternative request should also be denied.

First, Defendants waited until the deadline for their summary judgment opposition to file a motion to extend their time to respond.

Second, if the proposed rule currently with OMB is not a basis for a stay, then there is also no basis for delaying adjudication of Plaintiffs' claims. The need for an expedited decision is precisely why Plaintiffs filed their summary judgment motion simultaneous with the filing of the complaint. The rules of this Court required Defendants to respond to plaintiffs' motion within 14 days, L.R. 7(b), and Plaintiffs agreed to the extension of time requested by Defendants.[2]

Third, although courts may defer summary judgment motions until defendants file responsive pleadings and the parties develop evidence through discovery, here there will be no discovery, and the facts are undisputed. *See* Pls.' Mem. at 13 n.6. Defendants have offered no valid reason for failing to respond to Plaintiffs' summary judgment motion so that the case may be decided now. If they believe there are grounds for a motion to dismiss (Defendants have identified none), then Defendants have the option of filing a motion to dismiss at the same time they file their opposition to Plaintiffs' motion for summary judgment.[3]

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[2] Defendants suggest that the fact that Plaintiffs did not seek a preliminary injunction somehow justifies staying the case. Mot. at 6. That is obviously a non-sequitur. While an injunction would have required, among other things, proof of irreparable harm that could not have been remedied by monetary damages, plaintiffs were entitled to file a motion of summary judgment in this case, and defendants are obligated to respond, so that the court may issue an expedited decision if it deems expedited action to be appropriate.

[3] For one or more of these reasons, the cases Defendants cite are beside the point. In several of them, the defendants had *already* filed motions to dismiss, so the Court could assess whether judicial economy militated in favor of addressing the asserted dismissal arguments first. *See, e.g., Freedom Watch, Inc. v. Dept. of State*, 925 F. Supp. 2d 55, 59 (D.D.C. 2013); *Furniture Brands Int'l v. U.S. Int'l Trade Comm'n*, No. 1:11-00202 (JDB), 2011 WL 10959877, *1 (April

CONCLUSION

Plaintiffs have been forced to wait for more than eight years for the benefit of regulations required by Congress to protect them from overcharging by drug manufacturers. Defendants' submission to OMB of a proposed rule—without any assurance that the Final 340B Rule will actually be implemented by January 1, 2019—is not a basis for a stay, and Defendants' other arguments for delay are meritless. The Court should deny Defendants' motion for a stay, and should order Defendants to respond to Plaintiffs' summary judgment motion within 7-10 days, to permit an expeditious resolution of Plaintiffs' claims.[4]

8, 2011). Here, Defendants have not filed a motion; and they have not even identified any arguments that they intend to raise in such a motion. In other of Defendants' cited cases, discovery was going to be necessary to decide whether there were material disputes of fact, *see, e.g.*, *Baginski v. Lynch*, 229 F. Supp. 3d 48, 57-58 (D.D.C. 2017), a circumstance with no relevance in this APA challenge. In the last category of cited cases, the case was *already* moot. *See, e.g.*, *Schmidt v. United States*, 749 F. 3d 1064, 1068 (D.C. Cir. 2014) (noting that "[a]ll parties . . . agree" that the only claim at issue on appeal had been "rendered moot").

[4] Both the 2010 amendments and the January 5, 2017 regulation require that HHS post the ceiling prices on a secure website available to the covered entities eligible for section 340B discounts. Plaintiffs recently learned that Defendants do not have a timetable for complying with this provision of the amendments, even if the final regulations were made effective on January 1, 2019. Plaintiffs' position is that Defendants should begin posting ceiling prices on the HHS website on April 1, 2019, at the latest. HRSA has had the funding for the IT system to post ceiling prices since 2014, and testified in July 2017 – fifteen months ago – that the system would be ready in "the coming months." *See* Pls.' Mem. at 23-24 (citing *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Transcript, at 47, 2017 WL 3104702 (Jul. 18, 2017)).

Dated: October 18, 2018

Respectfully submitted,

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