

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

THE AMERICAN HOSPITAL)	
ASSOCIATION, <i>et al.</i> ,)	
)	
Plaintiffs,)	
v.)	No. 1:18-cv-02112-JDB
THE DEPARTMENT OF HEALTH)	
AND HUMAN SERVICES, <i>et al.</i> ,)	
)	
Defendants.)	
_____)	

REPLY IN SUPPORT OF DEFENDANTS’ MOTION FOR A STAY

The Federal Rules of Civil Procedure afford federal defendants 60 days to respond to a complaint, making the response deadline November 13, 2018 in this case. That deadline is still several weeks off. Yet plaintiffs argue that defendants should respond to their early summary judgment motion almost immediately – i.e., before the deadline to respond to the complaint has even passed – because time is of the essence. Plaintiffs’ Memorandum in Opposition to Defendants’ Motion to Stay (“Stay Opp.”), ECF No. 16, Oct. 18, 2018, at 1-2. This need for speed seems to be a recent development. The challenged rule postponing the implementation of the 340B Drug Pricing Rule was issued on June 5, 2018. 83 Fed. Reg. 25,943 (June 5, 2018). Plaintiffs waited **98 days**, until September 11, 2018, to file their complaint and summary judgment motion. This long delay, along with plaintiffs’ failure to file a motion for a preliminary injunction, undercuts their argument that the facts on the ground demand the utmost expedition at the expense of both the government and the orderly resolution of this case. Rather, as defendants explained in their opening motion, the Court should stay this case pending the expected rulemaking, or in the alternative, stay briefing on plaintiffs’ summary judgment motion

pending resolution of defendants' planned motion to dismiss. Memo. in Support of Defendants Motion for a Stay ("Stay Mtn."), ECF No. 15, Oct. 15, 2018.

The Court should exercise its inherent power to stay the case in light of the expected rulemaking as it may provide the plaintiffs all of the relief that they seek, or at least narrow the issues for decision. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). HHS expects to issue a notice of proposed rulemaking that would propose a January 1, 2019 implementation date for the 340B Drug Pricing Rule. *See* <https://www.reginfo.gov/public/do/eoDetails?rrid=128548> (last visited Oct. 15, 2018) (notice indicating that the proposed rule has been sent to OMB for its review). This is the earliest that the rule could realistically take effect, given that changes to the program must be implemented on a quarterly basis. *See* 42 U.S.C. 256b(a); 77 Fed. Reg. 43342, 43343 (July 24, 2012). And even if, after the rulemaking and stay, there are some remaining disputes about the details of implementation, the Court will not have to unnecessarily resolve other questions (such as those about the propriety of the June 5, 2018 rule). Accordingly, a stay is warranted.

Plaintiffs oppose a stay based on the planned rulemaking, primarily because the expected rulemaking is not certain to moot the case. Stay Opp. at 4-5. They are right – it is not *certain* to moot the case. But defendants are not asking the Court to dismiss the complaint on mootness grounds. Defendants are simply asking for a stay to conserve the Court's and the parties' resources because of the potential that the rulemaking will obviate the need for the Court to address some or all of the issues presented in the litigation. And if the planned rulemaking does not fully moot plaintiffs' suit, then the litigation can be recommenced in several months, most likely with significantly fewer issues for the Court to resolve. Plaintiffs' delay in bringing this suit indicates that such a short delay would not prejudice plaintiffs.

Plaintiffs contend that it is unlikely that Defendants will finalize a rule with an effective date of January 1, 2019. Plaintiffs' position is speculative and undermined by the Agency's approach to previous changes of the effective date of the 340B Drug Pricing Rule: Defendants have used multiple mechanisms to quickly implement previous changes to the effective date of the rule. Plaintiffs argue that the agency will likely allow the standard 30-day comment period. Stay Opp. at 4-5. However, when timing was an issue, Defendants used a 15-day comment period for the most recent change of the effective date. 83 Fed. Reg. 20008, 2009 (May 7, 2018). On multiple occasions, Defendants have also invoked good cause exemptions to shorten required time requirements for previous changes to the effective date of the 340B Drug Pricing Rule. 82 Fed. Reg. 45511, 45512 (Sep. 29, 2017); 82 Fed. Reg. 22893, 22893 (May 19, 2017); 82 Fed. Reg. 14332, 14333 (Mar. 20, 2017).

To the extent plaintiffs are concerned about when drug pricing information will be made publicly available on an HHS website,¹ Stay Opp. at 7 n.4, the posting of information on the website cannot happen by January 1 regardless of whether the 340B Drug Pricing Rule is implemented by the agency or is ordered to be implemented by the Court. Before the Agency can post the information on its website, it must first receive pricing information from the Centers for Medicare & Medicaid Services. It must then collect the information from the manufacturers and verify that the correct calculations have been made. 42 U.S.C. 256b(d)(1)(B); 80 Fed. Reg. 22207, 22208 (April 21, 2015). Thus, there will be a time period that elapses between the effective date of the rule and the posting of verified drug pricing information on the website.

¹ 42 U.S.C. § 256b(d)(1)(B)(iii) (requiring the agency to provide "access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner . . . that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure").

Moreover, as the statute indicates, the Agency has to make sure that the website is secure to protect “privileged pricing data,” and, as such, has an obligation to ensure appropriate security protocols are in place. In short, given that the 340B Program operates on a quarterly basis, the 340B Drug Pricing Rule is not currently in place, and creating a new structure for collecting and securely posting drug prices takes time, plaintiffs’ suggestion that everything could be in place by January 1 with the Court’s intervention now is incorrect.²

In the alternative to a stay based on the expected rulemaking, the Court should stay briefing on plaintiffs’ summary judgment motion pending resolution of defendants’ planned motion to dismiss. As defendants explained in their opening brief, Courts often stay summary judgment briefing pending the resolution of motions to dismiss, as doing so facilitates the orderly resolution of the case in line with the Federal Rules of Civil procedure. Stay Mtn. at 4-6.

Plaintiffs offer two primary objections to this alternative, but neither is persuasive. First, plaintiffs argue that there is no justification for a stay because defendants have not specified the arguments that they intend to raise in their planned motion to dismiss, or yet made such a motion. Stay Opp. at 6 n.3. But filing a premature summary judgment motion should not entitle plaintiffs to a preview of defendants’ arguments, nor should defendants be forced to air arguments that are still being formulated and refined just because plaintiffs have jumped the gun.

² Plaintiffs seek to graft on the 340B Drug Pricing Rule a purpose that it was not intended to effectuate. The 340B Drug Pricing Rule satisfies the Agency’s statutory obligation to promulgate a rule addressing the calculation – rather than posting – of 340B ceiling prices. The 340B Drug Pricing Rule also provides clarity on the Agency’s statutory mandate to establish standards for the imposition of civil monetary penalties. The changes that would take effect under the 340B Drug Pricing Rule necessarily must precede any posting of 340B ceiling prices on a website. And, as the Agency stated in its rulemaking “[t]he development of the 340B ceiling price reporting system is proceeding under a separate [] [information collection request] process that is operational in nature and is not contingent on the specific provisions contained in this final rule.” 82 Fed. Reg. 1210, 1214 (Jan. 5, 2017).

Otherwise, plaintiffs would have an incentive to file such premature motions. And if the fact defendants had not yet filed a motion to dismiss were a serious consideration, then plaintiffs in future cases would have the incentive to file summary judgment motions as early as possible – i.e., with the filing of the complaint – to increase the chances of being able to argue that no stay is appropriate because no motion to dismiss has been filed yet. Indeed, the reason for the stay request is, in part, that the Federal Rules of Civil Procedure afford government defendants 60 days to formulate their response to the complaint, and a premature summary judgment motion should not speed up that clock in the absence of any compelling showing by plaintiffs. Moreover, defendants may raise threshold arguments that should be addressed before the Court reaches the merits questions presented in plaintiffs’ summary judgment motion.

Second, plaintiffs argue that “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.” Stay Opp. at 6. This is an overstatement. While there is a presumption against discovery on the merits in Administrative Procedure Act (“APA”) cases (because review is to be based on the administrative record), *see Camp v. Pitts*, 411 U.S. 138, 142 (1973), there is no such presumption against defendants taking jurisdictional discovery of plaintiffs in APA cases, *see Wildearth Guardians v. Salazar*, 2010 WL 2998667, at *1 (D. Colo. July 26, 2010). Plaintiffs’ claims of standing depend on their allegations that they have been overcharged for drugs.³ *See* Compl. ¶ 27; *NB ex rel. Peacock v.*

³ Whether plaintiffs are being overcharged is also important to plaintiffs’ claims that they have been denied access to information, Compl. ¶ 26, because standing to demonstrate an informational injury depends on a plaintiff showing that “it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure,” *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016).

District of Columbia, 682 F.3d 77, 82 (D.C. Cir. 2012) (describing standing requirements for prospective relief). Defendants may need jurisdictional discovery to test the factual bases of these allegations. The potential need for discovery on a threshold question militates against addressing plaintiffs' summary judgment motion prior to resolving defendants' planned motion to dismiss.⁴

Thus, for the reasons stated in defendants' opening memorandum and this brief, the Court should stay this case pending the expected rulemaking, or in the alternative, stay briefing on plaintiffs' summary judgment motion pending the resolution of defendants' planned motion to dismiss.

⁴ Plaintiffs argue that the timing of defendants' motion to stay, i.e., that it was filed on the deadline for responding to their early summary judgment motion, counsels against granting a stay. Not so. Whether a stay is appropriate depends on the Court's assessment of how best to facilitate the resolution of this case, not on the timing of defendants' motion for a stay. In any case, as defendants previously explained, Stay Mtn. at 1 n.1, they filed their motion on the day their opposition was due because they were negotiating with plaintiffs in an effort to resolve matters without contested briefing.

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Respectfully submitted,

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