

**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.)	
_____)	

MOTION FOR A STAY

Defendants hereby request that the Court (1) stay this case pending the outcome of the U.S. Department of Health and Human Services’ planned rulemaking that may moot the case or limit the issues to be decided by the Court, or in the alternative, (2) stay briefing of plaintiffs’ early summary judgment motion pending resolution of defendants’ planned motion to dismiss. A memorandum of points and authorities in support of this motion is attached.

Date: October 15, 2018

Respectfully submitted,

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Plaintiffs,)	
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_____)	

MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION FOR A STAY

Defendants – the U.S. Department of Health and Human Services (“HHS”) and HHS Secretary Alex M. Azar II, in his official capacity – hereby move for a stay of this Administrative Procedure Act (“APA”) case pending the outcome of a rulemaking that may moot the case or significantly narrow the issues to be decided by the Court. In the alternative, defendants ask that the Court stay the deadline to respond to plaintiffs’ early summary judgment motion (filed simultaneously with the Complaint) pending resolution of defendants’ planned motion to dismiss, which is due on November 13, 2018. A stay of the summary judgment briefing will ensure that defendants have sufficient time to first respond to the Complaint, including to raise any potential threshold defenses under Rule 12, in a case in which no motion for a preliminary injunction has been or could be filed claiming any irreparable injury. Defendants’ summary judgment response is currently due October 15, 2018.¹ Plaintiffs oppose this motion.

¹ Defendants are filing this motion on the deadline for their response to the summary judgment motion because, until Friday, October 12, 2018, the parties attempted unsuccessfully to negotiate ways to potentially obviate the need for contested briefing (in light of the Agency’s intent to conduct rulemaking on the precise issue raised in this case).

BACKGROUND

Congress created a program by which certain hospitals, community health centers and other federally funded entities serving low-income patients could receive drug discounts. The program is commonly known as the 340B Program, because it was created by section 340B of the Public Health Service Act. Drug manufacturers must offer their drugs for sale through the 340B Program in order to have their drugs covered through the separate Medicaid program. 42 U.S.C. 1396r-8(a)(1); 42 U.S.C. 256b(a). The 340B Program operates on a quarterly basis, *i.e.*, changes to prices and other conditions occur at the beginning of every quarter (January 1, April 1, July 1, and October 1). 42 U.S.C. 256b(a) (indicating pricing is done on a quarterly basis); 77 Fed. Reg. 43342, 43343 (July 24, 2012) (indicating registration of covered entities is done on a quarterly basis).

Congress modified the 340B Program in the Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, 124 Stat. 119 (March 23, 2010) (“Affordable Care Act”), 124 Stat. at 823-25 (codified at 42 U.S.C. § 256b(d)). More specifically, it instructed the Secretary of the Department to, among other things, “develop[] and publish[] through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices [*i.e.*, the highest price that can be charged for a drug under the 340B Program],” and “impos[e] . . . sanctions in the form of civil monetary penalties which . . . shall be assessed according to standards established in regulations promulgated by the Secretary.” 42 U.S.C. § 256b(d).

On January 5, 2017, the Department issued a Final Rule, with an effective date of March 6, 2017, to satisfy this statutory directive. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) (the “340B

Drug Pricing Rule”). The effective date of the Final 340B Rule has been delayed a handful of times over the ensuing 21 months, most recently to July 1, 2019. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 25,943, 25,945 (June 5, 2018).

On September 11, 2018, plaintiffs – entities that purportedly participate in the 340B Program and associations with members who are such entities – filed a complaint alleging that the most recent delay is arbitrary and capricious under 5 U.S.C. § 706(2), and that HHS has “unlawfully withheld or unreasonably delayed” agency action under 5 U.S.C. § 706(1). Compl. ¶¶ 57-62, ECF No. 1. Plaintiffs filed their summary judgment motion on the same day. See ECF No. 2. Plaintiffs did not file a motion for a preliminary injunction. Nor had they challenged in court any of the other delays in the preceding 21 months. After receiving a 17-day extension of time from the court, Minute Order, September 26, 2018, Defendants’ response to Plaintiffs’ summary judgment motion is now due October 15, 2018, but their response to the Complaint is not due until November 13, 2018, Fed. R. Civ. P. 12(a)(2).

ARGUMENT

The Court should exercise its inherent authority to control its docket to stay this case pending the outcome of an expected rulemaking² that could moot this case or narrow the issues to be resolved. *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936) (holding that court has the inherent authority to “control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants”). HHS intends to issue a notice of proposed rulemaking

² Indeed, the proposed rule currently appears on the website of the Office of Management and Budget, which is a precursor to publication in the Federal Register for public comment. See: <https://www.reginfo.gov/public/do/eoDetails?rrid=128548> (last visited Oct. 15, 2018).

by November 1, 2018, which will propose that the 340B Drug Pricing Rule take effect January 1, 2019, rather than July 1, 2019.³ This is the earliest that the 340B Drug Pricing Rule could take effect as a practical matter, given that program is designed for changes to take place at the beginning of a quarter, rather than in the middle of a quarter, and that the next quarter starts January 1.

Implementing the 340B Pricing Rule by January 1 would effectively provide plaintiffs with all of the relief they have sought in their Complaint, *see* Compl. at 19, ¶ B. (seeking as relief “[a]n order directing Defendants, within 30 days after judgement, to make the Final 340B Rule effective’), and thereby moot the case, *Schmidt v. United States*, 749 F.3d 1064, 1068 (D.C. Cir. 2014) (stating that a case is moot when “the court can provide no effective remedy because a party has already obtained all the relief that it has sought”) (brackets and quotations omitted). Even if there were lingering disputes after the 340B Pricing Rule goes into effect, the issues before the Court would be narrower, as the Court would not have to decide, for example, whether the challenged rule delaying implementation of the 340B Pricing Rule until July 1, 2019 was warranted or not.

In the alternative, the Court should stay the deadline to respond to plaintiffs’ early summary judgment motion until it resolves defendants’ planned motion to dismiss.

Nothing in Rule 56 requires the parties and the Court to press forward with a summary judgment motion prior to defendants’ having a fair opportunity to respond to the Complaint. To the contrary, while it is true that Federal Rules of Civil Procedure permit the filing of early summary judgment motions, the Advisory Committee notes for Rule 56 encourage courts to issue

³ Of course, HHS will not know the substance of the final rule until it has reviewed and considered the comments that might be submitted.

orders that will prevent the premature briefing of summary judgment motions filed at the commencement of a case: “Although the rule allows a motion for summary judgment to be filed at the commencement of an action, in many cases the motion will be premature until the nonmovant has had time to file a responsive pleading or other pretrial proceedings have been had. Scheduling orders or other pretrial orders can regulate timing to fit the needs of the case.” Fed. R. Civ. P. 56 advisory committee’s note (2010 amendments).

Indeed, Rule 12(b) “promotes the early and simultaneous presentation and determination of preliminary defenses.” 5B Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. § 1349 (3d ed. 2004). Adjudicating motions under Rule 12(b) thus helps to streamline the case by ensuring that “all available Rule 12 defenses are advanced before the consideration of the merits,” *George Wash. Univ. v. DIAD, Inc.*, No. CIV. A. 96-301-LFO, 1996 WL 470363, at *1 (D.D.C. Aug. 9, 1996), and to “produce an overall savings in time and resources as well as avoid delay in the disposition of cases, thereby benefiting both the parties and the courts.” Wright & Miller, § 1349; *see also Furniture Brands Int’l, Inc. v. U.S. Int’l Trade Comm’n*, 2011 WL 10959877, at *1 (D.D.C. Apr. 8, 2011), at *1 (Bates, J.) (“[S]uspending briefing of the summary judgment motion [pending resolution of defendants’ 12(b)(1) motion to dismiss] will allow the Court to manage the orderly disposition of this case.”). Plaintiffs should not be permitted to preempt defendants’ rights under Rule 12 by filing a premature summary judgment motion.

For these reasons, district courts routinely defer consideration of motions for summary judgment while dispositive motions to dismiss remain pending. *See, e.g., Furniture Brands Int’l, Inc.*, 2011 WL 10959877, at *1 (“[S]taying further briefing of the plaintiff’s summary judgment motion will allow the parties to avoid the unnecessary expense, the undue burden, and the expenditure of time to brief a motion that the Court may not decide.”); *Freedom Watch, Inc. v.*

Dep't of State, 925 F. Supp. 2d 55, 59 (D.D.C. 2013) (“Not needing more lawyers to spend more time on more briefs on more subjects in order to decide the motion to dismiss, the Court granted the motion to stay [summary judgment briefing.]”); *Baginski v. Lynch*, 229 F. Supp. 3d 48, 57 (D.D.C. 2017) (noting that it had “deferred” consideration of plaintiff’s motion for summary judgment “until it was able to assess the government’s motion to dismiss”); *Montgomery v. IRS*, No. 17-cv-918 (D.D.C. Nov. 6, 2017), Min. Order (staying summary judgment briefing until after resolution of threshold issues); *Cierco v. Lew*, 190 F. Supp. 3d 16, 21 (D.D.C. 2016), aff’d on other grounds sub nom. *Cierco v. Mnuchin*, 857 F.3d 407(D.C. Cir. 2017) (same); *Daniels v. United States*, 947 F. Supp. 2d 11, 15 (D.D.C. 2013) (noting that court stayed summary judgment briefing pending its ruling on motion to dismiss); *Angulo v. Gray*, 907 F. Supp. 2d 107, 109 (D.D.C. 2012) (same); *Magritz v. Ozaukee Cty.*, 894 F. Supp. 2d 34, 37 (D.D.C. 2012) (same); *Ticor Title Ins. Co. v. FTC*, 625 F. Supp. 747, 749 n.2 (D.D.C. 1986), aff’d, 814 F.2d 731 (D.C. Cir. 1987) (holding in abeyance plaintiff’s motion for summary judgment “pending resolution of threshold questions of jurisdiction and justiciability”).

Absent a stay, plaintiffs’ summary judgment motion would be an ersatz motion for emergency relief, but one that did not need to meet the stringent requirements for obtaining such extraordinary relief under *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Indeed, plaintiffs could not establish the prerequisites for emergency relief for a number of reasons, including that they could not demonstrate irreparable harm, having filed this suit over 18 months after HHS’s first delay of implementation and about three months after the most recent one. *Davis v. D.C. Child & Family Servs. Agency*, 2014 WL 12802260, at *1 (D.D.C. Aug. 19, 2014) (delay weighs against irreparable harm); *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 44 (D.D.C. 2000) (noting a two-month delay before seeking a preliminary injunction “militates against a

finding of irreparable harm”). In short, there is no reason to treat plaintiffs’ summary judgment motion as a “preliminary-injunction lite,” and defendants accordingly request that the Court order that summary judgment briefing be stayed pending resolution of defendants’ planned motion to dismiss.

CONCLUSION

For the reasons stated above, the Court should: (1) stay this case pending the outcome of HHS’s planned rulemaking that may moot the case or limit the issues to be decided by the Court, or in the alternative, (2) stay briefing of plaintiffs’ early summary judgment motion pending resolution of defendants’ planned motion to dismiss.

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