IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF JURISDICTION

INTRODUCTION

Plaintiffs filed a complaint challenging, under the Administrative Procedure Act (APA), the delay by U.S. Department of Health and Human Services (HHS or Department) in issuing the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (340B Drug Pricing Rule), 82 Fed. Reg. 1,210 (Jan. 5, 2017). The Complaint seeks declaratory relief and an injunction requiring the Department to implement the 340B Drug Pricing rule by January 1, 2019. Defendants filed a motion to dismiss on November 13, 2018,[1] and since then the Department has published a final rule in the Federal Register setting an effective date of January 1, 2019 for the 340B Drug Pricing Rule. The publication of this final rule moots all the relief requested in plaintiffs' complaint.

[1] Although the motion initially challenged plaintiffs' standing to sue, defendants no longer do so given plaintiffs' response.

Plaintiffs, however, also sought a mandatory injunction for the first time in their opposition to Defendants' motion to dismiss, namely, an order imposing an April 1, 2019 deadline for the publication of drug pricing information on a publicly accessible website, which publication is separately required by statute.

The Court should decline plaintiffs' new request. In addition to the fact that the case is moot and the requested mandatory injunction is outside of the Complaint, creating a publicly accessible website with about 50,000 drug prices and the necessary security provisions is no mean feat. And while the Department aims to have the website operational on April 1 and has devoted significant resources to achieving that goal, the final and near final preparations for launching the website are technically complex may reveal problems that had not previously been evident. Equity does not require the issuance of a mandatory injunction in these circumstances.

BACKGROUND

In their complaint, plaintiffs contend that the Department (i) acted arbitrarily and capriciously, in violation of the APA, 5 U.S.C. § 706(2), by issuing the June 2018 rule delaying the implementation of the 340B Drug Pricing Rule, *see* 83 Fed. Reg. 25,943 (June 5, 2018), and (ii) unreasonably delayed the issuance of the 340B Drug Pricing Rule under 5 U.S.C. § 706(1). Compl. ¶¶ 57-62. As relief, plaintiffs' complaint requests a declaratory judgment that the most recent delay is improper and an injunction "directing Defendants, within 30 days after judgement, to make the Final 340B [Drug Pricing] Rule effective." Compl., Prayer for Relief,

¶ B, at 19. In their Memorandum in Opposition to Defendants' Motion to Dismiss and Reply Memorandum in Support of Plaintiffs' Motion for Summary Judgment (Opp. and Reply), Nov. 21, 2018, ECF No., 26, plaintiffs sought, for the first time, an injunction requiring Defendants to publish pricing data on a publicly accessible website by April 1, 2019, *id.* at 19.

On November 30, 2018, after notice and comment, the Department published in the Federal Register a final rule establishing an effective date of January 1, 2019 for the 340B Drug Pricing Rule. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (Implementation Date Rule), 83 Fed. Reg. 61,563 (Nov. 30, 2018). The 340B Drug Pricing Rule "sets forth the calculation of the 340B ceiling price and application of civil monetary penalties." 82 Fed. Reg. at 1210.

Separately, Congress has directed the Department to provide "access through the Internet website of the Department . . . to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure." 42 U.S.C. § 256b(d)(1)(B)(iii). As the Department noted in the 340B Drug Pricing Rule, "[t]he development of the 340B ceiling price reporting system is proceeding under a separate ICR [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. at 1214 (Jan. 5, 2017); *see also* Reply in Support of Defendants' Motion for a Stay, Oct. 25, 2018, ECF No. 17, at 4 n.2.

In furtherance of the congressional directive to post pricing data on the website, the Department "developed the Office of Pharmacy Affairs Information System (OPAIS), a new, integrated information system that focuses on security, user accessibility, and data accuracy." Declaration of Krista Pedley, Director of the Office of Pharmacy Affairs, HHS, Dec. 3, 2018, ¶ 7 (attached as Exhibit 1). OPAIS is the platform on which the Department is building the drug pricing website, and "[a]fter several years of development and a significant financial investment in developing a functional and secure system, the OPAIS infrastructure has been completed." *Id.* ¶ 9. But significant work remains to be done to transform that basic infrastructure into a fully functioning, secure, and publicly accessible website with drug pricing data by April 1, 2019. Notably, the Health Resources & Services Administration, the component of HHS charged with developing the website, must obtain pricing data on approximately 50,000 drugs from 600 manufacturers, the Centers for Medicare & Medicaid Services (another component of the Department), and a third-party vendor. *Id.* ¶¶ 13-14. It must then verify the data to make sure that it is publishing the correct prices. *Id.* ¶ 18, 20. Moreover, the Department will have to work quickly, as it will not have all of the necessary pricing data until late February 2019. *Id.* ¶ 19. The Department will then have to ensure that these thousands of prices are correct and available – but only to entities entitled to access. *Id.* ¶¶ 5, 17.

ARGUMENT

A claim is moot if a plaintiff has "obtained all the relief that [it] sought" with respect to the claim. *Conservation Force, Inc. v. Jewell*, 733 F.3d 1200, 1204 (D.C. Cir. 2013). Plaintiffs' claim for an injunction requiring issuance of the 340B Drug Pricing Rule by January 1, 2019, is moot because, by virtue of the publication of the final Implementation Date Rule on November 30, 2018, 83 Fed. Reg. 61,563, the 340B Drug Pricing Rule now has an effective date of January 1, 2019 – and plaintiffs have obtained all of the relief that they sought with respect to their claim for an injunction. Moreover, plaintiffs' "request for declaratory judgment [does] not resuscitate" its claim. *Ctr. for Biological Diversity v. Tidwell*, 239 F. Supp. 3d 213, 226 (D.D.C. 2017). Because the controversy over the specific agency action challenged – here the delayed implementation of the 340B Drug Pricing Rule – is no longer live, the "declaratory judgment can no longer affect[ ] the behavior of the defendant towards the plaintiff," and plaintiffs' request for it too is moot. *NBC-USA Hous., Inc., Twenty-Six v. Donovan*, 674 F.3d 869, 873 (D.C. Cir. 2012).[2]

As noted earlier, in their most recent filing, plaintiffs – for the first time – ask for an order requiring the Department to publish pricing data on a publicly accessible website by April 1, 2019. This request is not in the Complaint. (Recall, website publication is not addressed by the 340B Drug Pricing Rule, because a separate information collection process is used to govern the implementation of the

[2] There are exceptions to this mootness principle, such as when a challenge to a specific action is moot but an ongoing underlying policy continues in effect, but none is applicable here.

website publication of pricing data, *see* 80 Fed. Reg. 22207, April 21, 2015.) Given that the complaint defines the limits of plaintiffs' case, *see* Fed. R. Civ. P. 8(a), *Fitz v. Commc'ns Workers of Am.,* 1989 WL 226082, at *10 (D.D.C. Aug. 17, 1989), and that a complaint cannot be amended in an opposition or reply brief, *e.g., Sai v. Transportation Sec. Admin.*, 326 F.R.D. 31, 33 (D.D.C. 2018), the Court should reject plaintiffs' request for an injunction directed to the website publication of pricing information.

Moreover, Federal Rule of Civil Procedure 54(c), which (with an inapplicable exception) permits courts to "grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings," does not support a contrary outcome. As plaintiffs have received all of the relief they requested, the case is moot, and the D.C. Circuit has concluded that the "possible availability of [ ] relief [under Rule 54(c)] would not . . . defeat mootness objections." *Hedgepeth ex rel. Hedgepeth v. Washington Metro. Area Transit Auth.*, 386 F.3d 1148, 1152 (D.C. Cir. 2004); *see also Fox v. Bd. of Trustees of State Univ. of New Yo*rk, 148 F.R.D. 474, 478 (N.D.N.Y. 1993) (noting that Rule 54(c) cannot "be used as a vehicle for reviving an otherwise moot action"). In any case, there is no possibility of relief under Rule 54(c), because the rule does not permit the court to award relief for new claims never raised. *USX Corp. v. Barnhart*, 395 F.3d 161, 165 (3d Cir. 2004) ("While inasmuch as the demand for relief does not constitute part of the pleader's claim for relief, a failure to demand the appropriate relief will not result in a dismissal, the converse is not true.") (quotation marks and brackets omitted from parenthetical).

Even if the Court concludes that granting the injunction regarding website publication lies within its discretion, it should decline to issue the injunction. "An injunction is a matter of equitable discretion; it does not follow from success on the merits as a matter of course." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008). Moreover, "[a] mandatory injunction, which requires an affirmative change to the pre-litigation status quo, is an extraordinary remedy, especially when directed at the United States Government." *U.S. Airline Pilot Ass'n v. Pension Benefit Guar. Corp.,* 2010 WL 3168048, at *1 (D.D.C. April 16, 2010).

The Court should not issue a mandatory injunction imposing an April 1, 2019 deadline because the Department is already committed to make every effort to publish pricing data on the website by April 1, 2019. *See, e.g.*, Pedley Decl. ¶ 21. But publishing drug pricing data on a publicly accessible website is no easy task. The website "will list approximately 50,000 ceiling prices from over 600 different drug manufacturers." Pedley Decl. ¶ 13. (The ceiling prices is the maximum allowable price for a drug as determined by statute and regulation.) Moreover, "[p]rior to publication of the 50,000 340B ceiling prices every quarter, the Department must verify each ceiling price, which requires the collection and comparison of [multiple data points] from several different sources." *Id.* ¶ 14. The Department will obtain average manufacture price (AMP) and unit rebate amount (URA) pricing data from the Centers for Medicare & Medicaid Services; AMP, URA, package size, and case package size data from manufacturers; and drug package size data from a third-party vendor. *Id.*

Also, as the Department will need to compile the data from CMS, the manufacturers, and the third-party vendor, and conduct a comparison across all 50,000 340B prices, "the validation process [will be] complex and require[ ] pricing data expertise." *Id.* ¶ 18. And to meet the April 1, 2019 target date, the process will have to be done quickly, because the Department will not have all of the pricing data until the end of February. *Id.* ¶ 19. A further time-consuming, required step is that the website must be secure, as Congress directed that ceiling price posting occur in a way that "limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure." 42 U.S.C. § 340B(d)(1)(B)(iii).

While HHS is striving to have the website ready by April 1, 2019, a number of things could go wrong with the system in the process of validating 50,000 prices using data from a number of sources (in the span of a month) and posting them a website that is both accessible and secure – especially the first time. For example, the process of reconciling differences in the data may take more time than the Department expects. Pedley Decl. ¶ 22. Or, for reasons outside of the Department's control, there may be disruptions in the receipt of necessary price data, e.g., manufacturers may make mistakes in transferring data or have their own technical problems. *See id.* ¶ 23. Or there may be unforeseen technical issues, given that the new system involves 270,000 lines of code and that "there may be unforeseen technical issues that do not reveal themselves until drug manufacturers begin reporting data." Id. ¶ 24.

In view of the Department's commitment to establishing the website and the challenges of doing so, equity does not counsel in favor of binding the Department to its April 1, 2019 target date via an injunction. HHS, part of a co-equal branch of government, should not be under the coercive effect of an injunction because a large and complex technical task that it is undertaking on the public's behalf is not ready exactly on April 1, 2019. *U.S. Airline Pilot Ass'n*, 2010 WL 3168048, at *1. On this score, it is useful to note that while the statute set a 180-day deadline for HHS's issuance of civil monetary penalty regulations, it did not establish a deadline for HHS to post the drug pricing information on a secure, publically accessible website. 42 U.S.C. § 256b(d)(1)(B)(iii). Congress evidently was aware of the challenges of setting up new and complex systems on tight deadlines. Indeed, much of the Department's work cannot be performed until it has all of the pricing data, which will not happen until the end of February. Thus, the same insight that likely swayed Congress from imposing a tight deadline on the creation of the website, should convince the Court to similarly eschew an injunction binding the Department to a tight deadline. Defendants accordingly request that the Court deny plaintiffs' request for a mandatory injunction setting an April 1, 2019 deadline.

CONCLUSION

For the reasons stated above, the Court should dismiss plaintiffs' action as moot, and, in any case, should, as a discretionary matter, decline to issue an injunction requiring the website publication of pricing data by April 1, 2019.

Date: December 3, 2018

Respectfully submitted,

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