

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC.,

Plaintiff,

v.

UNITED STATES OF AMERICA, *et al.*,

Defendants.

No. 21-cv-2608 (DLF)

**MOTION FOR EXTENSION OF TIME TO RESPOND TO COMPLAINT**

Defendants respectfully move for an extension of time to file their response to Plaintiff's Complaint for Declaratory and Injunctive Relief, ECF No. 1, which is currently due on December 17, 2021. *See* ECF No. 10. The grounds for this motion are as follows.

Plaintiff filed its complaint on October 6, 2021, challenging the Health Resources and Services Administration's ("HRSA") interpretation of drug manufacturers' obligations under the 340B Program, 42 U.S.C. § 256b. *See generally* ECF No. 1. In particular, Plaintiff claims that "HRSA's new policy prohibiting manufacturers from placing any conditions—including requiring production of basic claims data—on their offers to sell drugs to covered entities at the statutory ceiling price exceeds the scope of HRSA's statutory authority under Section 340B." *See id.* ¶ 83.

On November 5, 2021, this Court issued a joint memorandum and order in the related cases of *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C.), and *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C.). There, the Court vacated 340B violation letters issued by HRSA to two drug manufacturers and declared "that the conditions set forth in their new 340B policies are not prohibited by Section 340B on the grounds stated in the" violation letters—"namely that the statute's plain language, purpose, and structure prohibit manufacturers from imposing any conditions on their offers." *See Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C.), ECF Nos. 31

at 1–2, 32 at 20–21.

On or by December 8, 2021, Defendants intend to file a motion to stay the proceedings in this case to permit the Government sufficient time to decide whether to file appeals in *Novartis* and *United Therapeutics* and, if appeals are filed, to stay the proceedings in this case pending resolution of those appeals. Plaintiff has indicated that it intends to oppose Defendants’ stay motion. Defendants therefore respectfully request that the Court extend the deadline to respond to Plaintiff’s complaint until after the Court has resolved their forthcoming stay motion. Specifically, Defendants request that their response deadline be extended until three weeks after either (1) any stay is lifted or (2) the Court denies the stay motion—whichever is sooner.

There is good cause to grant this request. As they will explain in their forthcoming stay motion, Defendants believe a stay of the proceedings in this case is the most prudent course at this juncture. The disposition of any appeal in *Novartis* or *United Therapeutics* will likely be relevant to the Court’s resolution of Plaintiff’s claims in this case. Moreover, Plaintiff asks the Court to weigh in on the validity of drug manufacturers’ 340B policies that are currently subject to litigation pending in various courts of appeals and another district court, and seeks injunctive and declaratory relief that could impact that litigation if granted. *Sanofi Aventis US LLC v. U.S. Dep’t of Health & Hum. Servs.*, No. 21-3167 (3d Cir.); *Novo Nordisk Inc. v. U.S. Dep’t of Health & Hum. Servs.*, No. 21-3168 (3d Cir.); *Eli Lilly & Co. v. Becerra*, No. 21-3128 (7th Cir.); *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 21-cv-27 (D. Del.); *see also, e.g.*, ECF No. 1, at 33 (seeking “[a]n injunction barring Defendants from taking any enforcement action based on HRSA’s new policy on manufacturer conditions.”). If Defendants’ response deadline is not extended, they will likely need to begin working on their response to Plaintiff’s complaint before the Court has an opportunity to decide their stay motion, and thus would be denied a portion of the relief they seek in that motion. Additionally, this motion is Defendants’ first request for an extension of time in this case.

Undersigned counsel conferred with counsel for Plaintiff regarding this extension motion, and Plaintiff indicated it takes no position on the motion.<sup>1</sup>

For these reasons, Defendants respectfully request that the Court extend their deadline to respond to Plaintiff's complaint until three weeks after either (1) any stay is lifted or (2) the Court denies Defendants' motion to stay the proceedings in this case—whichever is sooner.

Dated: December 1, 2021

Respectfully submitted,

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<sup>1</sup> Plaintiff asked Defendants to include the following statement:

Plaintiff takes no position on the request by Defendants, as the Court is in the best position to determine whether this request will facilitate the Court's consideration of Defendants' forthcoming motion for a stay. Plaintiff does not believe a stay is appropriate here and will oppose that motion. Plaintiff is concerned about the importance of proceeding expeditiously in this case. Plaintiff believes it is being harmed by Defendants' position that no conditions may be asserted under the 340B program and that unnecessary delay in the resolution of this issue will increase the harm faced by Plaintiff.