

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

_____)	
NOVARTIS PHARMACEUTICALS)		
CORPORATION,)		
)		
<i>Plaintiff,</i>)		
)		
v.)	Civil Action No. 1:21-cv-1479-DLF	
)		
DIANA ESPINOSA,)		
in her official capacity as)		
ACTING ADMINISTRATOR, HEALTH)		
RESOURCES AND SERVICES)		
ADMINISTRATION)		
)		
and)		
)		
XAVIER BECERRA,)		
in his official capacity as SECRETARY,)		
UNITED STATES DEPARTMENT OF)		
HEALTH AND HUMAN SERVICES,)		
)		
<i>Defendants.</i>)		
_____)	

NOTICE OF DEFENDANTS’ RECENT ENFORCEMENT ACTION REFERRAL

Novartis respectfully provides the Court notice of the attached letter from HRSA, received yesterday, notifying Novartis that it has referred the company to the Office of Inspector General (OIG) for enforcement action relating to its 340B contract pharmacy policy. This is precisely the government action that Novartis sought to enjoin in its pending motion for preliminary injunction, which is scheduled for argument in October.

Procedural Background

A brief reminder of how we got here: In May 2021, HRSA took final agency action on Novartis’s 340B contract pharmacy policy by determining that it was unlawful. Novartis filed

this action shortly thereafter, and promptly sought a preliminary injunction to prevent “[d]efendants and any others in active concert or participation with them” from “taking enforcement or any other action against Novartis based on HRSA’s determination that Novartis’s 340B contract pharmacy policy violates the 340B statute and/or applicable regulations.” Text of Proposed Order, ECF No. 5-3 at 4. The Court set a hearing on Novartis’s preliminary injunction motion for July 28, 2021.

On July 15, after United Therapeutics filed a parallel lawsuit, the Court proposed that its decision on the preliminary injunction motion in this case be consolidated with a ruling on the parties’ cross-motions for summary judgment. July 15, 2021 Minute Order. Novartis agreed, but urged a quick hearing. ECF No. 20 at 2. Defendants instead urged delay, requesting “that the Court set a hearing to jointly consider the motions submitted by the parties in both cases at a date and time most convenient to the Court after the current briefing schedule in United Therapeutics is complete.” *Id.* at 3. After considering the parties’ positions, the Court rescheduled the hearing for October 12, 2021.

Defendants’ Conduct Is Improper and Subverts This Court’s Case Schedule

Rather than allowing the judicial process to play out on the new schedule that they urged and endorsed, Defendants have taken advantage of the postponed hearing date to refer Novartis to OIG for potential imposition of Civil Monetary Penalties—subverting both the pending preliminary injunction motion and the Court’s ability to hear and decide this dispute on a reasonable timeline. That is both procedurally improper and fundamentally unfair.

Novartis respectfully requests a telephonic status conference to discuss this development. Novartis also suggests that the government should rescind the OIG referral as to Novartis until at least such time as the Court issues a ruling on the pending motions. If the government is

unwilling to agree to that request, Novartis requests that the Court move up the hearing on its preliminary injunction motion to next week.

Respectfully submitted,

/s/ Catherine E. Stetson

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Counsel for Novartis Pharmaceuticals Corporation

Dated: September 23, 2021



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville, MD 20857

September 22, 2021

Mr. Dan Lopuch
Managed Market Finance
Novartis Pharmaceuticals Corporation
One Health Plaza, 135/4110F
East Hanover, New Jersey 07936

Dear Mr. Lopuch:

By letter dated May 17, 2021, HRSA instructed Novartis Pharmaceuticals Corporation (Novartis) to comply with its 340B statutory obligations and to immediately begin offering Novartis' covered outpatient drugs at the 340B ceiling price to covered entities that dispense the discounted medications through their contract pharmacy arrangements. HRSA informed Novartis that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties.

Given Novartis' continued refusal to comply,¹ HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.²

Sincerely,

/Michelle Herzog/

Michelle Herzog
Acting Director
Office of Pharmacy Affairs

¹ Novartis provided HRSA its basis for refusing to comply in a letter dated May 27, 2021.

² 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(a)