IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1479 (DLF)

RESPONSE TO THE COURT'S SEPTEMBER 23, 2021 MINUTE ORDER AND PLAINTIFF'S NOTICE OF DEFENDANTS' RECENT ENFORCEMENT ACTION REFERRAL

On September 23, 2021, Novartis Pharmaceuticals Corporation filed a notice informing the Court that the Health Resources and Services Administration ("HRSA") has referred Novartis's decision to no longer provide 340B-priced drugs to certain covered entities that intend to dispense those drugs to their patients through contract-pharmacy arrangements to the Department of Health and Human Services' Office of the Inspector General ("OIG"), to begin the process of determining whether to impose civil monetary penalties in light of these actions. Soon thereafter, the Court ordered Defendants to show cause why it "should not temporarily restrain [them] from bringing an enforcement action against [Novartis] until the October 12, 2021, Motions Hearing." For the following reasons, HRSA's referral of Novartis's actions to OIG for consideration of whether civil monetary penalties should be imposed is not final agency action and does not have any immediate impact on Novartis, much less cause it irreparable harm, and thus cannot warrant the extraordinary emergency relief of a temporary restraining order.

To begin, HRSA's recommendation that OIG investigate whether the imposition of CMPs is warranted triggers *no* adverse enforcement actions against Novartis. Rather, HRSA's referral is merely

the first step in a separate *investigatory* process that may be initiated and conducted by OIG; OIG is the component of HHS that has been delegated the authority "to impose sanctions in the form of civil monetary penalties against manufacturers that knowingly and intentionally charge a 340B covered entity a price for purchase of a drug that exceeds the maximum applicable ceiling price." 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210-01, 1356 (Jan. 5, 2017); *see also* 42 C.F.R. § 1003.150; 82 Fed. Reg. at 1220–21 ("HHS will [thus] defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' 340B drug overcharge based on the specific case being investigated."). The administrative process that OIG is required to follow before it may issue a final, effective decision imposing penalties on a manufacturer for knowing and intentional overcharges under the 340B Program cannot be completed in the 19-day period between now and the October 12, 2021 motions hearing.

This process is conducted "pursuant to the applicable procedures at 42 CFR part 1003." 42 C.F.R. § 10.11(a). Under these procedures, OIG must first conduct an investigation to evaluate whether a manufacturer's actions constitute knowing and intentional overcharges, in violation of its statutory obligation under 42 U.S.C. § 256b. And *if* OIG determines—after completing its investigation—that the manufacturer's actions justify the imposition of civil monetary penalties, the applicable regulations provide manufactures with the following procedures to challenge such an adverse decision:

First, OIG must provide the manufacturer with written notice of its "intent to impose a penalty." 42 C.F.R. § 1003.1500(a). That notice must include, among other things: (i) an explanation of the statutory basis for the penalty; (ii) a description of the specific violation; and (iii) OIG's rationale for why the violation subjects the manufacturer to a penalty. *Id.* Additionally, the notice must provide the manufacturer with instructions for providing a response to OIG's written notice and must inform the manufacturer that it has the "right to a hearing" before an Administrative Law Judge ("ALJ"). *Id.*

Second, a manufacturer has the right to request a hearing to be conducted by an ALJ pursuant to the trial-like procedures provided under 42 C.F.R. Part 1005. *See* 42 C.F.R. § 1005.2(a). Under these procedures, a manufacturer may be represented by an attorney, conduct discovery of documents, present relevant evidence, present and cross-examine witnesses, present oral argument, and submit written briefs and proposed findings of fact and conclusions of law. *See id.* § 1005.3; *see generally* 42 C.F.R. Part 1005.

Third, in the event that an ALJ issues an adverse decision against a manufacturer, the manufacturer may appeal that decision to the Departmental Appeals Board ("DAB") within 30 days (or 60 days, if permitted by the DAB). 42 C.F.R. § 1005.21. A manufacturer's request for review by the DAB automatically stays the effective date of the ALJ's decision and imposition of any civil monetary penalties. *Id.* § 1005.22(a). The DAB's decision "becomes final and binding" 60 days after the date on which the DAB serves the parties with a copy of its decision. *Id.* § 1005.21(j).

Fourth, and finally, in the event the DAB issues an adverse decision against a manufacturer, the manufacturer has 60 days from the date it was served with the decision to file a petition for judicial review in a United States Court of Appeals. *Id.* § 1005.21(k). If a manufacturer seeks judicial review, it may also request from the ALJ a "stay of the effective date of any penalty" while the penalty decision is pending judicial review. *Id.* § 1005.22(b)(1).

In short, HRSA's referral of Novartis's actions to OIG does not itself trigger any direct action (aside from the possible initiation of an investigation), much less an adverse enforcement measure against Novartis. And there is simply no conceivable way in which OIG, through the mandatory process described above, could impose a penalty on Novartis before the October 12, 2021 motions hearing. There is thus no cause for temporarily restraining this process in the interim.

Additionally, Novartis has not asked this Court for emergency relief and thus has not attempted to satisfy its burden to demonstrate that it is entitled to the "extraordinary remedy" of

emergency injunctive relief, which should never be "awarded as of right." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008). For one, Novartis does not—indeed, cannot—show that it will be irreparably harmed by HRSA's referral to OIG in the 19-day period between now and the October 12, 2021 motions hearing. As explained above, the governing regulations do not permit OIG to proceed through the necessary process to impose a final, effective penalty on Novartis in that two-and-a-half-week period. In fact, that Novartis is entitled to seek both administrative and judicial review (in the appropriate judicial forum) of any adverse decision by OIG forecloses any perceived claim of irreparable harm resulting from the mere initiation of OIG's investigatory process. In other words, if OIG were to complete its investigation *and* determine that imposition of CMPs were warranted *and* fail to reach resolution of such claim with Novartis, Novartis still would have a full and fair opportunity to challenge OIG's findings before an ALJ, then the DAB, and finally before a circuit court of appeals—demonstrating that no irreparable harm could occur. Moreover, Congress's choice to vest review of any final decision to impose CMPs in the courts of appeals means that this Court would lack jurisdiction to review any such decision even in the exceedingly unlikely event it were rendered while proceedings in this matter remain ongoing.

Setting aside the impropriety of emergency relief, it is also worth addressing Novartis's characterizations of the record. Contrary to what Novartis suggests, HRSA has been transparent from the beginning when it informed Novartis in the May 17, 2021 letter that its continued failure to comply with its obligations under the 340B Program could result in civil monetary penalties. Novartis was thus on notice since May that HRSA could refer its actions to OIG to begin the investigatory process of determining whether penalties should be imposed, which HRSA has done in the normal course of this administrative process. And HHS has been transparent in this litigation that the May 17, 2021 violation letters are the beginning of an agency enforcement process. The simple fact that Novartis has challenged in this litigation HRSA's determinations in the May 17, 2021 letter does not mean that

HHS must put a halt on its enforcement of the 340B Program. And there is no logic to Novartis's claim that HRSA's referral to OIG somehow affects this "Court's ability to hear and decide this dispute on a reasonable timeline." *See* ECF No. 26 at 2. On the contrary, OIG's investigation is a wholly separate administrative process and this Court lacks jurisdiction to review its final outcome even if that result is unfavorable to Novartis.

Even more, there is no merit to Novartis's assertion that Defendants "urged delay" of this Court's resolution of the motions now pending. ECF No. 26 at 2. Novartis and Defendants "*both* consent[ed] to consideration of Novartis's preliminary-injunction motion with an expedited ruling on the cross-motions for summary judgment." ECF No. 20 at 1 (emphasis added). Defendants agreed with the Court's initial determination that a joint hearing on the parties' motions with the motions pending in *United Therapeutics Corp. v. Espinosa*, 1:21-cv-1686-DLF (D.D.C.), could be "resolved most efficiently" if considered simultaneously. *Id.* at 2. And at that time, Defendants did not seek a modification of the briefing schedule in *United Therapeutics*, which had been set to be fully brief on August 31, 2021—a week before Novartis's "prefer[red]" joint-hearing date of September 8, 2021, and weeks before HRSA made its referral to OIG. *See id.*

In conclusion, there is no cause for this Court to grant extraordinary relief that Novartis has neither requested, briefed, nor supported. HHS thus respectfully asks this Court to proceed with the current schedule, whereby this fully briefed matter will be heard by the Court in 19 days.

Dated: September 23, 2021

Respectfully submitted,

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