

April 4, 2023

BY CM/ECF

Mark J. Langer, Clerk
United States Court of Appeals
for the District of Columbia Circuit
United States Courthouse, Room 5205
333 Constitution Avenue, N.W.
Washington, D.C. 20001

Re: *Novartis Pharmaceuticals Corp. & United Therapeutics Corp. v. Johnson*,
Nos. 21-5229 & 21-5304 (argued October 24, 2022)

Dear Mr. Langer:

We write to bring to the Court's attention an impending revision to Novartis's contract pharmacy policy.

The above-captioned appeal presents the legal question whether pharmaceutical manufacturers may impose restrictions on delivery of drugs purchased at the statutory 340B discount to covered entities' outside "contract pharmacies." In this and other appeals presenting the same issue (*United Therapeutics Corp. v. Johnson*, No. 21-5304 (D.C. Cir.); *Sanofi-Aventis U.S. LLC v. HHS*, Nos. 21-3167, 21-3380 (3d Cir.); and *Eli Lilly v. HHS*, Nos. 21-3128, 21-3405 (7th Cir.)), the Government uniformly maintains that the 340B statute prohibits *any* restrictions on contract pharmacy deliveries—and thus that each manufacturer's contract pharmacy policy, no matter its particulars, violates the statute.

Novartis announced on April 3 that it is revising its contract pharmacy policy, effective May 3, 2023. Novartis currently delivers units purchased by a hospital covered entity at the 340B price to any contact pharmacy within a 40-mile radius of that hospital covered entity. The revised policy states that Novartis will deliver units

purchased by a hospital covered entity at the 340B discount to the hospital covered entity's in-house pharmacy, or, if the hospital covered entity lacks an in-house pharmacy, to one designated contract pharmacy location. Federal grantee covered entities continue to be exempt; Novartis delivers and will continue to deliver units purchased at the 340B discount to any contract pharmacy of any federal grantee.

The revisions to Novartis's contract pharmacy policy mirror in material respect the policies of the manufacturers in *Sanofi-Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023), the ruling brought to this Court's attention by Rule 28(j) letter dated January 31, 2023, as well as the delivery policy of the other appellee in this consolidated appeal, United Therapeutics.

Because the Government's consistent position across this and the other appeals on the same issue is that *no* restrictions on contract pharmacy deliveries are permissible under the statute, Novartis's revised policy does not impact the legal arguments at issue in this appeal. Novartis nevertheless brings the impending policy revision to the Court's attention for its awareness.

Respectfully submitted,

/s/ Catherine E. Stetson
Catherine E. Stetson

Counsel for Novartis Pharmaceuticals Corp.

cc: All counsel of record (via CM/ECF)