

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et. al.,

Defendants.

Civil Action No. 21-00634 (FLW)

ORDER

NOVO NORDISK INC.,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et. al.,

Defendants.

Civil Action No. 21-00806 (FLW)

THIS MATTER having been opened to the Court by Sanofi-Aventis, U.S., LLC, through counsel Jennifer Lynn Del Medico, Esq., and Novo Nordisk, Inc., through counsel Israel Dahan, Esq. (collectively, “Plaintiffs”), on separate motions for summary judgment, *see* Case No. 21-634, ECF No. 62, Case No. 21-806, ECF No. 37; it appearing that Defendants United States Department of Health and Human Services and other governmental entities and officials (collectively, “HHS”), through counsel Kate Talmor, Alex D. Silagi, and Jody D. Lowenstein, Esqs., oppose Plaintiffs’ motions, and they cross-move for summary judgment, *see* Case No. 21-634, ECF No. 68, Case No. 21-806, ECF No. 45; it appearing that these matters involve three agency actions relating to 42 U.S.C. § 256b, commonly known as the 340B statute, which establishes discount drug prices

for safety-net providers: a December 2020 Advisory Opinion (“AO”), a December 2020 administrative dispute resolution procedure (“ADR Rule”), and May 2021 Violation Letters issued by HHS to both Plaintiffs; it appearing that because the parties’ motions in both above-captioned cases concern similar issues, the Court resolves these motions in this omnibus Order and the accompanying Opinion; it appearing that the Court having considered the parties’ submissions in connection with the motions pursuant to Fed. R. Civ. P. 78, for the reasons set forth in the Opinion filed on this date, and for good cause shown,

IT IS on this 5th day of November, 2021,

ORDERED that the parties’ summary judgment motions as to the AO are **DENIED** as **MOOT** in light of HHS’ decision to withdraw the AO and cease enforcement under it; and

ORDERED Plaintiffs’ summary judgment motions as to the ADR Rule are **DENIED**, and HHS’ respective motion on this issue is **GRANTED**; and

ORDERED that the parties’ motions as to the Violation Letters are **GRANTED in part and DENIED in part** as follows:

ORDERED that the following aspects of the Violation Letters are consistent with § 340B statutory scheme:

- i. a reasonable construction of the 340B statute permits contract pharmacy arrangements as a dispensing mechanism; and
- ii. Plaintiffs’ subject policies violate the 340B statute insofar as they impose conditions on offers related to contract pharmacy arrangements; and
- iii. HHS’s construction of the 340B statute regarding contract pharmacies is not a taking under the Fifth Amendment; and
- iv. the Violation Letters do not contravene the APA’s procedural requirements;

ORDERED that the Violation Letters are **VACATED** to the extent they seek to impose any fines and/or penalties against Plaintiffs for any overcharges, and the Letters are

VACATED to the extent they require Plaintiffs to remit any refunds to Covered Entities;
and it is further

ORDERED that consistent with the dictates of the accompanying Opinion, the
aforementioned vacated-aspect of the Violation Letters are **REMANDED** for further
consideration, and HHS shall determine whether the 340B statute permits multiple or
unlimited number of contract pharmacies; and it is further

ORDERED that the Clerk's Office is directed to **CLOSE** the above-captioned matters.

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge