

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

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

Defendants.

No. 3:21-CV-634

NOTICE

Defendants hereby respectfully notify the Court and other parties to this action that the United States Department of Health and Human Services' Office of the General Counsel has withdrawn Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program. *See* Notice of Withdrawal (June 18, 2021), attached as Ex. 1. It is Defendants' position that such withdrawal renders claims challenging the Advisory Opinion moot. In accordance with the Court's direction, however, Defendants will still address the impact of the decision in *AstraZeneca Pharmaceuticals LP v. Becerra, et al.*, No. 1:21-CV-27 (D. Del.) in its supplemental filing due June 24, 2021. As explained in Defendants' briefing, and in the attached notice of withdrawal, the Health Resources and Services Administration's ("HRSA") May 17, 2021 letter does not rest upon the Advisory Opinion, and HRSA's enforcement of the 340B statute against Sanofi is not affected by withdrawal of the Advisory Opinion.

Dated: June 18, 2021

Respectfully submitted,

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/s/ Kate Talmor

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Exhibit 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

NOTICE OF WITHDRAWAL
JUNE 18, 2021

***Withdrawing Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program
(issued December 30, 2020)***

The Office of the General Counsel (OGC) is withdrawing Advisory Opinion 20-06 (Opinion) in light of ongoing confusion about the scope and impact of the Opinion.

The Opinion has been challenged in lawsuits brought by various drug manufacturers. See *AstraZeneca Pharma. LP v. Becerra et al.*, 21-cv-27 (D. Del.); *Eli Lilly and Co. et al. v. Becerra et al.*, 21-cv-81 (S.D. Ind.); *Sanofi-Aventis U.S. LLC v. HHS et al.*, 21-cv-634 (D.N.J.); *Novo Nordisk Inc. et al. v. HHS et al.* (D.N.J.). The Opinion was never intended to do what plaintiffs in those suits allege: to create new, binding obligations on plaintiffs or to serve as the predicate for enforcement against those plaintiffs. As stated in the Opinion, it was meant to “set forth the current views of [OGC]” on the proper interpretation of the statute without “the force or effect of law.” Opinion at 8.

OGC maintains that the Opinion was not intended to impose new, binding obligations on regulated entities, and we respectfully disagree with the decision of the District Court in *AstraZeneca Pharmaceuticals*. However, in the interest of avoiding confusion and unnecessary litigation, OGC withdraws the Opinion.

OGC notes that its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA’s May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements. HRSA’s enforcement process operated independently from the issuance of the Opinion, and operates independently from the Opinion’s withdrawal.

Daniel J Barry

Daniel J. Barry
Acting General Counsel