



William B. Schultz
PARTNER
Zuckerman Spaeder LLP
wschultz@zuckerman.com
202-778-1820

January 7, 2021

VIA EMAIL

Thomas N. Kendris
President
Novartis Pharmaceuticals Corporation
1 Health Plaza
East Hanover, New Jersey 07936
thomas.kendris@novartis.com.

Elizabeth McGee
General Counsel
Novartis Pharmaceuticals Corporation
1 Health Plaza
East Hanover, New Jersey 07936
Elizabeth.mcgee@novartis.com

Dear Mr. Kendris and Ms. McGee:

We represent the American Hospital Association, 340B Health, the Association of American Medical Colleges, America's Essential Hospitals, National Association of Children's Hospitals d/b/a the Children's Hospital Association, American Society of Health-System Pharmacists, Avera St. Mary's Hospital, Riverside Hospital, Inc., d/b/a Riverside Regional Medical Center, and Dignity Health d/b/a St. Mary's Medical Center in a lawsuit filed in the Northern District of California against Secretary Alex Azar and the Department of Health and Human Services (HHS) challenging the Department's failure to enforce the statutory requirement that Novartis Pharmaceuticals Corporation (Novartis) and five other drugs companies provide 340B covered entities covered outpatient drugs at or below the 340B ceiling price when 340B drugs are dispensed from a contract pharmacy. *American Hospital Association et al v. Department of Health & Human Services et al.*, No. 3:20-cv-08806-YGR.

After the lawsuit was filed, the General Counsel of HHS issued an advisory opinion on December 30, 2020, in which the Department agrees with us that the 340B statute requires drug companies to provide 340B entities covered outpatient drugs at or below the 340B ceiling price when those covered entities use contract pharmacies to dispense the drugs. *See* Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program. Accordingly, Novartis's policy of not providing 340B discounts to 340B providers when Novartis's drugs are dispensed through

1800 M STREET NW, STE. 1000, WASHINGTON, DC 20036-5807 | T 202.778.1800 | F 202.822.8106

ZUCKERMAN SPAEDER LLP | WASHINGTON, DC | NEW YORK | TAMPA | BALTIMORE

Thomas N. Kendris
Elizabeth McGee
January 7, 2021
Page 2

contract pharmacies outside of a 40-mile radius is in clear violation of the statute, and Novartis should immediately discontinue its illegal practice. In addition, Novartis should reimburse 340B entities for the damages they have incurred due to Novartis's policy.

If Novartis continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties.

We look forward to your response.

Sincerely,



William B. Schultz
Margaret M. Dotzel