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VIA EMAIL

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Dear Mr. Lee and Mr. Siedel:

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 Sanofi-Aventis U.S. LLC (Sanofi) 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. The Department further explained that "neither the agency nor a private actor is authorized by section 340B to add requirements to the statute." *Id.* at 2. Accordingly, Sanofi's policy of requiring 340B covered entities to submit

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claims data for 340B prescriptions of Sanofi products filled through contract pharmacies and refusing covered entities that do not provide such claims data 340B prices on products filled through contract pharmacies is in clear violation of the statute, and Sanofi should immediately discontinue its illegal practice. In addition, Sanofi should reimburse 340B entities for the damages they have incurred due to Sanofi's policy.

If Sanofi 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