American Hospital Association™
Advancing Health in America

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August 21, 2020

Adam Gluck
Head of Sanofi U.S. and Sanofi Genzyme Corporate Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Gluck:

We are writing to express our profound concern about actions Sanofi is taking to collect data intended to limit the distribution of certain 340B drugs to hospitals and health systems. If allowed to continue, these actions, which violate statutory, administrative and ethical guidelines and principles, will negatively impact the ability of those hospitals that participate in the 340B program to care for vulnerable communities.

Your action to demand, on short notice, superfluous, detailed reporting on 340B drugs distributed through hospitals' contract pharmacies to limit the distribution of these drugs is both burdensome and unwarranted. The ostensible reason for these actions is to investigate whether Sanofi is providing duplicate discounts – one through the 340B program and another through a state Medicaid program. However, your company has not provided the targeted 340B hospitals with evidence to support the validity of such a concern nor has your company apparently explored less burdensome ways to obtain such information if this is, in fact, a valid concern.

It is an outrage that these actions are being taken at a time when hospitals are in the midst of their response to the COVID-19 public health emergency, which has further demonstrated the fractured, inadequate state of the prescription drug supply chain. Instead of supporting the hospitals caring for communities ravaged by the public health crisis, Sanofi is attempting to compel hospitals to divert critical resources away from the pandemic.

It is apparent that these actions are in direct conflict with the statute and the Health Resources and Services Administration's (HRSA's) 2010 guidance on contract pharmacy arrangements. By any reading, the 340B statute is clear that drug manufacturers participating in the Medicaid program must enter into agreements with

the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1] The implementing guidance from HRSA clearly notes that: "Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[2] That guidance also makes it clear that the 340B-covered entity is responsible for ensuring that the entity meets all requirements of the 340B program, including efforts to ensure against duplicate discounts and diversion, and HRSA then ensures participating entities' compliance through audits.

As further noted in the guidance, contract pharmacies were established and expanded to improve access to 340B drugs for vulnerable populations served by the 340B program. Nothing in the 340B statute or the HRSA guidance would allow a drug manufacturer to deny 340B pricing to a covered entity, or to require that a drug purchased by a covered entity be shipped only to locations that the manufacturer has approved on the basis of specious concerns about duplicate discounts.

We urge Sanofi to cease this conduct immediately and to work to ensure that 340B drugs are available and accessible to vulnerable communities and populations. 340B hospitals serve communities with a high volume of low-income patients. For a drug company to jeopardize hospitals' ability to care for patients who are already under severe economic, emotional and health-related strain during a public health crisis is unconscionable.

Please contact me if you have questions, or have a member of your team contact Molly Collins, director of policy, at (202) 626-2326 or mcollins@aha.org or Aimee Kuhlman, senior associate director of federal relations, at (202) 626-2291 or akuhlmanl@aha.org.

Sincerely,

/s/

Richard J. Pollack
President & Chief Executive Officer

[1] 42 U.S.C. 256b(a)(1)
[2] https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf