United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

May 24, 2011

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs. As senior members of the United States Senate and as Chairman and a senior member of the Committee, we have a special responsibility to the more than 100 million Americans who receive health care coverage under those programs to ensure that beneficiaries receive pharmaceuticals that are safe, effective, and affordable.

Also, as you know, there is an intense focus on entitlement reform in this Congress. Any effort to block cost savings in the Medicare Part D program is of great concern to the Committee.

On June 24, 2010, *The Wall Street Journal* reported that two medical groups and a Duke University professor with financial ties to Sanofi-Aventis (Sanofi) submitted letters to the Food and Drug Administration (FDA) in support of a citizen petition filed by Sanofi in 2003. Sanofi's citizen petition requested that the FDA delay approval of generic versions of the blood-thinner Lovenox. *The Wall Street Journal* reported that the professor and the two medical groups did not disclose their financial relationship with Sanofi in their letters to the FDA.[1] Lovenox sales totaled $2.9 billion for Sanofi in 2009.[2]

Accordingly, we requested and received records from Sanofi detailing its financial connections and communications with the North American Thrombosis Forum (NATF), the Society of Hospital Medicine (SHM), and Dr. Victor Tapson.[3]

As outlined in the staff report attached to this letter, the internal Sanofi documents suggest that medical societies and doctors with financial ties to Sanofi served as components of a

[1] Alicia Mundy, Groups Seek to Block Generic Heparin, *Wall Street Journal*, June 24, 2010.
[2] Thomas Gryta, *Momenta Shares Fall On Fear Of Teva Launching Generic Lovenox*, DOW JONES, January 25, 2011.
[3] Letter from Chairman Baucus and Ranking Member Grassley to Sanofi-Aventis, August 11, 2010.

coordinated public relations strategy to use FDA's citizen petition process to prevent or delay generic alternatives to its blockbuster drug Lovenox from coming on the market.

When there are questions or concerns about the safety of a drug, they ought to be raised and resolved in a timely and thorough manner. The citizen petition process is one way that individuals and entities can express their concerns and seek appropriate government action. However, when misused or abused, the process can lead to delays in patient access to potentially affordable, safe, and effective generic alternatives.

The Wall Street Journal article suggested that the medical groups and university professor may have been acting on behalf of Sanofi. For example, an email from the CEO of SHM to Sanofi states:

> SHM has no history of making similar comments to the FDA or any government agency of this kind. While the Ec [Executive Committee] might be supportive they may feel this is not something that SHM has the expertise or knowledge to say much about.…That being said when something is important to any of our partners (like Sanofi) that we have a long term relationship with we want to give any issue that is important to our partner careful consideration.[4]

Patients can benefit from collaborations between pharmaceutical companies and physicians and medical organizations. However, to ensure accountability, these financial relationships ought to be disclosed to the public. For purposes of the citizen petition process, the public and the FDA should be informed of the connections between pharmaceutical companies and the non-profit groups that seem to be working on the companies' behalf. As Dierdre Connelly, the President of GlaxoSmithKline said in a speech last year, "Society expects our business to be conducted openly and transparently and in a way that does not create even a perception of inappropriate influence."[5]

A 2010 study conducted by the non-partisan Congressional Budget Office noted that generic drugs reduced costs for consumers and the Federal Government by roughly $33 billion in the Medicare Part D program in that year alone."[6] Every day that pharmaceutical companies successfully delay safe and effective generic alternatives to their brand name drugs by attempting to manipulate the citizen petition process is another day that Americans pay more for their drugs.

You recently spoke about the need to reform the FDA process for approving generic drugs. In light of the information presented in this letter regarding Sanofi's citizen petition effort, we would appreciate your response to the following questions:

1. Has FDA considered requiring organizations that submit letters to the FDA under the citizen petition process to disclose their financial relationships with entities affected by FDA's decision to grant or dismiss a citizen petition? If not, please explain why not.

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[4] Email from the CEO of the Society of Hospital Medicine Larry Wellikson to Sanofi's Rachel Couchenour, "FW:LMWH Safety Letter," June 27, 2008, SA-SFC-0000422.

[5] GlaxoSmithKline President Dierdre Connelly, CBI 8th Annual Pharmaceutical Industry Compliance Congress, January 24, 2010.

[6] Congressional Budget Office Summary, *Effects of Using Generic Drugs on Medicare's Prescription Drug Spending,* September 2010.

2. What steps has FDA taken to ensure the integrity and transparency of the citizen petition process?

Thank you for your attention to this matter. We would appreciate a response by no later than June 20, 2011.

Sincerely,

Charles E. Grassley

Max Baucus

Enclosure: Staff Report on Sanofi's Strategic Use of Third Parties to Influence the FDA