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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

May 13, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Hamburg:

Pursuant to Rules X and XI of the U.S House of Representatives, the Committee on Energy and Commerce is investigating management concerns at the Food and Drug Administration (FDA). Specifically, the Committee has questions about the circumstances surrounding the May 3, 2013, resignation of Acting Deputy Commissioner for Medical Products and Tobacco, Leona Brenner-Gati, M.D., and what her role has been at the FDA.

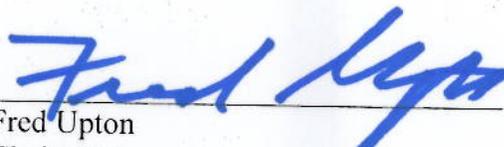
Since the week of February 18, 2013, through the last available listing in April 2013, the FDA's Public Calendar has listed Dr. Brenner-Gati as the Acting Deputy Commissioner for Medical Products and Tobacco with no significant meetings. However, the FDA posted on its website the FDA organizational chart approved and signed on March 4, 2013, by the FDA Reorganization Coordinator listing the position of Deputy Commissioner for Medical Products and Tobacco as vacant. Nevertheless, the Committee has another version of the FDA organizational chart approved and signed on March 4, 2013, by the FDA Reorganization Coordinator listing Dr. Brenner-Gati as the Acting Deputy Commissioner for Medical Products and Tobacco. Moreover, Dr. Brenner-Gati continued to be listed on the FDA's Public Calendar into April 2013, and the FDA web page for the Office of Medical Products and Tobacco last updated on March 22, 2013, listed Dr. Brenner-Gati as the Acting Deputy Commissioner for Medical Products and Tobacco. Several days before her resignation, Committee staff could not locate Dr. Brenner-Gati on the online HHS employee directory and she was not featured on FDA's leadership profiles. The discrepancies in FDA public information about the status of Dr. Brenner-Gati, and the lack of significant meetings held since she was appointed Acting Deputy Commissioner for Medical Products and Tobacco, raise questions about whether she was actively working in her position over the last two months, and the circumstances surrounding her resignation.

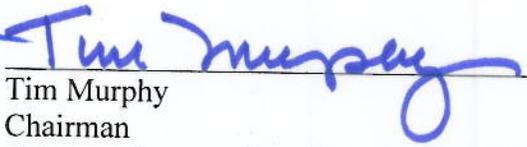
To determine the circumstances surrounding Dr. Brenner-Gati's resignation and her activities at the FDA, please provide the following by May 27, 2013:

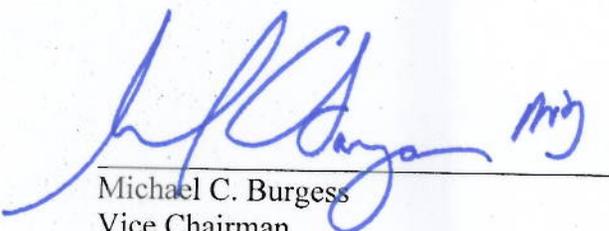
1. Was Dr. Brenner-Gati placed on administrative leave? If so, please explain when, why, and indicate whether she was paid during this leave.
2. What were Dr. Brenner-Gati's responsibilities as the Acting Deputy Commissioner for the Office of Medical Products and Tobacco? What were her accomplishments since she became the Acting Deputy Commissioner for the Office of Medical Products and Tobacco?
3. All documents related to Dr. Leona Brenner-Gati's financial disclosure report(s).
4. All documents from FDA ethics officials related to Dr. Leona Brenner-Gati.
5. All documents related to Dr. Leona Brenner-Gati's hiring for her positions at the FDA and her resignation.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,


Fred Upton
Chairman


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations


Michael C. Burgess
Vice Chairman
Subcommittee on Oversight
and Investigations

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations