ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 2, 2010

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

Dear Dr. Hamburg:

We are examining the medical device approval process at the Food and Drug Administration (FDA) known as the 510(k) process, which was established under the Medical Device Amendments of 1976. Under the 510(k) process, manufacturers must submit a 510(k) notification to the FDA at least 90 days prior to introducing a device to the market. A 510(k) submission is required for all devices intended for human use unless the device is exempt by regulation (in the case of many Class I & II devices) or is a higher risk Class III device that is subject to premarket approval (PMA) requirements. The device may only enter the market if the applicant receives clearance from FDA. The FDA will only clear an application through the 510(k) process if the Agency finds that the new device is substantially equivalent to a previously approved and marketed product.

While the 510(k) process is but one element of a complicated regulatory framework used by the FDA to ensure the safety and efficacy of medical devices, it is notable for its ability to encourage incremental improvement and innovation to proven technologies. Currently, 510(k) submissions are the means by which the vast majority of medical devices enter the U.S. market. For these reasons it is essential that the Committee continue to ensure that proper oversight is in place within the 510(k) program.

In recent months, your agency has taken steps with the clear intent of issuing new 510(k) guidance. On February 18, 2010, the FDA held its 510(k) meeting. On March 1, 2010, the Institute of Medicine (IOM), which has been tasked with or participating in the evaluation of the 510(k) process, held its first meeting on the subject. Committee staff has been told that FDA representatives have expressed a desire to have new guidelines in place before August 2010 and

implemented shortly thereafter. Curiously, these updates will come at least nine months prior to the issuance of the IOM report on the matter.

It is important to note that FDA has not submitted the statutorily mandated MDUFA performance report and has only just released its financial report on July 7, 2010, products that were due to our Committee in January 2010 under the Medical Device User Fee Amendments of 2007 (MDUFA II). Such data would seem to be a necessary and critical consideration in any review of the program.

We request that you provide replies and any relevant documents that explain, describe, or address the following issues: the regulatory concerns, market forces, and safety issues involved; what regulators feel should be addressed in the new guidelines; and where future guidelines may fall short in their ability to continue a workable 510(k) process. Please respond to the following in writing, with appropriate supporting documentation, within four weeks of the date of this letter:

1. The focus and findings of the review of the 510(k) program to date, including justifications for the areas of focus.

2. An accounting of any new guidelines regarding the 510(k) process, including the reasoning behind the need for the new guidance, how it would improve safety and efficacy, how it would enhance the predictability of the program for manufacturers and Agency reviewers, and how it would help the Agency meet MDUFA goals.

3. The status of the performance report due to the Energy and Commerce Committee per MDUFA II.

4. The impetus behind the issuance of new regulations prior to the release of the IOM report.

5. A complete analysis as to why the Agency is not meeting MDUFA performance commitments, specifically those related to PMA and 510(k) review goals. Further, is there any relationship between the pending guidance and the ability of the Agency to meet MDUFA goals?

Thank you in advance for your prompt attention to this timely matter. If you have any questions, or need additional information, please contact the Minority Committee staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member

Michael C. Burgess
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Henry Waxman, Chairman

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations