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

January 15, 2009

Via Electronic Transmission

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

As Ranking Member of the United States Senate Committee on Finance (Committee), I have a responsibility to the more than 80 million Americans who receive health care coverage under the Medicare and Medicaid programs to oversee the proper administration of these programs and ensure that taxpayer dollars are appropriately spent on safe and effective drugs and devices.

Almost four years ago, Senator Max Baucus and I initiated an inquiry into the Food and Drug Administration's (FDA/Agency) handling of a premarket approval (PMA) application for an implantable medical device for treatment-resistant depression. Our staff found, among other things, that a senior official in FDA's Center for Device and Radiological Health (CDRH/Center) approved the device after overruling the scientific evaluation of more than 20 FDA review and management staff who concluded that the data submitted by the manufacturer did not demonstrate a reasonable assurance of safety and effectiveness for approval.

I am again concerned about CDRH's handling of device reviews in light of a new report from the Government Accountability Office (GAO) issued today. The GAO's mandated report found that despite the passage of more than 14 years, the FDA has not yet completed the task of (1) reclassifying certain class III device types as class I or II devices or (2) requiring those devices to remain in class III before December 1, 1995, as instructed by Congress under the Safe Medical Devices Act of 1990. According to the FDA, class III devices are devices for which "insufficient information exists to assure safety and effectiveness solely through general or special controls." In addition, they are usually devices that are life-supporting or life-sustaining, are of substantial importance in preventing the impairment of health, or present a potential, unreasonable risk of illness or injury, such as pacemakers and heart valves. The new GAO report also says that the FDA has yet to issue regulations requiring device manufacturers to submit a PMA application for each class III device type on the market before May 28, 1976 that the FDA does not reclassify as class I or II. As a result, some "unreasonably" high risk medical devices may continue to be cleared by CDRH under FDA's less stringent 510(k) review process.

I am further concerned by serious allegations of misconduct and retaliation within the Center's Radiology Devices Branch in connection with the review of Computer Assisted Detection (CAD) devices for screening and diagnostic mammography. Last week, a group of FDA physicians and scientists wrote a letter to the Presidential Transition Team stating that "Managers at CDRH have ignored the law and ordered physicians and scientists to assess medical devices employing unsound evaluation methods" and "ordered, intimidated, and coerced FDA experts to modify scientific evaluations, conclusions and recommendations in violation of the laws, rules and regulation." I find such allegations very troubling, especially in light of the fact that more than four years ago I wrote to the Agency regarding similar allegations at FDA's Center for Drug Evaluation and Research.

It is my understanding that the physicians and scientists in CDRH communicated directly with you and other high level officials within the Agency about their allegations. These allegations include misconduct on the part of FDA employees and concerns regarding the safety and effectiveness of the new CAD devices being reviewed by the FDA. I also understand that the FDA's Assistant Commissioner for Integrity and Accountability, Mr. William McConagha, has been conducting an internal investigation of these allegations since last summer. According to a letter to Mr. McConagha dated October 20, 2008, the physicians and scientists stated that Mr. McConagha characterized the documentary evidence they provided to him as "'compelling,' 'convincing' and 'sufficient' to justify curative and disciplinary actions." Nonetheless, the letter also stated that the Center Director allowed management reprisals to continue by allowing the managers who allegedly engaged in misconduct to remove physicians and scientists from the Radiology Devices Branch and avoid any disciplinary actions or accountability.

Accordingly, I would appreciate a briefing for my Committee staff by no later than February 5, 2009, regarding the status of Mr. McConagha's review and any actions taken to date by the FDA in response to the allegations. In addition, I would appreciate FDA's response to the following questions and requests for information. Please repeat the enumerated question and follow with the appropriate response.

1. Please provide a copy of any report, evaluation or assessment documenting Mr. McConagha's findings and recommendations upon completion of his investigation.

2. Please provide a copy of all internal communications between the concerned FDA physicians and scientists and you, Mr. McConagha, the CDRH Director and other CDRH managers related to their allegations and the review of the CAD devices for the period of January 1, 2008 through January 14, 2009.

3. Please describe any actions and/or initiatives that FDA plans to take in response to the allegations and/or Mr. McConagha's recommendations.

4. Please describe any ongoing initiatives related to improving the administration and management of CDRH.

As part of my inquiry into these allegations, I rely on the Agency's employees as well as other sources to provide me with information that may be relevant to the matter. Senior officials in any government agency are expected to cooperate with legitimate Congressional oversight activities, not to impede Congressional inquiries, conceal information from Congress, or threaten employees who might speak out. Interfering with Congressional oversight hurts not only the agency, but also the American public.

It is also important that senior officials assure their employees that it is both acceptable and within their rights to speak to Congress, should they feel compelled to do so. With that in mind, I would like to remind you that FDA employees have a right to talk to Congress without interference and/or threats from the Agency and its senior officials. Furthermore, they have a right to talk to Congress confidentially.

I would also like to reiterate that interfering with a Congressional inquiry is against the law. I have attached a copy of 18 U.S.C. § 1505 to this letter for your reference. That law states in pertinent part that:

> Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress--
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> Shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

Additionally, denying or interfering with employees' rights to furnish information to Congress is also against the law. I have attached a copy of 5 U.S.C. § 7211 to this letter for your reference. That law states:

> The right of employees, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied.

Finally, federal officials who deny or interfere with employees' rights to furnish information to Congress are not entitled to have their salaries paid by taxpayers' dollars. The Consolidated Appropriations Act of 2008 ***(P.L.110-161, 121 Stat. 1844, 2023)*** states:

SEC. 717. No part of any appropriation contained in this or any other Act shall be available for the payment of the salary of any officer or employee of the Federal Government, who—

> (1) prohibits or prevents, or attempts or threatens to prohibit or prevent, any other officer or employee of the Federal Government from having any direct oral or written communication or contact with any Member, committee, or subcommittee of the Congress in connection with any matter pertaining to the employment of such other officer or employee or pertaining to the department or agency of such other officer or employee in any way, irrespective of whether such communication or contact is at the initiative of such other officer or employee or in response to the request or inquiry of such Member, committee, or subcommittee; or
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> (2) removes, suspends from duty without pay, demotes, reduces in rank, seniority, status, pay, or performance or efficiency rating, denies promotion to, relocates, reassigns, transfers, disciplines, or discriminates in regard to any employment right, entitlement, or benefit, or any term or condition of employment of, any other officer or employee of the Federal Government, or attempts or threatens to commit any of the foregoing actions with respect to such other officer or employee, by reason of any communication or contact of such other officer or employee with any Member, committee, or subcommittee of the Congress as described in paragraph (1).

Thank you for your attention to this important matter. In cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee. Please respond to the questions and requests set forth in this letter by no later than February 13, 2009.

Should you have any questions regarding this letter, please contact Angela Choy or Chris Armstrong of my Committee Staff at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131.

Sincerely,

Chuck Grassley

Charles E. Grassley
Ranking Member