ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

November 17, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Dear Dr. von Eschenbach:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been investigating the ability of the Food and Drug Administration (FDA) to protect the American public from unsafe food, drugs, and medical devices. As part of that inquiry, we have recently received compelling evidence of serious wrongdoing in connection with FDA's review, clearance, and approval process of medical devices. In particular, we are deeply disturbed by documents we received on October 14, 2008, from a large group of scientists and physicians working in the Center for Devices and Radiological Health (CDRH) who report misconduct within CDRH that represents an "unwarranted risk to public health and a silent danger that may only be recognized after many years."

These scientists make well-documented allegations that senior managers within CDRH "ordered, intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law." The CDRH scientists also state that CDRH managers ordered them "to make safety and effectiveness determinations that are not in accordance with scientific regulatory requirements, to use unsound evaluation methods, and accept clinical and technical data that is not scientifically valid or obtained in accordance with legal requirements, such as obtaining proper informed consent from human subjects."

These concerned CDRH scientists echoed the solemn statement of the November 2007 FDA Science Board that "the nation is at risk if FDA science is at risk." Specifically, they supplied substantial evidence demonstrating that medical devices submitted for FDA review to be used by millions of Americans have been reviewed and/or cleared or approved in violation of agency regulation and guidance mandated to assure safety and effectiveness.

Furthermore, the Committee has learned that physicians and scientists within CDRH who objected to the management practices described above have been subject to reprisals including removal or threatened removal and illegal or inappropriate employee performance evaluations.

We were accordingly gratified to learn of your decision to task Mr. William McConagha, the Assistant Commissioner for Integrity and Accountability, to investigate these allegations in response to a letter you received from many of these same CDRH scientists on May 31, 2008. We understand, however, that despite Mr. McConagha's assessment that the "documentary evidence is 'compelling,' 'convincing,' and 'sufficient' to justify disciplinary and curative actions," no action has been taken to address the serious concerns raised by CDRH scientists or the retaliatory behavior of CDRH managers toward those concerned FDA employees.

We further understand that Mr. McConagha may have already recommended to you that the seriousness of the charges and credibility of the evidence support removal of certain CDRH managers. Certainly, our preliminary witness interviews and document review confirm that sweeping measures may be necessary to address the distortion of science alleged by so many CDRH scientists. Consequently, we urge you to take seriously the allegations of the CDRH scientists and physicians and take the necessary immediate actions with respect to management, procedural and organizational changes necessary to assure the safety and effectiveness of medical devices and a restoration of FDA's mission.

To protect the CDRH scientists who communicated with this Committee from additional reprisal and mistreatment, we will not disclose their identities at this time. Nevertheless, you and CDRH managers are well aware of the parties involved. Accordingly, while it is not a matter of Committee policy or practice to promote the private rights of Federal employees, we would remind you and other managers within your office that, pursuant to 5 U.S.C. 2302 (b)(8), it is a violation of Federal law to retaliate against whistleblowers. That statute states:

"(b) Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority—

(8) take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of—

(A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences—

(i) a violation of any law, rule, or regulation, or

> (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety,
>
> ...
>
> (B) any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences—
>
> (i) a violation of any law, rule, or regulation..."

Further, the Committee requests that you immediately remind all managers within your office that, pursuant to 18 U.S.C. § 1505, it is a violation of Federal law to interfere with a congressional inquiry:

> "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..."

In addition, we would remind you that it is also against the law to deny or interfere with employees' rights to furnish information to Congress. Title 5 U.S.C. § 7211, provides that:

> "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, we request a briefing by Mr. McConagha no later than December 1, 2008, to inform this Committee of what actions you have already taken or intend to take in response to the allegations by CDRH scientists and physicians contained in the October 14, 2008, letter to this Committee (attached with redactions necessary to protect the identities of the signatories).

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations