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

April 21, 2009

Via Electronic Transmission

Joshua Sharfstein, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Sharfstein:

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. This responsibility requires oversight of the Food and Drug Administration (FDA/Agency), which is charged with ensuring the safety and efficacy of America's drugs and devices.

On February 10, 2009, former Acting Commissioner Torti issued a memorandum titled, "EEO, Diversity and Whistleblower Protection Policy Statement." This memo described the Agency's commitment to promoting a workplace free of harassment and retaliation. Dr. Torti assured FDA employees that "allegations of discrimination and harassment, including sexual and non-sexual, will be taken seriously by agency managers and will be immediately addressed. Appropriate corrective action – up to and including termination – will be taken if allegations are substantiated." Against the backdrop of this statement, I write to you about what appears to be a case of serious harassment and intimidation at the Agency.

Based upon materials received by my staff, Cindy Demian joined the FDA's Center for Devices and Radiological Health (CDRH) in December 1999, after receiving her Masters in Biomedical Engineering from Clemson University. In the following years, she earned and maintained an excellent personnel record and received high performance reviews and other awards. In 2001, Ms. Demian was selected as the lead reviewer of CDRH's "Reuse Project," which dealt with the reprocessing of single use devices. Working in the newly renamed Cardiac Electrophysiology and Monitoring Devices Branch (CEMB), Ms. Demian was under the supervision of CEMB's Branch Chief (Branch Chief), from the summer of 2002 until April 5, 2005.

During this time, and based upon the documents in my possession, the CEMB Branch Chief 1) referred to Ms. Demian and other female FDA employees as "b****es;" 2) criticized Ms. Demian's religious views; and 3) despite Ms. Demian's positive

performance evaluations, refused to submit the paperwork required for her grade level and step increases even after he was directed to do so by his supervisor, Dr. Donna-Bea Tillman in both 2003 and 2004.

As time progressed, and based upon the documents reviewed, the Branch Chief continued referring to the FDA female employees as "b****es," and increased his direct supervision of Ms. Demian. I understand that there then came a time that the Branch Chief went on to charge Ms. Demian with allegations of eavesdropping. Ms. Demian states further that she spoke to Dr. Tillman about the Branch Chief's activities and that Dr. Tillman failed to address the issues, later stating she "did not want to get involved." On September 21, 2004, Ms. Demian filed an EEO Informal Complaint against the Branch Chief.

On August 29, 2008, Administrative Law Judge Charles G. Shubow issued his Decision in the case. Judge Shubow concluded that:

1) The FDA promoted a hostile working environment when it was aware of the Branch Chief's actions and did nothing to address them;

2) Ms. Demian suffered a "consistent hostile environment permeated by derogatory comments and adverse employment actions on the basis of her sex," and;

3) The FDA "failed to provide legitimate, nondiscriminatory reasons for the [Branch Chief's] actions with respect to the terms and conditions of [Ms. Demian's] employment."

Judge Shubow confirmed in his Decision that by the Branch Chief's own admission, he openly referred to women (FDA employees and corporate sponsors) as "b****es," and that the FDA refused to correct this behavior. The Judge also found that there was no justification for the Branch Chief's disciplining Ms. Demian in the eavesdropping matter and evidence suggested these allegations were false.

Dr. Sharfstein, the settlement process that is used by the FDA rests squarely in the hands of the FDA. However, I am troubled by some of the representations made by Ms. Demian; namely that she must agree to terminate her position at the FDA and be barred from FDA employment for a minimum of five years as part of any settlement agreement. This is the case despite the fact that a judge determined that she was the victim. I am also troubled by what looks like a promotion received by the Branch Chief—he was allegedly promoted to an Acting Deputy Director position and had been designated as the CDRH Prefector for the Commissioner's Fellowship Program, a position in which one serves as a mentor to subordinates.

Ms. Demian's individual circumstances are troubling, but what is even more troubling is that it is alleged that this is not the first time that FDA has taken action against a victim of harassment while insulating and perhaps even rewarding the wrongdoer. Accordingly, I request that the FDA provide a briefing for my Committee

staff on the FDA's handling of these and similar allegations. In addition, and prior to such a meeting, please provide written responses to the following questions:

1) Does the FDA have any internal procedures for the filing of discrimination or retaliation complaints, and if so, what are those procedures? Please provide copies of those procedures for the past three fiscal years.

2) In addition to Dr. Torti's February memorandum, does the FDA have other documents related to the Agency's policies regarding the treatment of individuals found to have engaged in discrimination? If so, please provide a copy of the document(s) for the past three fiscal years.

3) After receiving a complaint from Ms. Demian, Dr. Donna-Bea Tillman "did not want to get involved." What is the FDA policy regarding complaints of discrimination and how is management instructed to respond?

4) Describe in detail the responsibilities of FDA managers who receive complaints of discrimination.

5) Describe the training that FDA managers have completed over the past three fiscal years related to the prevention of discrimination in the workplace.

6) Please provide a list of all complaints of discrimination lodged against the Agency either in a civil process or internally for the past three fiscal years.

    a. For each complaint, please describe the venue, the nature of the complaint, and whether the complaint was found to have merit.

    b. For each complaint found to have merit, please describe the settlement agreement and whether the complainant resigned as required by such agreement.

    c. For each complaint found to have merit, please describe what corrective actions were taken regarding the individuals accused of discrimination.

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. Therefore, I direct you to the provisions of law referenced in my previous letters to the FDA, including protections for federal employees who communicate with Congress, found in 18 U.S.C. § 1505 and 5 U.S.C. § 7211, as well as the Consolidated Appropriations Act of 2008.

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 May 8, 2009.

Should you have any questions regarding this letter, please contact Angela Choy or Christopher 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,

Charles E. Grassley
Ranking Member

Attachment