United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

January 31, 2012

VIA ELECTRONIC TRANSMISSION

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD, 20993

Dear Commissioner Hamburg:

I write to express my concerns over your agency's treatment of whistleblowers as a result of their disclosures to Congress, and specifically disclosures to my office. Whistleblowers point out fraud, waste, and abuse when no one else will, and while they do so while risking their professional careers, they are often treated like skunks at a picnic. Whistleblowers have played a critical role in exposing harmful government actions and retaliation against whistleblowers should never be tolerated. Thus, I am particularly concerned about the treatment of whistleblower P.J. Hardy by the Food and Drug Administration (FDA).

P.J. Hardy is one of nine FDA physicians and scientists that wrote a letter to the Presidential Transition Team in 2009 advising 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." A week after that letter was sent I wrote to FDA expressing my concern over such troubling allegations, especially in light of the fact that more than six years ago I wrote to the Agency regarding similar allegations at FDA's Center for Drug Evaluation and Research.

Shortly after P.J. Hardy sent the letter, the FDA asserted that Hardy may have engaged in criminal misconduct. The Department of Health and Human Service Office of Inspector General (DHHS OIG) reviewed the FDA's alleged complaint that Hardy released unauthorized information to the press and to Congress, specifically my office. In November 2011, DHHS OIG informed the FDA they were closing their investigation because the allegations made by the FDA could not be substantiated. Despite the fact that DHHS OIG found no evidence of criminal conduct, the FDA appears to have attempted to retaliate against P.J. Hardy for his protected disclosures to Congress. Prior to November 2011, Hardy scored as either Fully Successful or

Exception on his performance evaluations. In both November and December 2011, this changed drastically and his evaluation included vague comments such as "Needs most improvement in leadership, communication, professionalism, planning and judgment."

The FDA also began contacting outside entities to harm Mr. Hardy's reputation. In a May 5, 2011 memo to the Acting Director of the Office of Commissioned Corps Operations in the Office of the Surgeon General, Gregory Stevens, entitled "Misconduct of LTJG Paul J. Hardy," the FDA wrote:

> "CDRH management had concerns regarding the release of confidential classified information and began monitoring LFJG Hardy's government email account, along with others in the organization. I find the information received as a result of this monitoring to demonstrate a serious lack of character on the part of LTJG Hardy."
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> "Based on the information we are providing to your office, CDRH management cannot allow LTJG Hardy to continue to work in our organization. We simply cannot trust him."

The memo goes on to list several exhibits that "back-up" the agency's "lack of trust," including an October 15, 2010 email which states that P.J. Hardy sent an e-mail "on his government computer via his personal email account to an individual named Emilia, who appears to be a staffer for Senator Grassley." The e-mail goes on to say that, "LTJG Hardy's email to Emilia requests further investigation into FDA." It is clear that FDA was referring to Emilia DiSanto, my former Chief Investigator and that the agency actually did intercept emails with my staff.

That same day, the Public Health Service placed P.J. Hardy in a "Non-Duty with Pay Status," which forced him to surrender his employee identification badge and prohibited him from entering any FDA/DHHS facility. Consequently, P.J. Hardy appealed to the Merit Systems Protection Board. On October 7, 2011, the Office of Special Counsel (OSC) filed for a retroactive stay of the performance evaluation given by DHHS to P.J. Hardy due to a hindrance by the agency's "objection to our investigation and lack of cooperation."

On October 12, 2011, DHHS responded that P.J. Hardy is not an "employee" covered by the Whistleblower Protection Act (WPA) and therefore the OSC lacks jurisdiction to issue a stay. While Hardy was technically a Public Health Service employee, which is not technically covered by the WPA, at the time of his disclosures, he was detailed to the FDA and functioned as and FDA employee under FDA supervision. FDA employees are covered by the WPA. Therefore, not only did OSC support its initial ruling that FDA violated the WPA by threatening to take personnel actions against an "employee," the OSC strongly opposed DHHS's attempt to strip Hardy of his protected status. Ultimately, on November 23, 2011, the Merit System Personal Board terminated P.J. Hardy's stay.

It is troubling to me to see your Agency actively pursue the dismissal of an employee against the advice of the OSC - not because they violated procedure and leaked genuinely confidential classified information, but simply because you "cannot trust him." During your confirmation hearing in the Senate in 2009 you stated, "I think whistleblowers serve a very important role in

government in surfacing critical issues and concerns and making sure they're addressed. As leader of FDA, I would very much want to create a culture that enables all voices to be heard." The actions taken by your agency with respect to P.J. Hardy directly contradict your testimony. I ask that you honor your statements and ensure that all FDA employees feel comfortable expressing their opinion, both inside the Agency and to Congress.

Let me be clear. If your agency had concrete evidence of any criminal wrong-doing, by all means the Agency should exercise the right to monitor actions taken on government computers. However, the FDA had no evidence. In fact, the FDA heard from both the DHHS OIG and the OSC that P.J. Hardy acted in accordance with the law and within his whistleblower rights.

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. § 505 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 of2012 (P.L.112-74) states:

> SEC. 713. 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-
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> > (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

(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).

To help better understand this issue, please provide the answers to the following questions by February 17, 2012:

1. Who authorized the monitoring of all of the whistleblowers email accounts for communications with Congress?

2. Are any of the original nine FDA physicians and scientists that wrote the letter to the Presidential Transition Team in 2009 still employed by FDA? If not, please provide the circumstances surrounding each of their departures.

3. Did the FDA monitor all employee email accounts, including personal accounts, or was the monitoring targeted only at the nine whistleblowers?

4. Did FDA obtain the passwords to the employees' personal email accounts, which would allow emails to be intercepted even when not sent or received from a government computer?

5. Is FDA currently monitoring any employee email accounts? If so, please provide the circumstances surrounding the monitoring.

6. What steps have you taken to reassure employees that they have a right to have direct communications with Congress?

7. Does FDA have any procedures to ensure that Congressional correspondence remains confidential?

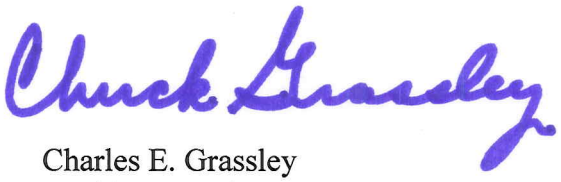
8. Please produce copies of all emails that were intercepted to or from my office by FDA.

9. To whom did the Agency give access to any email correspondence to or from Congress, and why?

10. Please provide all records relating to communications between FDA and iCAD Inc with respect to the release of confidential business information.

Thank you for your attention to this matter. Should you have any comments or questions, please do not hesitate to contact Erika Smith of my Committee staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on the Judiciary