Weinstein, Les S

From: Smith, John J. [JJSmith@HHLAW.com]
Sent: Tuesday, January 13, 2009 12:57 PM
To: Weinstein, Les S
Cc: Schultz, Daniel; Tillman, Donna-Bea; Ken Ferry; Darlene Deptula-Hicks; Stacey Stevens; Maha Sallam; John DeLucia
Subject: Discussion follow-up
Attachments: iCAD confidentiality letter 1_13_09.PDF; FDA Articles.pdf

Les, thanks again for your call earlier today. In follow-up to our discussion, I've attached a PDF of iCAD's letter to FDA concerning the potential release of confidential information by agency staff. I've also attached a PDF containing a series of media stories that strongly suggest that an unauthorized disclosure has occurred. These documents will be formally filed with the Document Mail Center letter today.

When you've had the opportunity to review this material, I'd appreciate the opportunity to further discuss this matter with you.

Again, we greatly appreciate your time and consideration.

Best regards,

John

JOHN J. SMITH, M.D., J.D., PARTNER
HOGAN & HARTSON LLP
Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004
direct +1.202.637.3638 | tel +1.202.637.5600 | fax +1.202.637.5910
jjsmith@hhlaw.com | http://www.hhlaw.com

Never stop looking™

iCAD

January 13, 2009

Les S. Weinstein
Ombudsman and Quality Assurance Manager
Center for Devices and Radiological Health (HFZ-5)
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Possible Disclosure of Confidential iCAD, Inc., PMA Application Information

Dear Mr. Weinstein,

I am writing to bring to the Food and Drug Administration's attention a possible serious breach of confidentiality concerning the Company's premarket approval applications on the part of an unknown individual or individuals at the agency. It was our intention to bring this matter to the attention of the agency's Integrity Officer but it is our understanding that the position is vacant at this time.

On Thursday, January 8, 2009, I was contacted by Ms. Jeanine Rader, the Director of Women's Health for Fujifilm Medical Systems USA, Inc., a company with which iCAD has partnered in regard to iCAD's SecondLook® Digital Computer-aided Detection for Mammography device (P010038). In our discussion, Ms. Rader related that Fuji had received a telephone call earlier that day from Gardiner Harris, an individual representing himself as a reporter from the New York Times. Ms. Rader noted that Mr. Harris was under the misimpression that "iCAD" was a Fuji device and was seeking Fuji's opinion concerning very specific questions on certain documents related to the approval of this "device" that had come into the possession of the New York Times. Ms. Rader indicated that Mr. Harris further implied that a member of Congress had intervened in this product's review process and had pressured an FDA official to support approval of the device. During the course of the conversation, it became apparent to Ms. Rader that Mr. Harris was referring to the approval of iCAD's SecondLook® device for use with Fuji's computed radiographic mammography system (P010038/S12). Accordingly, Mr. Harris was informed that iCAD was a separate corporate entity. Mr. Harris in turn indicated that he would contact iCAD regarding these documents and the SecondLook®.

98 Spit Brook Road, Suite 100 Nashua, NH 03062 USA
+1 866 280 2239 toll free +1 603 882 5200 phone +1 603 880 3843 fax
www.icadmed.com

Never stop looking™

iCAD

On Friday, January 9, I personally spoke with Mr. Harris by phone with Ms. Darlene Deptula-Hicks, our EVP and CFO, also present in the room during the conversation. In our discussion, Mr. Harris stated that he was in receipt of "internal FDA documents" that were sent to him by "Scientific Officers of the FDA." During the course of our conversation, Mr. Harris asked a number of questions that clearly reflected a depth of detail and knowledge that only would be known to either the Company or the FDA, and not generally available to the public. I can assure you that the Company has not disclosed this sensitive information to the New York Times, or to any other individuals or organizations outside of its business partners or attorneys, and only then with the appropriate confidentiality protections in place.

As you are aware, under 21 C.F.R. § 814.9, confidential information submitted to the agency as part of a premarket approval application or a supplement to that application cannot be released by FDA without the explicit permission of a PMA sponsor. From the discussion with Mr. Harris, I am deeply concerned that information concerning P010038/S12, and potentially other Company submissions, have been shared with the New York Times. Further, articles that have contemporaneously appeared in other media outlets suggest that the disclosure of this information may have involved organizations beyond the New York Times. I have attached a sample of these articles for your reference.

We appreciate your attention to this serious matter. Should you require any additional information, please do not hesitate to contact me.

Sincerely,

Ken Ferry

Ken Ferry
President and Chief Executive Officer

Cc: Daniel G. Schultz, M.D.
Donna-Bea Tillman, Ph.D.
John J. Smith, M.D., J.D.

98 Spit Brook Road, Suite 100 Nashua, NH 03062 USA
+1 866 280 2239 toll free +1 603 882 5200 phone +1 603 880 3843 fax
www.icadmed.com

Articles written by *Associated Press* and *Wall Street Journal* reporters specifically reference that the letter to the Obama transition team "singled out mammography computer-aided detection devices as an example of a technology that should not have gone forward." The *Associated Press* article has appeared in a number of national and international media outlets including *MSNBC* and the *Seattle Post Intelligencer.*

Please find below the full articles for your review.

FDA scientists complain to Obama of 'corruption'

By RICARDO ALONSO-ZALDIVAR

January 8, 2009

WASHINGTON (AP) — In an unusually blunt letter, a group of federal scientists is complaining to the Obama transition team of widespread managerial misconduct in a division of the Food and Drug Administration.

"The purpose of this letter is to inform you that the scientific review process for medical devices at the FDA has been corrupted and distorted by current FDA managers, thereby placing the American people at risk," said the letter, dated Wednesday and written on the agency's Center for Devices and Radiological Health letterhead.

The center is responsible for medical devices ranging from stents and breast implants to MRIs and other imaging machinery. The concerns of the nine scientists who wrote to the transition team echo some of the complaints from the FDA's drug review division a few years ago during the safety debacle involving the painkiller Vioxx.

The FDA declined to publicly respond to the letter, but said it is working to address the concerns.

In their letter the FDA dissidents alleged that agency managers use intimidation to squelch scientific debate, leading to the approval of medical devices whose effectiveness is questionable and which may not be entirely safe.

"Managers with incompatible, discordant and irrelevant scientific and clinical expertise in devices...have ignored serious safety and effectiveness concerns of FDA experts," the letter said. "Managers have ordered, intimidated and coerced FDA experts to modify scientific evaluations, conclusions and recommendations in violation of the laws, rules and regulations, and to accept clinical and technical data that is not scientifically valid."

A copy of the letter, with the names of the scientists redacted, was provided to The Associated Press by a congressional official.

"Currently, there is an atmosphere at FDA in which the honest employee fears the dishonest employee, and not the other way around," the scientists wrote.

FDA spokeswoman Judy Leon said in response: "We have been working very closely with members of the transition team and any concerns or questions they have on any issue, we will address directly with the team. Separately, the agency is actively engaged in a process to explore the staff members' concerns and take appropriate action."

Senior Democratic and Republican lawmakers are urging Obama to appoint a commissioner who will shake up the FDA and restore the confidence of its working-level scientists and medical experts. But industry officials fear that approval of new drugs and devices could be delayed by endless scientific disputes — which is the agency's reputation.

The FDA dissidents have previously taken their concerns to Congress and found support from lawmakers in the House.

In the letter the group singled out mammography computer-aided detection devices as an example of a technology that should not have gone forward. The devices were supposed to improve breast cancer detection, but instead studies showed they were associated with false alarms that led to unnecessary breast biopsies.

Since 2006, FDA experts have recommended five times against approving the devices without better clinical evidence, the letter said. In March of last year, a panel of outside advisers supported some of the concerns of the FDA's in-house scientists. Nonetheless, FDA managers overruled the objections and ordered approval.

Top FDA managers "committed the most outrageous misconduct by ordering, coercing and intimidating FDA physicians and scientists to recommend approval, and then retaliating when the physicians and scientists refused to go along," the letter said.

A spokeswoman said the Obama transition team had no comment.

THE WALL STREET JOURNAL.
WSJ.com

JANUARY 8, 2009, 10:50 A.M. ET

FDA Scientists Ask Obama to Restructure Drug Agency

By ALICIA MUNDY and JARED A. FAVOLE

lWASHINGTON -- A group of scientists at the U.S. Food and Drug Administration on Wednesday sent a letter to President-elect Barack Obama's transition team pleading with him to restructure the agency, saying managers have ordered, intimidated and coerced scientists to manipuate data in violation of the law.

The nine scientists, whose names have been provided to the transition team and to some members of Congress, say the FDA is a "fundamentally broken" agency and describe it as place where honest employees committed to integrity can't act without fear of reprisal.

"There is an atmosphere at FDA in which the honest employee fears the dishonest employee," according to the letter, addressed to John Podesta, head of Mr. Obama's transition team.

The letter will likely increase pressure on Tom Daschle, Mr. Obama's choice to head the Department of Health and Human Services, to make sweeping changes at the agency.

The scientists' main concerns are with the agency's scientific review process for medical devices, which they characterize as having been "corrupted and distorted by current FDA managers, thereby placing the American people at risk."

They sent a similar letter in October to the powerful House Energy and Commerce Committee, but the latest one provides more detailed allegations about problems at the agency, such as the threat of disciplinary action against scientists who dissent from management.

The FDA has been working "very closely" with Mr. Obama's transition team and will address any issues or concerns the team presents, said agency spokeswoman Judy Leon.

She said the agency is "actively engaged in a process to explore the staff members' concerns and take appropriate action."

The group says they have taken their concerns to the head of the FDA, Commissioner Andrew von Eschenbach, and his assistant commissioner for accountability and integrity, attorney Bill McConagha. The scientists say no one has been held accountable, and say some of the problematic managers have been promoted and rewarded.

The Energy and Commerce Committee's Democratic and Republican leaders sent a letter to von Eschenbach in November, saying it had "received compelling evidence of serious wrongdoing" at the agency. The members wrote that they were told McConagha had found the FDA doctors' evidence compelling, and that their findings supported removal of certain managers in the device division.

The agency has been under fire from both parties in both Houses of Congress as being too close to industry. Several leading politicians, including Sen. Chuck Grassley have complained that FDA leaders often ignore or suppress their own scientists' opinions on safety issues involving drugs and devices.

Those concerns were also aired in a report by the National Academy of Sciences' Institute of Medicine in 2006. FDA leaders, including drug division chief Janet Woodcock, have said they are working to improve the culture at the FDA, and are listening to dissent from their experts and doctors.

In addition to Mr. Daschle, the letter was sent to the doctor leading the transition team's assessment of problems at the FDA, Joshua Sharfstein, and to nine members of Congress including Sen. Edward Kennedy who chairs the Health Committee.

Members of the transition team weren't available to discuss the letter or whether they intend to address it publicly.

The scientists appear to hope that their concerns will pressure Mr. Daschle to quickly change leadership at the FDA. Von Eschenbach has said he is planning to step down on Jan. 20, the date of Mr. Obama's inauguration.

Indeed, the group said Mr. Daschle has recognized in his book, Critical: What We Can Do About the Health-Care Crisis, that the 1998 approval of some mammography computer-aided detection devices is an example of the breakdown of the independent scientific review process at the FDA.

The group says the FDA approved such devices without clinical evidence showing they were effective in detecting breast cancer. Since 2006, FDA physicians and scientists have recommended five times that these devices not be approved without valid scientific and clinical evidence.

The group said there needs to be a complete restructuring of the evaluation and approval process, and that Mr. Obama needs to sign new legislation giving protection to government employees who speak out against corruption.

Write to Alicia Mundy at alicia.mundy@wsj.com and Jared A. Favole at jared.favole@dowjones.com

The New York Times

January 13, 2009

In F.D.A. Files, Claims of Rush to Approve Devices

By GARDINER HARRIS

An official at the Food and Drug Administration overruled front-line agency scientists and approved the sale of an imaging device for breast cancer after receiving a phone call from a Connecticut congressman, according to internal agency documents.

The legislator's call and its effect on what is supposed to be a science-based approval process is only one of many of accusations in a trove of documents regarding disputes within the agency's office of device evaluation.

Nine agency scientists complained in May to Andrew C. von Eschenbach, the F.D.A. commissioner, and the agency began an internal review. Dissatisfied with the pace and results of that review, the scientists wrote a letter to Congress in October pleading for an investigation, and the House Committee on Energy and Commerce announced in November that it would begin one. Last week, the scientists wrote a similar letter to President-elect Barack Obama's transition team. Agency documents that are part of the internal investigation, including e-mail messages, were provided to The New York Times. Details of the investigations have not previously been made public.

The documents show that front-line agency scientists, like many outside critics of the agency, believe that F.D.A. managers have become too lenient with the industry. In medical reviews and e-mail messages, the scientists criticize the process by which many medical devices gain approval without extensive testing. And in e-mail correspondence, they contend that an agency supervisor improperly forced them to alter reviews of the breast imaging device and others.

William McConagha, the agency's assistant commissioner for integrity and accountability, said he was continuing to investigate the scientists' claims. Mr. McConagha said that Dr. von Eschenbach had offered to meet with the nine scientists before Friday, his last day in office.

"We in the Office of Commissioner are extremely concerned about allegations like this," Mr. McConagha said.

In the documents, Representative Christopher Shays, a Connecticut Republican who lost re-election in November, is described as having called an agency supervisor a year ago to express

concern about the fate of a computer device that is supposed to help radiologists detect breast tumors.

The device, the iCAD SecondLook Digital Computer-Aided Detection System for Mammography, is used with screening equipment made by Fujifilm Medical Systems.

Fujifilm Medical is based in Stamford, Conn., the heart of Mr. Shays's former district. In the documents, Mr. Shays is referred to as "Congressman Fuji."

"I am the Fuji congressman because I represented that district," Mr. Shays said in an interview Friday. Mr. Shays said he had called the agency supervisor only to demand that the agency make a final decision, not that it approve the product.

He scoffed at suggestions in the documents that his call led the supervisor to overrule scientists and approve the device. "That would be idiotic for someone to approve something they don't think should be approved," he said.

A spokeswoman for Fujifilm Medical, Courtney A. Kraemer, said the company had called its "local Congressional offices to ask them to help us get clarification on the F.D.A. process."

The dissenting scientists protested, according to the internal documents, that "iCAD never tested the device by the intended users (i.e. radiologists) under the intended conditions of use. This is the most basic and fundamental requirement of all F.D.A. submissions."

An internal review said the risks of the iCAD device include missed cancers, "unnecessary biopsy or even surgery (by placing false positive marks) and unnecessary additional radiation."

Ken Ferry, iCAD's chief executive, said, "We have done all the appropriate testing to get the product approved."

Mr. Ferry said that F.D.A. scientists were increasingly asking for more rigorous testing of devices, and that his company complied with those demands.

Diana Zuckerman, president of the National Research Center for Women and Families, said the Bush administration had "finally made the device approval process so meaningless that it's intolerable to the scientists who work there." Ms. Zucker, a longtime critic of the agency's device approval process, particularly as it relates to breast implants, added, "Virtually everything gets approved, no matter what."

The F.D.A. has a three-tiered approval process for medical devices that, depending on their newness or complexity, requires varying amounts of proof.

A growing chorus of critics contends that the agency requires few devices to complete the most rigorous of these reviews and instead allows most devices to be cleared with minimal oversight. In 2007, 41 devices went through the most rigorous process, compared with 3,052 that had abbreviated reviews.

According to internal documents, some scientists in the agency's device division seem to agree with these critics. One extensive memorandum argued that F.D.A. managers had encouraged agency reviewers to use the abbreviated process even to approve devices that are so complex or novel that extensive clinical trials should be required.

For instance, Shina Systems, an Israeli company, applied for approval for AngioCt, a device that combines CT images with X-rays to help guide cardiac surgeons during angioplasty and stenting procedures. The company sought an abbreviated review, according to the documents.
An F.D.A. reviewer said the company should conduct a clinical trial to prove that the device works since it is novel and risky.

"Should the images be misleading," Dr. Brian Lewis, an agency cardiologist, wrote in a memorandum, "F.D.A. could expect immediate misguidance of catheters and possibly puncture of coronary vessels or overaggressive, inappropriate or inadequate stent or balloon use."
Nonetheless, an F.D.A. supervisor — after meeting with Shina representatives — pressed scientists to consider allowing an abbreviated review, according to the documents. The agency's decision on the device is pending, according to the documents.

Dr. John Smith, a lawyer for Shina, wrote in an e-mail message that he would not comment on "ongoing regulatory matters."