



DEPARTMENT OF HEALTH & HUMAN SERVICES

2010 JUN 29 AM 11:50

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 28, 2010

GENERAL

Daniel Levinson, Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
Washington, DC 20201

RE: Case Number: Unauthorized Disclosure of Information
OI File#: H100001413

Dear Mr. Levinson:

We are in receipt of the letter dated May 18, 2010, from Scott A. Vantrease, Assistant Special Agent in Charge, Special Investigations Branch. Thank you for your quick response to our request for an investigation. However, we are now making a new request for an OIG investigation. We have obtained new information confirming the existence of information disclosures that undermine the integrity and mission of the FDA and, we believe, may be prohibited by law. Furthermore, these disclosures may be ongoing. We request that the OIG promptly review this new information.

On May 17, 2010, the FDA Office of Internal Affairs (OIA), Mark McCormack, Special Agent in Charge, requested that the OIG review what the FDA determined to be an inappropriate disclosure of confidential commercial information in the potential release of information related to a pending GE Healthcare application. The OIG determined based on the information presented at the time that the referral lacked evidence of criminal conduct and declined to take action.

(b)(5), (b)(4)

OIG-000003

FDA 00065

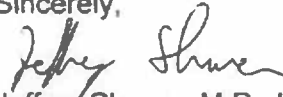
We request that you review the attached communications to determine whether this would warrant opening an investigation to determine whether one or more employees may have engaged in unlawful conduct. We believe that the emails and attached documents represent disclosures that may be prohibited by law. Among other things, the federal Food, Drug, and Cosmetic Act (the Act) prohibits anyone "revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant..., any information acquired under the" FDA's authority to review and approve applications for devices and other products. 21 U.S.C. § 331(j). Moreover, the Act prohibits the disclosure of confidential commercial information without the written consent of the sponsor who submitted the information. 21 U.S.C. § 331(y). In the case of a device not on the market, for which the intent to market the device has not been disclosed, and that has been submitted to the FDA for premarket approval or premarket notification review, FDA generally may not disclose the existence of the premarket submission. 21 C.F.R. §§ 807.95 & 814.9. More generally, any federal employee who discloses confidential trade secret information is subject to a fine or imprisonment. See also 45 C.F.R. § 73.735-307(3) (prohibiting FDA employees from disclosing information obtained in confidence, in accordance with applicable federal laws).

OIG-000004

FDA 00066

We are particularly concerned that the continued release of confidential information has compromised or will compromise the integrity of the ongoing premarket review of the subject device applications. Therefore, we request that the OIG immediately review this new information and open an investigation.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Shuren".

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices
and Radiological Health
Food and Drug Administration

Attachments

OIG-000005

FDA 00067

The image is a composite. On the left is a close-up, high-contrast photograph of a dog's face, possibly a pit bull or similar breed, with its mouth slightly open, showing teeth. On the right is a screenshot of a web browser window, specifically Microsoft Internet Explorer. The browser's address bar shows a URL starting with 'http://www.microsoft.com'. The main content area displays search results for 'Microsoft Office Word 2003'. A large red rectangular box redacts a portion of the search results. Below the redacted area, there are several search results listed, including 'Microsoft Office Word 2003' and 'Microsoft Office Word 2003'. The browser's status bar at the bottom indicates the page is 'http://www.microsoft.com' and the search results are 'Microsoft Office Word 2003'.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Hand Delivery

THIS NOTICE AT YOUR OWN OPTION MAY BE FURNISHED TO NTEU

Date: December 6, 2010

From: Deputy Director for New Device Evaluation
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Subject: Notice of Proposed Removal

To: Ewa Czerska
Biologist

This is advance notice that, in order to promote the efficiency of the service, I am proposing to remove you from the Federal Service and from your position of GS 0401-13, Biologist, for Unauthorized Release of Agency information.

Background

In your position of Interdisciplinary Scientist, GS-13, you are expected to review scientific data in support of pre-market submissions including Premarket Approvals (PMA), Product Development Protocols (PDP), Investigational Device Exemptions (IDE), Humanitarian Device Exemptions (HDE) and 510k Premarket Notifications (510k) with respect to accuracy, precision, and reliability and make a judgment on whether supporting data substantiates claims by the sponsor and your pre-market recommendation. The data and information you review include trade secret, commercial confidential information, and sensitive device information. As a Federal Employee it is your responsibility to safeguard FDA files and information.

During network monitoring, it was discovered that you have sent internal Agency files/documents and confidential commercial information from your government email account, ewa.czerska@fda.hhs.gov (hereinafter, "your government email account"), to a personal email account, [REDACTED] (hereinafter, "your personal email account"), using your government-issued laptop computer. Further, a review of email account activity revealed that you forwarded this same information, using your government-issued laptop from your personal email to at least one unauthorized private e-mail address [REDACTED] (hereinafter, "non-government individual email account").

Charge: Unauthorized Release of Agency Information

The charge of unauthorized release of Agency files, documents, and/or information, which also included confidential commercial information, is based on the following specifications:

Specification 1. On July 12, 2010, Ahava Stein an employee of Regulatory Affairs Consulting Ltd sent an email to your government email account with the subject line "K032350." In this email, Ms. Stein asked you questions regarding the Food and Drug Administration's ("FDA's") review of the Breastscan IR System, no. K032350. The information contained in this email from Ms. Stein contained commercial confidential information. Commercial confidential information is almost never released outside of the Agency, and only then under specific conditions.

On July 13, 2010, using your government-issued laptop computer, you forwarded this same July 12 email from your government email account to your personal email account. At approximately 3:31 p.m. using your government-issued laptop, you forwarded the aforementioned email from Ms. Stein from your personal email account to a non-government individual email account. You did not have a work-related reason to send the email or the information from Ms. Stein to any non-government email account. When you sent Ms. Stein's email and its information to your personal email account and to a non-government individual email account, this was an unauthorized release of Agency documents and/or information, which included commercial confidential information.

Specification 2. On July 20, 2010, using your government-issued laptop, you sent an email from your personal email account with the subject line, "Irwin," to two non-government individual email accounts. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency documents and/or information, which included commercial confidential information.

Specification 3. On August 2, 2010, using your government-issued laptop and your government email account; you forwarded an email to your personal email account with the subject line "K032350." Subsequently, using your government computer you forwarded the aforementioned email from your personal email account to a non-government individual email account. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency files, documents, and/or information, which included commercial confidential information.

Specification 4. On August 4, 2010, using your government computer and personal email account, you sent an email to a non-government individual email account regarding a medical device review. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of

Agency files, documents, and/or information, which included commercial confidential information.

Specification 5. On August 12, 2010, using your government-issued laptop and your government email account, you sent an email to your personal email account, regarding a medical device review. Using your government laptop, you then forwarded that email from your personal email account to a non-government individual email account. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency files, documents, and/or information, which included commercial confidential information.

Specification 6. On August 13, 2010, using your government computer and your personal email account, you forwarded an email to a non-government individual email account, regarding a medical device review. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency files, documents, and/or information, which included commercial confidential information.

Specification 7. On August 17, 2010, using your government-issued laptop you forwarded an email, from your government email account to your personal email account, regarding a medical device review. Subsequently, from your government laptop you forwarded that same email from your personal email account to a non-government individual email account. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency files, documents, and/or information, which included commercial confidential information.

Specification 8. On August 17, 2010, using your government-issued laptop and your personal email account, you forwarded an email to a non-government individual email account, regarding a medical device review. You did not have a work-related reason to send the email or the information to any non-government email account. This was an unauthorized release of Agency files, documents, and/or information, which included commercial confidential information.

The specifications above demonstrate that you have forwarded Agency files, documents, and/or information to non-government email accounts, [REDACTED] and [REDACTED].

[REDACTED] These emails contained commercial confidential information. The above documented activities are clearly unauthorized releases of Agency files, documents, and/or information. Your conduct, as detailed above, constitutes gross misconduct. Moreover, the improper release of commercial confidential information may be considered to be unlawful.

Therefore, based on the charge and specifications stated above and the record evidence, I am proposing your removal from Federal service and your position as a GS-13 Biologist to promote the efficiency of the service.

Penalty Considerations

In deciding to propose this action rather than a lesser action, I considered several factors.

I have considered that your actions have violated, at a minimum, the following regulations:

(1) Department of Health and Human Services (HHS) Standards of Conduct, Title 45, Code of Federal Regulations (CFR), Subpart C - Conduct on the Job, Section 73.735-304, Use of Government Property, which states: *"(a) An employee shall not directly or indirectly use, or allow the use of Government property of any kind, including property leased to the Government, for other than officially approved activities;"* and

(2) Title 5 CFR 2635, Subpart G – Misuse of Position, Section 2635.704, and Use of Government Property, which states (a) *Standard An employee has a duty to protect and conserve Government property and shall not use such property, or allow its use, for other than authorized purposes.* This includes the duty to protect information.

Your actions also violated the HHS OCIO Policy for Personal Use of Information Technology (2/17/06), HHS-OCIO-2006-0001, Section 5.3, which states:

"Unauthorized or inappropriate use of HHS IT resources could result in loss of use or limitations on use of equipment, disciplinary or adverse actions, criminal penalties and/or employees or other users being held financially liable for the cost of inappropriate use;" and Section 5.4, which states *"Employees are expected to conduct themselves professionally in the workplace and to refrain from using Government office equipment for activities that are inappropriate.*

Your actions also violated the Secure One HHS Information Security Program Rules of Behavior. Specifically, the rules state you should not:

- *Store sensitive information in public folders or other insecure physical or electronic storage locations.*
- *Share sensitive information, except as authorized and with formal agreements that ensure third parties will adequately protect it.*

- *Transport, transfer, email, remotely access, or download sensitive information, inclusive of PII, unless such action is explicitly permitted by the manager or owner of such information.*
- *Store sensitive information on portable devices such as laptops, personal digital assistants (PDA) and universal serial bus (USB) drives or on remote/home systems without authorization or appropriate safeguards, as stipulated by the HHS Encryption Standard for Mobile Devices and Portable Media, dated August 21, 2007.*

I find that the evidence supports that you engaged in unauthorized release of Agency files, documents, and/or information, including confidential commercial information, via your personal email account in an attempt to avoid detection by the Agency and that you forwarded this same information to a non-government individual email account, identified as [REDACTED]. This is particularly obvious, given the July 13, 2010 email exchange, in which the individual email account holder, [REDACTED], instructed you to "send all emails to me from your Gmail account," as well as advising you to "[j]ust forward your emails to Gmail, then forward to me." The record evidence demonstrates that you followed those instructions. This leads me to the conclusion that you were trying to circumvent security processes that are in place to protect the safety and confidentiality of information that is used for official purposes.

As an aggravating factor, I have considered the seriousness of your misconduct. Not only did you engage in the unauthorized release of Agency files, documents, and/or information to non-government email accounts, but the information you sent outside of the Agency contained commercial confidential information. You are entrusted to safeguard confidential information for official purposes, and you are responsible for upholding Federal regulations and ethical standards in your work.

Further, I find that during your employment you have been on notice that such actions were not appropriate. Specifically, each time that you log onto your government computer, there is a banner which states the following:

- *"You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.*
- *Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.*
- *By using this information system, you understand and consent to the following: You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At*

any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Further, like all other Agency employees, you are required annually to take and complete computer security training, under which these types of issues are addressed. It is also noteworthy that the emails you received from Ms. Stein clearly indicated that the information sent to you was intended only for you, as the addressee

I have considered the nature and seriousness of the offense cited above and its relation to your duties, position, and responsibilities, including whether the offense was intentional or technical or inadvertent or was committed maliciously or for gain or was frequently repeated. I considered that your misconduct is very serious and has a direct relationship to your ability to perform the duties of your position as a GS 13 Biologist. As a part of your Biologist duties, you are entrusted to protect Agency files, documents, and/or information, but particularly to protect commercial confidential information and use government property for official purposes. You are also responsible for upholding Federal regulations and ethical standards in your work. I considered that you circumvented Agency processes and requirements by sending Agency files, documents and/or information to non-government email accounts and to a non-government individual. You did not have a work-related reason to send these emails or the information to any non-government email account.

I considered your job level and type of employment, and the affect of your misconduct on your ability to do your duties, and my confidence in you to perform your duties. Your misconduct is unacceptable. I considered that on July 1, 2010, you were officially reprimanded for failure to follow supervisory instructions. I have considered that since receiving that reprimand, your improper release of Agency files, documents, and/or information, by circumventing Agency IT and security protocols, is another example of a pattern of disregard for management instructions, policies, and procedures that are in place. You are aware of what is expected of you regarding protecting confidential information and the appropriate use of the Government computer. Management must be able to trust that each employee uses his or her computer for the purpose for which it was intended (that is, to perform official job duties). Further, because you released, without authorization, Agency files, documents, and/or information, to include commercial confidential information, I have lost trust and confidence in you being able to perform your duties.

I have considered, in your favor, that you have twenty three (23) years of service; however your actions are so egregious they have resulted in my having lost trust and confidence in you as a Federal Employee.

I considered the potential for your rehabilitation and have concluded that it is poor. Your improper release of Agency files, documents, and/or information, to include commercial confidential information, is a significant indication that you are not willing to properly discharge your duty to protect sensitive and confidential information, the release of which could result in severe ramifications against the FDA by the public, including, but not limited to insider stock trading and sponsors being apprehensive about sending propriety information to the FDA for review. Your actions could have resulted in a "chilling effect" on the FDA's mission to protect and support public health. I believe a lesser penalty is not likely to cause a change in your behavior.

I have also considered if there are any mitigating circumstances surrounding your misconduct and have found none.

I have considered the clarity with which you had been informed that your misconduct was inappropriate and violated Federal or Agency policy. I find that you were on notice that you were engaging in serious misconduct. Specifically, all employees of FDA/HHS are required to familiarize themselves with the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR 2635) and DHHS Standards of Conduct (45 CFR 73). Besides mandatory annual computer security training that all employees receive, FDA/HHS also posts a warning that is visible each time you access the computer system. It states, *"This is a Food and Drug Administration (FDA) computer system and is provided for the processing of official U.S. Government information only. All data contained on this computer system is owned by the FDA and may, for the purpose of protecting the rights and property of the FDA, be monitored, intercepted, recorded, read, copied, or captured in any manner and disclosed by and to authorized personnel. USE OF THIS SYSTEM BY ANY USER, AUTHORIZED OR UNAUTHORIZED, CONSTITUTES CONSENT TO THIS MONITORING, INTERCEPTION, RECORDING, READING, COPYING, OR CAPTURING AND DISCLOSURE. THERE IS NO RIGHT OF PRIVACY IN THIS SYSTEM. Authorized personnel may give to law enforcement officials any potential evidence of crime found on FDA computer systems. Unauthorized access or use of this computer system and software may subject violators to criminal, civil, and/or administrative action. The standards of ethical conduct for employees of the Executive Branch (5 C.F.R. § 2635.704) do not permit the use of government property, including computers, for other than authorized purposes."*

I have considered the fact that your actions violated HHS and FDA's Policy on the Use of Government Equipment and Systems. As a CDRH employee, you are given access to government-owned computers and other electronic equipment for use in our daily official duties. Staff Manual Guide (SMG) 3140.1, "FDA POLICY ON USE OF GOVERNMENT ELECTRONIC EQUIPMENT AND SYSTEMS" authorizes appropriate and reasonable personal use of Government electronic equipment and systems by FDA

employees, on their own time, as a means to enhance their knowledge of and capabilities in using the equipment and systems in performing official duties. This SMG also specifically defines "**Misuse**", in part as follows: *"personal use of the Internet while the user is being paid to conduct Government work...inappropriate use of the Internet to conduct activities like sending E-mail messages containing racial slurs or sending proprietary or trade secret information to a friend,"*

Rights

You are allowed 14 calendar days following your receipt of this notice to respond to this proposal orally, in writing, or both orally and in writing. You may also submit affidavits and other documentary evidence in support of your reply(ies). Any reply you make is to be addressed to William H. Maisel, M.D., M.P.H., Deputy Director for Science, CDRH.

Main tel: 301-796-5900

Fax: 301-847-8510

Address: WO Bldg 66 Rm 5429
10903 New Hampshire Ave
Silver Spring, MD 20993

who will give full and careful consideration to any reply you submit within the allowed time before he makes and issues a written decision to you. **If you are considering an oral reply, you must contact the Deciding Official promptly so an appointment can be scheduled within the time period for reply.**

You are entitled to be represented in this matter by an attorney or other representative. If you choose someone to represent you, that person's name and address must be given to me and to Dr. Maisel in writing, providing your authorization for your representative to have access to official records personal to you and relevant to this proposed action. A sheet on which this may be accomplished is attached.

You may contact Catherine Sanders in the Workforce Programs Division at 301-492-4705 to make arrangements to obtain a copy of the material relied upon. You may also contact Ms. Sanders if you have any questions related to this Notice of Proposed Removal. Your authorized representative may also review the material. Non public information has been redacted in accordance with FDA Freedom of Information policies.

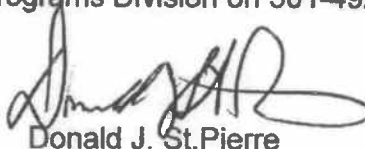
You and your authorized representative, if an employee of this Department in an active duty status, may be entitled to a reasonable amount of official time to review the supporting material, secure affidavits, and prepare and present your response. A request to use official time must be made to me in writing and in advance and you must receive written approval before using official time for this purpose. Your representative, if an employee of this Department, should request use of official time from his or her own supervisor.

If you have a medical condition which you wish the Agency to consider before reaching a final decision in this matter, you may raise it in connection with your reply. However, any such claim must be supported by medical documentation which defines the condition and establishes a causal connection between the condition and the above-described misconduct.

As soon as possible after receipt of your reply(ies), or after expiration of your reply period if you do not reply, Dr. Maisel will issue his decision to you in writing. If Dr. Maisel – sustains the proposed action and decides to remove you, the removal will be effective no sooner than 30 calendar days from the date you receive this advance notice.

Effective immediately, you will be placed on administrative leave status during the advance notice period. You must immediately surrender to me your work computer, keys and Federal ID Badge, and any other electronic data storage devices in your possession. Please be advised that until further notice, you are barred from entering any FDA owned or leased facility.

This action is proposed according to Title 5 Code of Federal Regulations, Part 752, Subparts C and D. If you have any questions about the regulations or procedures applicable to this proposal, you may contact Catherine Sanders, Labor and Employee Relations Specialist in the Workforce Programs Division on 301-492-4705.



Donald J. St. Pierre

Attachment
Representative Designation Form

Receipt Acknowledgment

To acknowledge that you have received this notice, please sign and date in the space below. Your signature does not mean that you agree or disagree with this notice and, by signing you will not forfeit any rights to which you are entitled. Your failure to sign will not void the contents of this memorandum.

I acknowledge receipt of this memorandum:

Date

*Dr. Czerksa refused to sign the acknowledgment. J.S.P.
12/6/10*

Thu, Sep 2, 2010 at 1:51 PM

R Smith <[REDACTED]>
To: [REDACTED]@mail.house.gov
Cc: [REDACTED]
[REDACTED]

I left you a voice mail with my contact info (cell phone [REDACTED]) I was requested to contact you by Congressman [REDACTED]
[REDACTED]

As I understand it, the Committee is conducting an investigation of some urgent FDA matters and will hopefully be holding hearings on the FDA in the near future. [REDACTED]
[REDACTED] have been designated as the primary contact person for the group (we are all current and former FDA employees who work/worked at the Center for Devices and Radiological Health). [REDACTED]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date: 25 February 2011

From: Gregory Campbell
Director, Division of Biostatistics

Subject: Memorandum of Caution

To: [REDACTED]

Center for Devices and Radiological Health

This memorandum is to caution you with regard to your conduct, as follows:

- As an FDA employee you have access to non-public data and information. This data may include trade secret, commercial confidential information, and sensitive device information. As a Federal Employee it is your responsibility to safeguard FDA files and information, and ensure that information is only used for official purposes and released through appropriate channels.

During network monitoring, it was discovered that you were aware that others in the organization had sent internal Agency data using their personal e-mail accounts, including what appears to be your personal e-mail account, [REDACTED] (hereinafter, "your personal email account").

Specifically, on July 28, 2010, the email account [REDACTED] forwarded an e-mail that contained Agency information to your personal email account.

Of particular concern to me is the contents of the July 28, 2010 email, which appears to be a revision of official Agency work. A non-government account, [REDACTED] sent this to another non-government account, [REDACTED] and it was ultimately forwarded to you. Yet, you did not report this.

Also, on May 27, 2010, the email account [REDACTED] sent an email to your personal email account stating, in part, "...I do believe that they have access to our email accounts at work."

In response, you wrote,

Page 2 - Memorandum of Caution

"I agree Cindy. More than one place it says you cannot expect any privacy so we shouldn't say anything we don't want every one to see. Like you said I worry about private accounts but don't know the answer to that.

██████████"

For your information, copies of the e-mail exchanges cited above are attached.

Your statements on May 27, 2010 demonstrate to me that you knew the actions being taken were not appropriate, yet you failed to instruct others to stop, or to ask that you not be included, or to report these serious violations.

As a ██████████, you are a member of the Center's management team, and you are expected to have refrained from participating in such an inappropriate exchange, to have advised others to cease and desist, and/or to have report these exchanges. You took none of these actions.

I am cautioning you based on the above listed reasons and details. This action is not considered a disciplinary action, but a warning that this type of conduct cannot happen again, but if it does, corrective action may result.

This memorandum will **not** be filed in your Official Personnel Folder, but I will retain a copy for future reference.

I consider you a good employee and a vital part of my management team. However, I need to take this action to impress upon you the importance of refraining from similar behavior in the future. I am confident that you will do so and nothing further needs to occur.


Gregory Campbell

Receipt Acknowledgment

To acknowledge that you have received this notice, please sign and date in the space below. Your signature does not mean that you agree or disagree with this notice and, by signing you will not forfeit any rights to which you are entitled. Your failure to sign will not void the contents of this memorandum.

I acknowledge receipt of this memorandum:

████████████████████

Date

From:

Date: 10:24 AM (10 minutes ago)

Cindy [REDACTED]
[REDACTED] : Robert

To:

Crisis	Percentage
Yes	85
No	15

BCU

Subject: FDA emails

If they have access to my email, can they please pay my bills? That would be more than welcome. And since they can now read my wishes, can they give me a new intestinal system. The two years difficulties have screwed that part. Thanks a lot.....

Sophie

- Show quoted text -

On May 27, 2010, at 10:07, Cindy [REDACTED] wrote:

I think they have access...

From:

To:



Sent: Thu, May 27, 2010 9:15:58 AM

Subject: Re: FDA emails

I agree Cindy. More than one place it says you cannot expect any privacy so we shouldn't say anything we don't want every one to see. Like you said I worry about private accounts but don't know the answer to that.

On Tue, May 25, 2010 at 9:44 AM, Cindy <[REDACTED]> wrote:
Hi All,

In general, this is a good reminder... I just wanted to let you all know that I received a copy of the RCI (Report of Investigation) in my 3rd L250 case and wanted to make you aware that I do believe that they have access to our email accounts at work. For example, I wrote an email to Lethal and Sharen and it was printed from Lesa Dootin's email. There was no forward or anything. I does personnel have this email? I don't have anything to worry about but can't emphasize enough do not put things in an email that you don't want them to know.

Email Activity

From: [REDACTED]
 Date: 29 Jul 2010 09:55:05 -0400
 To: [REDACTED]
 CC:
 BCC:
 Subject: Re: what I have.....

Thank you for sharing, Robert. I hope you understand that I do not mean to be mean! (what a sentence) to refer to our argumentative discussion yesterday or any other day. I hope you understand the message I am trying to convey to you. I do very much know how difficult it is for our buddy and I care about him. I will respect whatever he feels comfortable doing because I believe that he is dealing with a very evil person. I read that person at the last Friday meeting. I could not believe myself what was transpiring from the person and that such evil exists in our World, but I guess it better to know about it.

On Wed, Jul 28, 2010 at 11:12 PM [REDACTED] wrote:
 FYI.

Begin forwarded message:

From: R Smith <[REDACTED]>
 Date: July 28, 2010 22:40:32 EDT
 To: [REDACTED], Julian Nicholas <[REDACTED]>
 Subject: Fwd: what I have.....

----- Forwarded message -----
 From: R Smith <[REDACTED]>
 Date: Wed, Jul 28, 2010 at 10:32 PM
 Subject: Re: what I have.....
 To: Paul Hardy <[REDACTED]>

My edited version:

Drs. Barr and Finder.

Thank you both very much for attending the meeting last Friday. I am in the process of finishing up the lead review memorandum, and ensuring that the administrative file is complete, and I have a couple of points that are related to clinical matters for which I just needed some clarification:

I. With regard to the most recent Review memos that you both submitted:

(a) Dr. Finder stated the following in his review memo dated April 23, 2010:

- In my opinion, there are a number of confounding issues that make an assessment of the safety and effectiveness of the unit difficult. While Carestream met the primary endpoints it set for itself, in its last CFA subanalysis, it failed to meet its own criteria for microcalcifications.

file://H:\RCS\SOP_LV_7_29\SOP_LV_7_29.html

9/9/2010