

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

January 26, 2009

The Honorable Barack H. Obama
President of the United States
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

We, physicians and scientists of the U.S. Food and Drug Administration (FDA), wrote to Mr. Podesta and Members of Congress in a letter dated January 7, 2009.¹ We informed Mr. Podesta that FDA is fundamentally broken and that there is an atmosphere at FDA in which the honest employee fears the dishonest employee and where honest employees committed to integrity and the FDA mission cannot act without fear of reprisal. We recommended that you remove and hold accountable all managers who have ordered, participated in, fostered or tolerated the well-documented corruption, wrongdoing and retaliation at the Agency. In November 2008, the U.S. House of Representatives Committee on Energy and Commerce sent a letter to the FDA Commissioner² stating that they had "received compelling evidence of serious wrongdoing ... and well-documented allegations ... from a large group of scientists and physicians ... 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 ... and that physicians and scientists within CDRH who objected [to the misconduct]... have been subject to reprisals."

It has been brought to our attention that FDA management may have just recently ordered the FDA Office of Criminal Investigations (OCI) to investigate us, rather than the managers who have engaged in wrongdoing! It is an outrage that our own Agency would step up the retaliation to such a level because we have reported their wrongdoing to the United States Congress. FDA management has ignored the dire warnings from the United States Congress that all FDA managers immediately cease and desist from engaging in prohibited personnel practices in violation of 5 USC 2302, making false statements in government documents in violation of 18 USC 1001, interfering with a Congressional inquiry in violation of 18 USC 1505, or denying or interfering with an employees right to furnish information to the Congress in violation of 5 USC 7211. We note that violation of 18 USC 1505 subjects the violators to "be fined [or] imprisoned not more than 5 years."

¹ http://www.thegraysheet.com/nr/FDC/SupportingDocs/gray/2009/011209_Lettr2transitionteam.pdf

² http://energycommerce.house.gov/images/stories/Documents/PDF/Newsroom/110-ltr-111708_vonEschenbach.CDRH.pdf

We are asking for your immediate intervention. We are confident that you will follow through on your promises³ to protect "government employees committed to public integrity and willing to speak out" because you have stated that "such acts of courage and patriotism, which can sometimes save lives and often save taxpayer dollars, should be encouraged rather than stifled" in order to "empower federal employees as watchdogs of wrongdoing and partners in performance." This is the change that America so desperately seeks and has rightfully brought you to power.

Sincerely,

Robert C. Smith
MD, JD



Ewa Czarska
Ph.D.



Paul T. Hardy II
BS



Cc: Rahm Emanuel, Chief of Staff
Senator Tom Daschle, HHS Secretary-Designate
Senator Max Baucus
Senator Chuck Grassley
Congressman Henry Waxman
Congressman Bart Stupak
Congressman John Dingell
Congressman Joe Barton
Congressman John Shimkus
Senator Edward Kennedy
Senator Michael Enzi
Senator Barbara Mikulski
Senator Ben Cardin
Congressman Chris Van Hollen

³ http://change.gov/agenda/ethics_agenda/

(b)(5) - deliberative process, (b)(5) - Attorney Client privilege

Please let me know if you have any questions. I am off site today and can be reached via blackberry (b)(6) other than from 3:00-4:00. Thanks, Wendy

Email Activity

From: Julian Nicholas [REDACTED]
 Date: 9:24 AM (12 minutes ago)
 To: [REDACTED]
 CC:
 BCC:
 Subject: (no subject)

Hey PJ,

Its tough. Hang on in there. You'll be out of there soon, so just do what you're doing and keep being polite/ friendly when you write and when you talk to them. Just "play the fool" if you have to and document.

-j

--- On Mon, 6/21/10, Paul Hardy <[REDACTED]> wrote:

From: Paul Hardy <[REDACTED]>
 Subject: Re:
 To: "Julian Nicholas" <[REDACTED]>
 Cc: "R Smith" <[REDACTED]>
 Date: Monday, June 21, 2010, 3:10 AM
 - Show quoted text -

Thanks to both of you for all your help. I think I can incorporate some of the language from both of your review memos and work them into the e-mail. I apologize to the both of you for being rude and defensive as I was not feeling well all day and just tired. It just seems that it does not matter that we keep documenting the craziness of these people as nothing does not seem it is going to change and one has to make a choice if they want to keep fighting the fight even if it does not appear to be any end in sight. I am too young to be having all of this stress as it is not healthy. I am just trying to get out of OIVD as soon as possible and really don't want Don to screw me over in perhaps holding up any transfer that I want to any office, but at the end of the day I guess it really does not matter as they will do whatever they want.

On Mon, Jun 21, 2010 at 1:33 AM, Julian Nicholas [REDACTED]
 [REDACTED] wrote:

(b)(5) - deliberative process

(b)(4)

(b)(4) (b)(4)

(b)(5) - deliberative process

(b)(4) (b)(4)

(b)(5) - deliberative process

(b)(4)

(b)(5) - deliberative process

I hope this helps

Paul Hardy