# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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| PAUL T. HARDY      | )                            |
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| a.m.d              |                              |
| and                | )                            |
| EWA M. CZERSKA     | ) Case No. 1:11-cv-01739-RLW |
|                    |                              |
|                    | FIRST AMENDED COMPLAINT      |
| 1                  | ) Elled I.e. 25, 2012        |
| and                | ) Filed Jan. 25, 2012        |
| ROBERT C. SMITH    | )                            |
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| and                | )                            |
| JULIAN J. NICHOLAS | )                            |
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| D1 1 100           | )                            |
| Plaintiffs,        | )                            |
| v.                 | )<br>)                       |
| <b>v.</b>          | )                            |
|                    |                              |

| JEFFREY E. SHUREN Director, Center for Devices and Radiological Health U.S. Food and Drug Administration 10903 New Hampshire Avenue WO 66-5442 Silver Spring, MD 20993, | ) ) ) ) ) ) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| and                                                                                                                                                                     | )<br>)      |
| DONALD J. ST. PIERRE<br>OIVD, CDRH, FDA<br>Food and Drug Administration<br>WO 66-5682<br>10903 New Hampshire Avenue<br>Silver Spring, MD 20093,                         | )           |
| and                                                                                                                                                                     | )           |
| MARY PASTEL Division of Radiological Devices Food and Drug Administration 10903 New Hampshire Avenue WO 66-G310 Silver Spring, MD 20093,                                | )           |
| and                                                                                                                                                                     | )           |
| GREGORY CAMPBELL Division of Biostatistics Food and Drug Administration 10903 New Hampshire Avenue WO 66-2110 Silver Spring, MD 20993,                                  | )           |
| and                                                                                                                                                                     | )           |
| ALBERTO GUTIERREZ Director, OIVD, CDRH Food and Drug Administration 10903 New Hampshire Avenue WO 66-5680 Silver Spring, MD 20993,                                      | )           |
| and                                                                                                                                                                     | )           |

| KIMBERLY A. HOLDEN Assistant Commissioner for Management Office of the Center Director U.S. Food and Drug Administration 10903 New Hampshire Avenue WO 1-4239 Silver Spring, MD 20993,         |          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| and                                                                                                                                                                                            | )        |
| RUTH MCKEE Office of the Center Director, CDRH U.S. Food and Drug Administration 10903 New Hampshire Ave. WO 66-5434 Silver Spring, MD 20093,                                                  | )))))))  |
| and                                                                                                                                                                                            | )        |
| WILLIAM MAISEL WO-Building 66- Room 5429 10903 New Hampshire Ave. WO66-5410 Silver Spring, MD 20993,                                                                                           | ))))))   |
| and                                                                                                                                                                                            | )        |
| GREGORY A. STEVENS Deputy Director Office of Commissioned Corps Operations U.S. Public Health Service Commissioned Corps Office of the Surgeon General 1101 Wooton Parkway Rockville, MD 20852 | )))))))) |
| and                                                                                                                                                                                            | )        |
| REGINA M. BENJAMIN<br>Surgeon General<br>U.S. Public Health Service<br>200 Independence Ave. SW, Rm. 701-H<br>Washington, DC 20201                                                             | )))))    |
| and                                                                                                                                                                                            | )        |

| MARGARET A. HAMBURG<br>Commissioner<br>U.S. Food and Drug Administration<br>10903 New Hampshire Avenue<br>WO-31<br>Silver Spring, MD 20993,                                    | )))))))) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| and                                                                                                                                                                            | )        |
| KATHLEEN SEBELIUS<br>Secretary, Department of Health and<br>Human Services<br>200 Independence Ave. SW, Room 120F<br>Washington, DC 20201,                                     | ))))))   |
| and                                                                                                                                                                            | )        |
| JOHN AND JANE DOE<br>Employees 1-99<br>Department of Health and Human Services<br>10903 New Hampshire Ave<br>Silver Spring, MD 20993,                                          |          |
| and                                                                                                                                                                            | )        |
| UNITED STATES FOOD & DRUG<br>ADMINISTRATION<br>10903 New Hampshire Avenue<br>Silver Spring, MD 20993,                                                                          | )))))    |
| and                                                                                                                                                                            | ))       |
| UNITED STATES PUBLIC HEALH SERVICE<br>U.S. Public Health Service Commissioned Corps<br>Tower Building<br>Plaza Level 1, Room 100<br>1101 Wooton Parkway<br>Rockville, MD 20852 |          |
| and                                                                                                                                                                            | ))       |
| UNITED STATES DEPARTMENT OF<br>HEALTH AND HUMAN SERVICES<br>200 Independence Avenue SW                                                                                         | )))      |

| Washington, DC 20201,                                                                                                   | )           |
|-------------------------------------------------------------------------------------------------------------------------|-------------|
| and                                                                                                                     | )           |
| THE UNITED STATES OF AMERICA c/o United States Department of Justice 9th & Pennsylvania Avenue NW Washington, DC 20530, | )<br>)<br>) |
| Defendants.                                                                                                             | )<br>)      |

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#### **AMENDED COMPLAINT**

Plaintiffs Paul T. Hardy, Ewa M. Czerska, Robert C. Smith, Julian J. Nicholas,

(collectively "Plaintiffs") bring this action against

Defendants Jeffrey E. Shuren, Donald J. St. Pierre, Mary Pastel, Gregory Campbell, Alberto Gutierrez, Kimberly A. Holden, Ruth McKee, William Maisel, Gregory Stevens, Nelson Cabrera, James E. Simpson, Regina M. Benjamin, Margaret Hamburg, Kathleen Sebelius, John and Jane Doe Employees 1-99, U.S. Department of Health and Human Services ("HHS" or "Agency"), and The United States of America (collectively "Defendants"), in their official capacity, pursuant to the Administrative Procedure Act, the First, Fourth, and Fifth Amendment of the United States Constitution, and the Lloyd LeFollette Act, 5 U.S.C. § 7211.

Defendants have taken and converted private emails without due process or just compensation in violation of the Fifth Amendment of the United States Constitution. Defendants have initiated searches and seizures in violation of the First and Fourth Amendments.

Defendants have conducted searches and seizures of a scope that violates the First and Fourth Amendments. Defendants have violated the First Amendment by chilling free speech with searches and seizures. Defendants have violated the First Amendment by chilling Plaintiffs' and the public's right to associate with whistleblowers. Defendants have violated Plaintiffs' right to representation. Defendants have chilled Plaintiffs' protected First Amendment right to free speech.

#### **JURISDICTION AND VENUE**

1. This court has subject matter jurisdiction over Plaintiffs' claims and personal jurisdiction over Defendants pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-705; the First Amendment of the United States Constitution; the Fourth Amendment of the

United States Constitution; the Fifth Amendment of the United States Constitution; the Lloyd LaFollette Act, 5 U.S.C. § 7211; and pursuant to 28 U.S.C. §§ 1331, 1343, 1346, 1361, and 1367. Venue is proper in this District pursuant to the United States Code of Judicial Procedure, 28 U.S.C § 1391.

#### **PARTIES**

- 2. Plaintiff Paul T. Hardy ("Mr. Hardy") is a former officer of the U.S. Public Health Service Commissioned Corps, and is a U.S. citizen residing in the State of Maryland. He received his B.S. degree in biomedical engineering from Marquette University.
- 3. Plaintiff Ewa M. Czerska ("Dr. Czerska"), M.D., Ph.D., is a former employee of Defendant U.S. Food and Drug Administration ("FDA"), and is a U.S. citizen residing in the State of Maryland. Dr. Czerska received an M.D. following completion of medical studies in Poland in 1971, and a Ph.D. in Genetics in 1978. She performed extensive research in non-ionizing radiation, resulting in several publications and presentations in local and international meetings. From 2007-2009, she was President of the Bioelectromagnetics Society.
- 4. Plaintiff Robert C. Smith ("Dr. Smith"), M.D., J.D., is a former employee of the U.S. Food and Drug Administration, and is a U.S. citizen residing in the State of Maryland. He received his M.D. from Yale University.
- 5. Plaintiff Julian J. Nicholas ("Dr. Nicholas"), M.D., Ph.D., is a former employee of the FDA, and former federal contractor who worked for the FDA under the Oak Ridge Institute for Science and Education ("ORISE") program. Dr. Nicholas is a U.S. citizen residing in the State of California. Dr. Nicholas holds an M.D. from the University College of London and a Ph.D. from Oxford University in Neurosciences.

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- 8. Defendant Jeffrey E. Shuren is a U.S. citizen who works for FDA as the Director, Center for Devices and Radiological Health, and is being sued in his official capacity.
- 9. Defendant Donald J. St. Pierre is a U.S. citizen who works for the FDA and is being sued in his official capacity.
- 10. Defendant Michael O'Hara is a U.S. citizen who works for the FDA and is being sued in his official capacity.
- 11. Defendant Janine Morris is a U.S. citizen who works for the FDA and is being sued in her official capacity.
- 12. Defendant Mary Pastel is a U.S. citizen who works for the FDA and is being sued in her official capacity.
- 13. Defendant Gregory Campbell is a U.S. citizen who works for the FDA and is being sued in his official capacity.
- 14. Defendant Kimberly A. Holden is a U.S. citizen who works for the FDA as Assistance Commissioner for Management, Office of the Center Director, and is being sued in her official capacity.
- 15. Defendant Ruth McKee is a U.S. citizen who works for the FDA and is being sued in her official capacity.

- 16. Defendant William Maisel is a U.S. citizen who works for the FDA and is being sued in his official capacity. Defendant Gregory A. Stevens is a U.S. citizen who works for the Agency as Deputy Director, Office of the Commissioned Corps Operations, U.S. Public Health Service Commissioned Corps., Office of the Surgeon General, U.S. Department of Health & Human Services, and is being sued in his official capacity.
- 17. Defendant Regina M. Benjamin is a U.S. citizen who is the Surgeon General, U.S. Public Health Service Commissioned Corps, and is being sued in her official capacity.
- 18. Defendants John and Jane Doe Employees 1-99 work for the Agency's IT department and are being sued in their official capacities.
- 19. Defendant Kathleen Sebelius is a U.S. citizen who works in the District of Columbia as the Secretary of the Department of Health and Human Services and is being sued in her official capacity.
- 20. Defendant Margaret Hamburg is a U.S. citizen who works as Commissioner for the FDA, U.S. Department of Health and Human Services, and is being sued in her official capacity.
- 21. Defendant Food and Drug Administration is an agency within the U.S. Department of Health and Human Services.
- 22. Defendant Public Health Service is an agency within the U.S. Department of Health and Human Services.
- 23. Defendant Department of Health and Human Services is a United States Government Agency.
- 24. Defendant United States of America is the government of the United States of America.

#### **FACTS**

# I. Plaintiffs Made a Protected Disclosure to John Podesta of the Presidential Transition Team

- 25. On November 17, 2008, the Chairman of the House Energy and Commerce Committee sent a letter to high ranking officials at the FDA stating that FDA scientists had made well-documented allegations to the Committee that senior managers within CDRH "ordered, intimidated, and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law."
- 26. Defendants were aware that Plaintiffs Robert C. Smith, Ewa M. Czerska, and Paul T. Hardy II were among the FDA "experts" referenced in the letter dated November 17, 2008 from the Chairman to of the House Energy and Commerce Committee.
- 27. On or about January 7, 2009, nine FDA employees, including scientists, experts, and medical doctors sent a letter to John Podesta of the Obama Transition Team.
- 28. Defendants were aware that Plaintiffs Robert C. Smith, Ewa M. Czerska, and Paul T. Hardy II were among the nine signatories to the letter dated January 7, 2009 addressed to the Obama Transition Team.
- 29. The January 7, 2009 letter from the FDA scientists to the Obama Transition Team raised issues of public concern, including, but not limited to, corruption within the FDA device review process, managerial misconduct, dangers to public health, welfare and safety, and retaliation against whistleblowers.
- 30. Whistleblowers are persons who raise allegations of official misconduct or allegations of threats to the public health and safety that are of public concern and that are protected under the First Amendment of the United States Constitution.

- 31. For example, in the January 7, 2009 letter to Mr. Podesta, the FDA scientists noted that in the past, computer-aided detection devices ("CAD") to be used with breast mammograms were not safe or effective, but the FDA approved the devices anyway in a flawed process that ignored the science. This has led to significant harm to large numbers of women and significant unnecessary costs to the public.
- 32. In their January 7, 2009 letter, the FDA scientists also warned Mr. Podesta that this type of behavior had not changed, was ongoing, and that FDA managers were still trying to approve similarly flawed CAD devices.
- 33. The January 7, 2009 letter from the FDA scientists, including Plaintiffs Smith, Czerska, and Hardy, to John Podesta of the Obama Transition Team constituted protected speech under the First Amendment of the United States Constitution.
- 34. The Defendants learned of the January 7, 2009 letter shortly after it was sent the FDA scientists, including Plaintiffs Smith, Czerska, and Hardy, to the Obama Transition Team.
- 35. After the Defendants learned about the January 7, 2009 letter to Mr. Podesta, FDA officials began to secretly refer to the signatories of the letter from the FDA scientists and including Plaintiffs Smith, Czerska, and Hardy, as the "FDA Nine" or "FDA 9."
- 36. The January 7, 2009 letter to Mr. Podesta and the allegations of government misconduct raised therein were soon thereafter discussed in the national news media. On or about Jan. 8, 2009, the *Wall Street Journal* published an article about the "FDA Nine," who were the signatories to the January 7, 2008 letter to Mr. Podesta. On or about Jan. 9, 2009, CNN broadcasted a news segment about "the FDA Nine." On or about Jan. 12, the *New York Times*

published an article about an FDA approved imaging device used for the diagnosis of breast cancer.

37. Special interests, with conflicts of interest with the FDA and whose products were pending approval at the FDA, privately complained about the whistleblowing of the "FDA Nine." These special interests stood to earn significant income by having their products approved by the FDA.

#### II. Senator Grassley Warns the FDA That Such Disclosures Are Protected

- 38. On or about January 15, 2009, Senator Charles Grassley wrote to FDA Commissioner Andrew C. Von Eschenbach.
- 39. Senator Grassley expressed concern about "serious allegations of misconduct and retaliation within the Center's Radiology Devices Branch in connection with the review of Computer Assisted Detection (CAD) devices," citing the January 7, 2009 letter from the FDA scientists, including Plaintiffs Smith, Czerska,
- 40. Senator Grassley specifically noted that his understanding was that Dr. Von Eschenbach and other high level officials within the FDA had already met the signatories to the letter, and thus already knew their identity.
- 41. Senator Grassley informed FDA Commissioner Von Eschenbach, "It is also important that senior officials assure their employees that it is both acceptable and within their rights to speak to Congress, should they feel compelled to do so." Senator Grassley reminded Commissioner Von Eschenbach that "FDA employees have a right to talk to Congress without interference and/or threats from the Agency . . . [and] they have a right to talk to Congress confidentially."

42. Senator Grassley then quoted the Lloyd LaFollette Act, 5 U.S.C. § 7211: "The right of employees, individually or collectively, to petition Congress . . . or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied."

#### III. The Covert Surveillance and Termination of the FDA Whistleblowers

- 43. On or before January 23, 2009, Defendants learned the identities of the persons who signed the Obama Transition Team letter, including Plaintiffs Dr. Smith, Dr. Czerska, Mr. Hardy, and
- 44. On or before January 29, 2009, despite Senator Grassley's warnings, Defendants commenced a covert and secret search and seizure operation on the "FDA Nine" in retaliation for their protected speech, which included, but was not limited to, the interception of private communications sent by or on behalf of Plaintiffs to Congressional representatives.
- 45. As part of this secret search and seizure operation, Defendants commenced intercepting private electronic correspondence created on Government issued computers, sent through Government networks, or remotely connected to Government networks.
- 46. The electronic communications include, but are not limited to, electronic mail ("email") sent from private, third-party, non-Governmental, password protected, and encrypted email accounts such as Google's email service, "Gmail," or Yahoo's email service, "Yahoo Mail" (hereinafter "Private Email Accounts"). These emails often included attached files and documents. The electronic communications also include emails sent from Private Email Accounts to other Private Email Accounts ("Private Emails"). Private Emails include emails sent from private networks, on private equipment, to other Private Email Accounts, but viewed

on HHS equipment, passing through HHS networks, or viewed while connected remotely to HHS networks.

- 47. Plaintiffs had explicit permission from Defendants to use their government issued computers for personal purposes.
- 48. Defendants secretly searched and seized the private electronic communications sent by Plaintiffs and other whistleblowers in the group of "FDA Nine" in circumstances in which the Plaintiffs had a reasonable expectation of privacy.
- 49. Defendants selected the Plaintiffs and their associates as the targets for this covert electronic surveillance based on the content and viewpoint of the target's speech, and based on the target's association with persons for whom Defendants knew had engaged in speech protected under the First Amendment.
- 50. As part of the searches and seizures of electronic communications, Defendants secretly installed or activated spyware on all of the government-owned computers, electronic hardware, and networks used by the Plaintiffs.
- 51. This spyware allowed Defendants to secretly conduct additional surveillance of the Plaintiffs, including Defendants to take real-time pictures or "screen shots" of the computer screens opened by the Plaintiffs without Plaintiffs' knowledge. These screen shots enabled Defendants to secretly view information on each of the Plaintiffs' computer screens, even if the information was not saved by Plaintiffs, and Defendants secretly learned the names of document files privately stored on each of Plaintiffs' computer. The information secretly obtained by Defendants included Plaintiffs' legally protected documents and information that was stored by Plaintiffs in folders labeled "For Congress" and other folders that clearly indicated the intent of Plaintiffs to raise issues of public concern with appropriate authorities.

- 52. When Defendants commenced the surveillance and intercept program, they developed an internal system for converting the Plaintiffs' private communications into the property of the United States and storing these communications in a non-disclosed record system.
- 53. The record system initially used a folder secretly labeled by Defendants as "FDA 9," with sub-directories created for each member of the "FDA Nine." Later intercepts by Defendants separated out emails involving individual whistleblowers by their initials. For example, "RCS" stood for Robert C. Smith, "EMC" stood for Ewa M. Czerska, "JJN" stood for Julian J. Nicholas, and "PTH" stood for Paul T. Hardy.
- 54. The screen shots and other electronic interceptions also enabled Defendants to secretly learn the identity of every whistleblower, and to learn the tactics and strategy the whistleblowers were using or planning to use in blowing the whistle to Congress, the Inspector General, among other proper authorities.
- 55. For example, some of the secretly obtained screen shots consisted of a picture of one of the Plaintiff's computer screen, in which that Plaintiff had created a sub-directory in the name of each of the members of the whistleblower group. Thus, by taking a picture of that screen, Defendants could learn the identity of every whistleblower who was working with the group.
- 56. Other subfolders and subfolder names included documents and document names describing the types of whistleblowing the Plaintiffs were planning. For example, some of the secret screen shots taken by Defendants consisted of pictures of one of the Plaintiff's computer screen, in which that Plaintiff had created a sub-directory that named the type of whistleblower disclosure the Plaintiffs intended on filing. In this particular case, the subdirectory was named

"OSC," which is widely understood by government employees to stand for the Office of Special Counsel, a government office which has jurisdiction to accept allegations of official corruption from employees and non-employees alike.

- 57. The Office of Special Counsel is a designated office for which any federal employee (or other person) can file allegations of official misconduct and threats to the public health and safety. The Office can also investigate the personal misconduct of high-level managers and take administrative action against these managers.
- 58. Prior to learning about the Defendants' interception and monitoring tactics, additional federal employees or contractors joined with the "FDA 9" employees (that included Plaintiffs Smith, Czerska, and Hardy) and made disclosures protected under the First Amendment.
- 59. Because the computers used by members of the "FDA 9" (including Plaintiffs Smith, Czerska, and Hardy) were under constant secret surveillance, Defendants were able to learn the identities of other employees and contractors who shared the concerns raised by the "FDA 9" (including Plaintiffs Smith, Czerska, and Hardy) and who also wanted to blow the whistle to appropriate authorities, including Congress.
- 60. Defendants targeted these newly identified individuals who associated with the "FDA 9" (which included Plaintiffs Smith, Czerska, and Hardy) and other potential whistleblowers for email searches and seizures, and converted their private email communications into the property of the United States.
- 61. Plaintiffs Julian Nicholas, M.D., Ph.D., then a contractor-employee for FDA, and joined the whistleblower group sometime

after the original group of "FDA 9" employees sent the letter to Mr. Podesta, head of the President-Elect's transition team.

- 62. Like the other Plaintiffs, Dr. Nicholas and had serious concerns regarding government misconduct and threats to the public health and safety.
- 63. Like the other Plaintiffs, Dr. Nicholas and relied upon Dr. Smith to act as their representative in raising concerns to various appropriate authorities, including the Office of the Inspector General and the United States Congress.
- 64. When Plaintiffs Dr. Nicholas and joined the whistleblower group, they were unaware that their private electronic communications were likewise searched, seized and converted by the Defendants.
- 65. Defendants did not make Plaintiffs aware of the secret intercepts and Plaintiffs were not aware that Defendants were secretly obtaining information from their computers at the time these improper intercepts took place.
- 66. Plaintiff Hardy was unaware of the existence of the Defendants' intercepts of private email communications between Plaintiff Hardy and Congressional staff until December 2011. At that time, representatives from the Public Health Service (PHS) confirmed to Plaintiff Hardy that Defendants HHS and FDA had notified the PHS about Defendants' secret interceptions of Plaintiff Hardy's private communications with Congressional staff. Defendants HHS and FDA informed PHS that Plaintiff Hardy could allegedly not be "trusted" by HHS and FDA, in part, because of communications Defendants HHS and FDA had secretly intercepted between Mr. Hardy and staff from the House Energy and Commerce Committee and the Senate Finance Committee.

#### a. First Amendment Disclosures by Dr. Nicholas

- 67. On or about May 2009, Dr. Julian J. Nicholas became associated with Dr. Robert C. Smith. Prior to his association with Dr. Smith, Dr. Nicholas was not a whistleblower.
- 68. Prior to his association with Dr. Smith, Dr. Nicholas received exemplary marks in his performance of his job duties.
- 69. Prior to his association with Dr. Smith, Dr. Nicholas had no trouble whatsoever in maintaining his employment at the FDA as a contractor.
- 70. Prior to his association with Dr. Smith, Dr. Nicholas had never had trouble in either obtaining or renewing the ORISE contract.
- 71. Prior to his association with Dr. Smith, there is no documentation of Defendants engaging in surveillance of Dr. Nicholas electronic communications.
- 72. Dr. Nicholas had independently come to the same scientific conclusions as Dr. Smith regarding a CT colonography device.
- 73. Both Dr. Nicholas and Dr. Smith believed the device to be ineffective and unsafe for its intended purpose, and recommended against clearing the device to be used for population screening of asymptomatic patients. Despite their strong scientific objections, FDA managers worked to clear the device.
- 74. Both Dr. Nicholas and Dr. Smith blew the whistle on FDA managers' attempts to approve the unsafe and ineffective device outside their immediate chain of command.
- 75. Dr. Nicholas was aware that Dr. Smith was also an attorney and was aware that Dr. Smith was representing members of the "FDA 9" employees (i.e. the whistleblower group) in disclosures being made to Congress and the Inspector General.
- 76. To facilitate Dr. Smith's representation of these whistleblowers and ensure that Defendants did not destroy evidence of government misconduct and/or health and safety

violations, a representative from the Office of Inspector General ("OIG") advised Dr. Smith, on June 25, 2009, to commence storing his communications "offline."

- 77. The Inspector General investigator knew that Dr. Smith was preparing major disclosures for his office using emails and other documents to form the basis of a "chronology" or timeline of the relevant events.
- 78. Defendants secretly intercepted this email, along with all other private communications between the Plaintiffs and the Inspector General.
- 79. Defendants secretly intercepted private communications between Dr. Smith and Dr. Nicholas that confirmed that Dr. Nicholas had joined the whistleblower group and was working with the group to raise health and safety concerns.
- 80. Defendants retaliated against Dr. Nicholas based on his protected speech on matters of public concern and his association with other whistleblowers within HHS/FDA and the Public Health Service.
- 81. Within four months of Dr. Nicholas agreeing with Dr. Smith in a scientific review of a device, the FDA refused to renew his ORISE contract.
- 82. By September 2009, FDA managers looked to see what rights Dr. Nicholas had as an ORISE contractor and concluded that he had none.
- 83. Defendants decided to wait until Dr. Nicholas' contract with FDA expired, and use the pretext of a contract non-renewal to terminate him in retaliation for his protected disclosures.
- 84. Defendants took these actions knowing that HHS lacked any other medical professional who could provide the quality of services provided to the United States by Dr. Nicholas.

- 85. On or about October 2009, the FDA refused to renew Dr. Julian J. Nicholas' ORISE contract, despite the fact that numerous professionals who worked at FDA with Dr. Nicholas supported the renewal, and despite the fact that there was no other medical doctor working for Defendants (either as an employee or a contractor) who could provide the services to the United States that were provided by Dr. Nicholas.
- 86. After October 2009, Dr. Nicholas, as a private citizen, continued to raise matters of public concern with Congress and other appropriate authorities.
- 87. After October 2009, Dr. Nicholas, as a private citizen, has had a strong interest in speaking, writing and publishing information regarding government misconduct and threats to the public health and safety based on the improper approval of devices by Defendants.
- 88. After October 2009, Dr. Nicholas, as a private citizen, has in fact made public statements concerning the actions of Defendants that have appeared in national news media, including *ABC News* and the *New York Times*.

#### b. Reaction to March 28, 2010, New York Times Story

- 89. On March 28, 2010, the *New York Times* published a page one article by Gardiner Harris, "Scientists Say F.D.A. Ignored Radiation Warnings." The article criticized the FDA device approval process. It stated that FDA medical experts were warning that the FDA was trying to approve ineffective and dangerous devices, while ignoring or suppressing the concerns of its own scientists. The article named Dr. Robert C. Smith as one such expert.
- 90. On April 16, 2010, the FDA received a letter from a private law firm representing General Electric, complaining about the *New York Times* article. The letter complained that confidential information may have been released to the *New York Times*, but did not point to any specific information for which the release would have been prohibited under law.

- 91. General Electric is a special interest group that does business with the FDA, and who stands to earn millions of dollars if their devices are approved by the FDA.
- 92. Defendants knew that General Electric had a conflict of interest with the Agency, and knew that General Electric was very unhappy with the actions of the Plaintiffs and FDA whistleblowers who had internally objected to the approval of their devices.
- 93. Despite knowing of these conflicts of interest, and without any direct evidence that any of the Plaintiffs (or any other FDA whistleblower or employee) had violated any law in providing information to the *New York Times* or to Congress, Defendants used this letter as a pretext to secretly make a criminal referral to the Office of Inspector General and attempt to have the Plaintiffs (and other whistleblowers) investigated and potentially charged with serious crimes.
- 94. On or about April 28, 2010, the FDA referred the matter to Internal Affairs to investigate, without Plaintiffs' knowledge.
- 95. The FDA and HHS Defendants also relied on the *New York Times* article as a pretext to secretly expand their surveillance activities and target employees, contractors or officers whom HHS/FDA suspected of sending information to the *New York Times*.
- 96. The surveillance was also targeted at people who associated with people suspected of sending information to the New York Times.
- 97. The initial attempt by Defendants to have the HHS Office of Inspector General criminally investigate the Plaintiffs (and other whistleblowers) was not successful.
- 98. On May 18, 2010, Scott A. Vantrease, Assistant Special Agent in Charge, Special Investigations Branch, HHS OIG, responded to the FDA.

99. Mr. Vantrease noted the complete lack of any evidence of criminal conduct on the part of any HHS employee, and specifically noted that the alleged disclosures were protected whistleblower activity (emphasis added):

The referral lacks any evidence of criminal conduct on the part of **any** HHS employee. Additionally, 5 U.S.C. § 1213, identifies that disclosures, **such as the ones alleged**, when they relate to matters of public safety may be made to the media and Congress . . . .

- 100. Despite the May 18, 2010, letter from the Office of Inspector General indicating that all the allegations were of protected whistleblower activity, the FDA continued its targeted investigatory secret surveillance of the Plaintiffs and their associates.
- 101. On May 21, 2010, despite the May 18, 2010 letter sent from the OIG, Defendants secretly intercepted additional private electronic correspondence stemming from the *NY Times* article. Among the emails and electronic correspondence and documents the FDA intercepted at this time (copies of which have been subsequently obtained by Plaintiffs) were the personal emails of Dr. Ewa M. Czerska, Mr. Paul T. Hardy, Dr. Robert C. Smith, Dr. Julian J. Nicholas, and
- 102. Defendants also secretly intercepted emails that included Plaintiffs' private attorney-client privileged information, which the FDA summarized for the attorneys in HHS.
- 103. At the time, Dr. Smith was acting as counsel for numerous FDA employees generally, and was acting as a representative for the employee whistleblower group.
- 104. At the time, Dr. Smith was also acting as a liaison to Congress for many FDA employees and former FDA employees. These people include, but are not limited to, Dr. Ewa M. Czerska, Mr. Paul T. Hardy, Dr. Julian J. Nicholas,

- and to prepare a filing with the Office of Special Counsel. Dr. Smith maintained the information for the Office of Special Counsel in a folder on the desktop of his FDA laptop computer whose name contained the abbreviation "OSC".
- 106. On or about June 28, 2010, the FDA filed a second request for an OIG criminal investigation without the knowledge of the Plaintiffs. Dr. Jeffrey Shuren submitted the request himself. Attached were several screen shots and documents obtained through spying on the private email correspondence of Dr. Robert C. Smith, Dr. Ewa M. Czerska, Mr. Paul T. Hardy, and Mr. Julian J. Nicholas. Dr. Shuren indicated that the attachments demonstrated unauthorized and illegal disclosures, and he feared that the disclosures were ongoing.
- 107. The attachments to Dr. Shuren's submission to the OIG were private electronic communications between Dr. Czerska, Mr. Hardy, Dr. Nicholas, Dr. Smith, that Defendants secretly obtained via their searches and surveillance of Plaintiffs' computers. The central document in the second request for an investigation filed by Dr. Shuren was a draft document called the "Optasia Chronology," which was to be part of a formal Complaint alleging government misconduct that Dr. Czerska intended to file with appropriate authorities.
- 108. Defendants secretly obtained and took possession of these documents and the private communications of the Plaintiffs.
- 109. Dr. Shuren, who made the new OIG referral, knew that the FDA whistleblowers (including Plaintiffs) were planning on making a filing with either the OIG or the Office of Special Counsel and that the Plaintiffs were accusing Dr. Shuren of official misconduct.

- 110. Dr. Shuren was able to learn of these planned activities through his access to the secretly intercepted communications and draft OSC/OIG filings.
- 111. Dr. Shuren filed his charge against the Plaintiffs to the OIG within one week of obtaining secret access to these materials prepared by the Plaintiffs.
- 112. For the next several months, from approximately June 2010 through September 2010, the FDA continued its secret surveillance of Dr. Czerska, Mr. Hardy, Dr. Smith, and their correspondence with Dr. Nicholas and among others.
- 113. On or about early July 2010, the FDA placed Dr. Smith on administrative leave on suspicion of unauthorized release of confidential information.
- 114. Throughout his employment at FDA, Dr. Smith was never questioned by FDA or HHS managers about his activities concerning the release of information.
- 115. Dr. Smith was never disciplined or reprimanded concerning any improper release of any government information.
- 116. Dr. Smith was never formally charged by any government official with having improperly leaked any information to any person.
- 117. On July 31, 2010, the FDA did not renew Dr. Smith's employment contract, and Dr. Smith's employment for the United States ended.
- 118. After July 31, 2010, Dr. Smith, as a private citizen, continued to act as a representative for the PHS and FDA employees (including Plaintiffs) who wanted to continue to raise matters of public concern with Congress and other appropriate authorities.
- 119. This included meeting with representatives from various Congressional committees both on behalf of himself and on behalf of persons still employed by Defendants.

- 120. Since July 31, 2010, Dr. Smith, as a private citizen, has a strong interest in speaking, writing and publishing information regarding government misconduct and threats to the public health and safety based on the improper approval of devices by Defendants.
- 121. On or about November 15, 2010, the OIG once again declined to take action against any of the Plaintiffs based on information provided by the Defendants to the OIG, including numerous intercepted emails and documents that Defendants obtained as part of the email interceptions. In its closing letter to FDA, the OIG noted that the Department of Justice ("DOJ") had also declined prosecution of any of the Plaintiffs or other whistleblowers.
- 122. The failure of the FDA to renew Dr. Smith's term employment contract had a chilling effect on all similarly situated employees/contractors/officers of the Defendants.
- 123. The failure of FDA to renew Dr. Nicolas' contract with ORISE had a chilling effect on all similarly situated employees/contractors/officers of the Defendants.
- 124. Defendants' searches, seizures, confiscations and other monitoring of whistleblowers is capable of repetition and has a chilling effect on future speech and associational rights of all persons employed by Defendants and all other similarly situated federal employees, federal contractors and officers of the Public Health Service.

## **IV.** First Amendment Violations

### a. Freedom of Speech

- 125. The searches, seizures, and confiscations were conducted in violation of the First Amendment of the United States Constitution.
- 126. Targeting employees who engage in constitutionally protected speech for highly intrusive searches and seizures of email communications between private, password protected,

encrypted, third-party, non-Governmental email services, did and will have a chilling effect on Plaintiffs and all similarly situated government employees, contractors and officers.

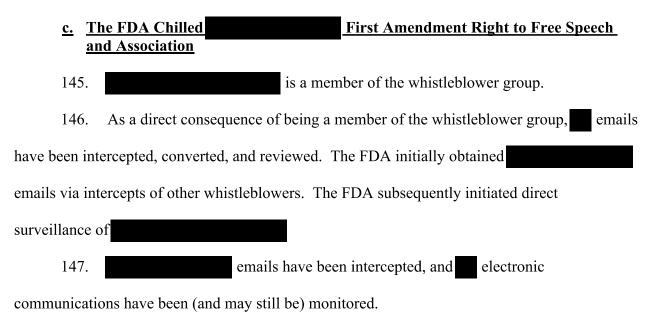
- 127. Defendants initiated and implemented a comprehensive plan to interfere with the ability of the Plaintiffs to effectively "blow the whistle" on government misconduct by secretly intercepting their private communications, using information obtained from these private communications to plan initiatives to discredit the whistleblowers and undermine the effectiveness of the whistleblower disclosures.
- 128. Defendants initiated and implemented their surveillance activities in order to obtain information that would permit Defendants to retaliate against the Plaintiffs and justify this retaliation based on information obtained during the surveillance.
- 129. Defendants initiated and implemented their surveillance activities in order to obtain information that would permit Defendants to obtain copies of their draft whistleblower disclosures for which they intended to file with appropriate government agencies.
- 130. Defendants intercepted and confiscated e-mails that Plaintiffs had sent to each other that contained draft whistleblower disclosures, including a comprehensive filing that was being prepared for the Office of Special Counsel, a government agency with jurisdiction to obtain information concerning misconduct by government officials submitted by whistleblowers.
- 131. Defendants' actions had and continue to have a chilling effect on Plaintiffs' First Amendment rights and rights of association
- 132. Defendants' actions had and continue to have a chilling effect on all similarly situated employees/contractors/officers of the United States.
- 133. Similarly situated employees include, but are not limited to, FDA employees and managers, HHS employees and managers, officers of the Public Health Service, and contractors

who work under the control and direction of the federal government through the ORISE program.

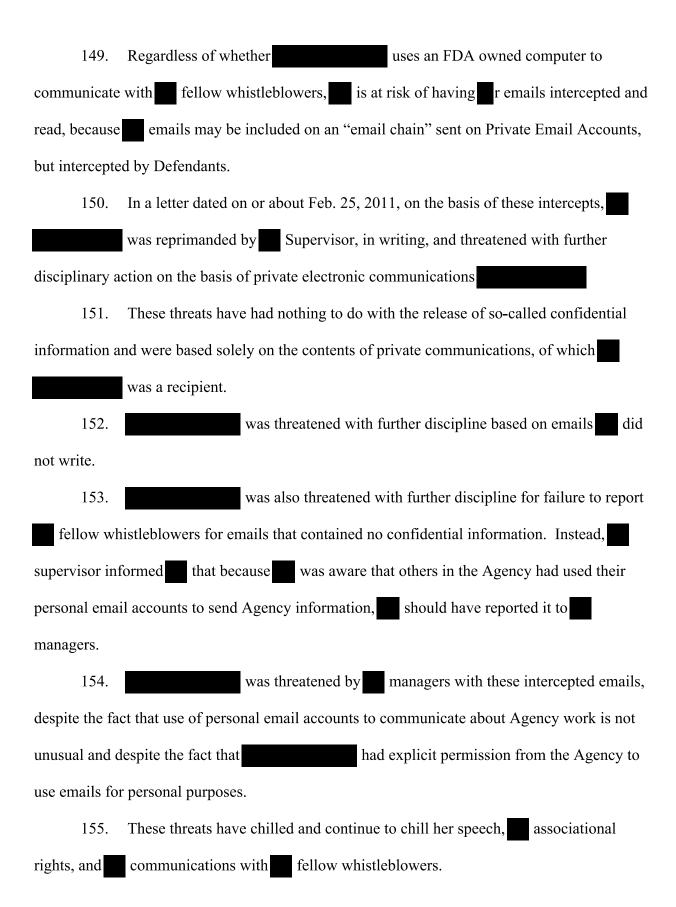
## b. Right to Freedom of Association

- 134. Whistleblowers engage in speech on matters of public concern that is protected under the First Amendment of the United States.
  - 135. Whistleblowers have a right to association under the First Amendment.
- 136. Whistleblowers also have a Right to Confidentiality in their association with known whistleblowers.
- 137. By targeting whistleblowers for surveillance, the right of people to confidentially associate with whistleblowers is severely chilled.
- 138. By targeting this group of whistleblowers, persons associated with the group became a target of surveillance as well.
- 139. This has had a chilling effect on the right of the Plaintiffs to associate with any person, and a chilling effect on the ability of any employee/contractor/officer of the Defendants to provide information to members of the FDA 9 (and other employees/contractors working with the FDA 9) and to otherwise communicate or associate with known whistleblowers.
- 140. Once it is generally known that whistleblowers may be targeted with increased surveillance, every employee would be afraid to communicate with them in any form.
- 141. Targeting known whistleblowers with increased surveillance and with the forms of surveillance documented in this Amended Complaint would have a chilling effect on the willingness of any federal employee/contractor/officer to associate with a known whistleblower.

- 142. The surveillance prevents, chills, and interferes with the existing group of whistleblowers with associating with each other and has pressured persons to leave the "whistleblower group" and/or to stop associating with the "whistleblower group."
- 143. The searches and seizures, and the chilling effect directly caused by this surveillance, interferes with the ability of the Plaintiffs (and other whistleblowers) to obtain information about government misconduct and threats to the public health and safety, and communicate that information to Congress and the American public.
- 144. The searches and seizures, and the chilling effect directly caused by this surveillance has caused and will cause workplace and social isolation of persons identified as whistleblowers (including, but not limited to, the Plaintiffs) and interferes with the ability of the Plaintiffs (and other whistleblowers).



148. Additionally, other whistleblowers with whom associates with have also been targeted and continue to be targeted.



- 156.
- 157. Due to association with Dr. Robert Smith, supervisor told that other managers in the FDA did not trust
- 158. Other employees of the FDA fear to become associated with lest they be considered whistleblowers as well and lose the trust of other FDA managers.

#### V. Defendants' Violation of Plaintiffs' Fourth Amendment Rights

- 159. Plaintiffs had a reasonable expectation of privacy in their private, password protected, non-Governmental, encrypted email communications when these communications were sent from or received on computers or networks that the FDA had explicitly stated could be utilized for personal communications.
- 160. Prior to becoming whistleblowers, the Plaintiffs were each provided with access to computers and laptop computers owned by Defendants.
- 161. Official FDA policy allowed Plaintiffs personal use of FDA electronic equipment, networks, email, and other communication equipment in their personal time.
- 162. The FDA policy on use of electronic equipment and networks allows this to promote worker efficiency.
- 163. It is common practice within the HHS/FDA/PHS for employees to use their FDA equipment for personal communications.
- 164. It is a common practice for emails originally generated privately on private computers to be attached as part of a chain of emails and sent through private Gmail servers, which are subsequently read using computers owned by the FDA.
- 165. The FDA never blocked access to Private Email Accounts, Gmail servers, or Yahoo servers.

- 166. Plaintiffs were permitted to access private, password protected Private Email Accounts from laptops and computers provided by FDA, but for which explicit permission was granted to use for personal purposes.
- 167. Plaintiffs' were never informed that these Private Email communications would be subjected to search or seizure or would be converted to government property.
- 168. In terms of privacy, Special Agent Les Hollie of the Health and Human Services
  Office of Inspector General told Dr. Smith that they should maintain "offline" copies of their
  communications regarding managerial misconduct, Congressional correspondence, and protected
  activity.
- 169. Dr. Smith interpreted this to mean that he and the other Plaintiffs should save relevant data files off the FDA network and that the FDA could not access private email communications.
- 170. Thus, Dr. Smith would communicate via his Private Email Account and urge other whistleblowers to do the same.
- 171. Dr. Smith informed all Plaintiffs of Special Agent Les Hollie's message and advised them to act accordingly.
- 172. Dr Smith did not expect the FDA to intercept his private email account when he sent communications and saved communications in a manner advised by the HHS Office of Inspector General.

#### a. Plaintiffs' FDA Offices

173. Plaintiffs Dr. Czerska, Mr. Hardy, Dr. Smith, and worked at the FDA as device reviewers. Each device reviewer had their own office. Each office had a door. Each door could be locked by the occupant of the office, or in the alternative, a key kept at the

building's security desk. Under normal circumstances, only the device reviewers were allowed direct access to their offices.

- 174. The FDA offers its device reviewers the opportunity to have a web camera installed on their computers. All Plaintiffs refused to have it installed, never used their web camera, turned their web camera towards the wall, or otherwise kept the web camera inoperable.
- 175. Many of the electronic communications between all Plaintiffs occurred in a private setting, either at home, in the evenings, or in an otherwise non-work setting.
- 176. Plaintiff Julian J. Nicholas conducted almost all of his electronic communications from his California offices or his home in California.

#### b. Plaintiffs' Private Email Accounts

- 177. Plaintiffs believed that their Private Emails and Private Email Accounts were private.
- 178. Private Email Accounts are password protected, encrypted, and inaccessible to anyone but the owner. They are not part of the FDA network.
- 179. Plaintiffs personal email accounts also contained extremely private and intimate correspondence with family (including spouses, ex-spouses, children, and parents), friends, and loved ones.
- 180. Plaintiffs' email accounts were also used for personal finances, banking, attorneyclient privileged communications, and other private or sensitive personal issues.
- 181. Defendants intercepted emails that are considered private by all traditional standards. That is, Defendants intercepted Private Email communications sent from non-government accounts on private computers and private networks in the privacy of a person's own home.

- 182. All of the Defendants' searches, seizures, and conversations at issue in this Amended Complaint were performed covertly.
- 183. All of the Defendants' searches and seizures were conducted without warrants or subpoenas.
  - 184. The Defendants' secret searches were not in the normal course of business.
- 185. The Defendants' secret searches were targeted to include whistleblowers and those who associated with whistleblowers.
  - 186. The Defendants' secret searches and seizures lasted for a period of two years.
- 187. Defendants made false statements concerning the interceptions and the basis upon which the interceptions were triggered.
  - 188. The Defendants' secrets searches resulted in criminal referrals.
- 189. Plaintiffs were unaware of the existence of the surreptitious interceptions at the time they took place and Plaintiffs are still unaware of the full nature and scope of the surreptitious surveillance.
- 190. Plaintiffs never consented to Defendants' search, seizure or confiscation of their Private Email communications or any other electronic information obtained by Defendants as a direct or indirect result of Plaintiffs' whistleblowing activities.
- 191. The HHS/FDA never informed Plaintiffs or employees generally that employees who engage in protected disclosures would be subjected to special secret searches targeting whistleblowers.
  - 192. The searches were targeted at FDA and PHS whistleblowers and contractors.
- 193. Defendant Donald St. Pierre, in a sworn affidavit, made false statements when he alleged that the searches and seizures were the product of "routine monitoring."

- 194. Defendant St. Pierre was trying to provide a pretext for justifying the searches and seizures and hide their true origin and intent.
- 195. However, Defendant Alberto Gutierrez, who was Mr. St. Pierre's first line supervisor, confirmed that Plaintiffs were subjected to "targeted email monitoring."

# c. The Inception of Defendants' Searches

- 196. Because the FDA initiated the searches based on protected disclosures, none of the searches conducted by Defendants were justified at their inception.
- 197. The searches, seizures and confiscations were commenced for an improper purpose. Those purposes include but are not limited to monitoring the First Amendment protected speech of Plaintiffs, obtaining evidence that could be used to retaliate against Plaintiffs for the First Amendment protected speech, and enabling the Government to learn of the planned activities of the whistleblowers before they engaged in these First Amendment protected activities, so that the government could undermine their efforts to ensure Government accountability.
- 198. Even if these searches were justified at their inception, when Defendants learned that the activities engaged in by the Plaintiffs constituted First Amendment protected speech, Defendants should have terminated the searches, deleted the data obtained through the searches, and closed the investigations. Defendants did not do so.
- 199. For example, in January 2009, it became widely known that nine anonymous FDA scientists and experts had sent a letter to the Obama transition team accusing the FDA of misconduct. The device approval held up as an example of the FDA managerial misconduct was called the iCAD SecondLook device, and Dr. Donna-Bea Tillman was named as a manager who engaged in that misconduct.

- 200. Within the FDA, a Branch Chief, two Deputy Division Directors, a Division Director, and four to five scientists in the Office of Science and Engineering Laboratories all opposed the approval in writing, emails, or at internal meetings. Two to three staff members in the PMA office had complained in emails about Dr. Tillman's mismanagement. Only three FDA experts and signatories of the letter to the Obama transition team were on the review team for the iCAD device.
  - 201. The other six members of the FDA 9 did not work on the iCAD device.
- 202. The FDA targeted all nine signatories of the letter to the Obama transition team, on suspicion of whistleblowing.
  - 203. The FDA did not target anyone else who had worked on the iCAD device.
- 204. This example demonstrates that it was not solely release of confidential information that initiated the surveillance. The fact that Plaintiffs were known whistleblowers or associated with other whistleblowers drove the decision to initiate the surveillance.

### d. The Scope of Defendants' Searches

- 205. The searches conducted by Defendants were intrusive and excessive and exceeded the scope of a reasonable search, even assuming the inception of the search was legitimate.
- 206. The stated objective of the searches was prevention of unauthorized disclosures of confidential information. None of the searches conducted by Defendants were limited to such disclosures.
- 207. For example, in its request to PHS to remove Mr. Hardy, the FDA cited an email from Mr. Hardy to fellow whistleblowers claiming that the FDA was corrupt, and claimed that it violated the PHS code of behavior.

- 208. The searches resulted in the interception of personal information, including private financial information, communications with spouses, ex-spouses, children, parents, and other loved ones.
- 209. The searches resulted in the interception of attorney-client privileged information, and HHS attorneys informed FDA managers of that fact.

# VI. Interference With Dr. Robert Smith's Communications as an Attorney, a Whistleblower, and a Private Citizen

- 210. Dr. Robert C. Smith, M.D., J.D., is medical doctor, attorney, and author.
- 211. Dr. Smith is a recognized national and international expert in radiology.
- 212. Dr. was a member of the faculty at Yale University School of Medicine, where eventually became Chief of Magnetic Resonance Imaging ("MRI").
- 213. Dr. Smith completed his residency in Diagnostic Radiology and a fellowship in Cross-Sectional Imaging, Computerized Tomography, and Ultrasound at the Yale University School of Medicine.
- 214. Dr. Smith served as Professor of Radiology and Associate Chairman of Radiology in the Department of Diagnostic Radiology at the Weill Cornell Medical College, Manhattan, NY, where he was actively involved in clinical research.
- 215. Dr. Smith received the Godfrey Hounsfield Award from the Society of Computed Body Tomography and Magnetic Resonance for his work pioneering the use of unenhanced CT for the diagnosis and management of patients with acute flank pain and kidney stones.
- 216. Dr. Smith speaks and writes on matters of public concern, primarily related to medicine, health care and public health and safety.

- 217. Dr. Smith has published more than 75 articles in the scientific literature as well as a book on the physics of Magnetic Resonance Imaging. He has given hundreds of scientific presentations at meetings of professional societies.
- 218. Dr. Smith is a member of numerous professional societies and has served on the editorial boards of several major professional journals.
- 219. Dr. Smith earned a J.D. in September 2005 from Fordham University School of Law.
- 220. Between September 2006 and January 2010, Dr. Smith was a Medical Officer at FDA in the Radiological Devices Branch at CDRH, and between January 2010 and July 2010, I was a Medical Officer at FDA in the Division of Radiological Devices at CDRH.
- 221. Dr. Smith is an active member of the Radiological Society of North America and the American Roentgen Ray Society, and a member of the Board of Directors of the National Whistleblower Center.
  - 222. Dr. Smith acted as the representative for the "FDA 9" and all of the Plaintiffs.
- 223. Defendants were aware of Dr. Smith's representational activities, and were also aware that he was an attorney-at-law.
- 224. Dr. Smith worked directly with the Plaintiffs in preparing information for Congress, the Office of Inspector General and in drafting an OSC filing.
- 225. Through the FDA's intercepts, the FDA was aware that Dr. Smith was acting as the groups' representative to Congress and other entities.
- 226. During his tenure at the FDA, Defendants' targeted Dr. Smith for surveillance, both because of his personal whistleblowing activities and as a means to learn about protected

speech made or being planned to be made by Plaintiffs', other members of the FDA 9 and other potential whistleblowers.

- 227. Defendants' initiated their surveillance activities because Dr. Smith was a whistleblower and because he represented other whistleblowers.
- 228. The surveillance was to obtain information communicated by the Plaintiffs' to Dr. Smith, and to learn about their internal communications between each other regarding matters of public concern.
  - 229. The surveillance was initially secret.
- 230. People who associated with Dr. Smith became targets of Defendants' highly intrusive surveillance of private electronic correspondence.
- 231. After Dr. Smith was removed from the FDA and Defendants disclosed the surveillance intercepts, it became widely known and notorious within FDA that Dr. Smith was a primary target of surveillance.
- 232. Defendants did in fact intercept and confiscate e-mails that Plaintiffs' had sent to their attorneys and/or representatives, and thereafter converted these emails into the property of the United States without any due process.
- 233. Defendants informed current employees that association with Dr. Smith would be harmful to their careers.
- 234. Federal employees reasonably fear that association with Dr. Smith will result in them being the target of highly intrusive electronic surveillance.
- 235. In the past, Defendants have chosen targets for surveillance by their association with Dr. Smith.

- 236. Federal employees reasonably fear that such highly intrusive surveillance could result in embarrassing information, statements, or emails that could be used as pretext for termination.
- 237. Defendants have picked out highly embarrassing emails in the past in an attempt to discredit those whistleblowers.
- 238. Federal employees reasonably fear that such highly intrusive surveillance would result in Defendants surreptitiously learning about whistleblowing activities, protected speech, future or current litigation, accusations against the FDA, or simply general disgruntlement.

  Defendants have picked out highly embarrassing emails in the past as reasons to terminate or suspend people associated with Dr. Smith.
- 239. Defendants' targeting of persons who associate with Dr. Smith for highly intrusive surveillance chills the willingness of current federal employees/contractors and officers to communicate or associate with Dr. Smith, and interferes with Dr. Smith's ability to access lawful information from FDA employees about health and safety issues, issues that he writes, speaks, and publishes about.
- 240. The Defendants' targeting of Dr. Smith interferes with his right to free speech and association as a private citizen.
- 241. The Defendants' targeting of whistleblowers and those who associate with whistleblowers interferes and chills their right to access lawful information from FDA employees about health and safety issues.

# VII. Interference with Right to Petition Congress

- 242. Defendants initiated and implemented their surveillance activities in order to obtain information communicated by the Plaintiffs' to Members of Congress and/or their staffs regarding matters of public concern.
- 243. Defendants intercepted and confiscated e-mails that Plaintiffs' had sent to Members of Congress and/or their staffs, and thereafter converted these emails into the property of the United States without any due process.
- 244. Defendants ignored admonitions from Senator Charles Grassley, warning them that retaliation against whistleblowers and interference with a legitimate Congressional inquiry was illegal.
- 245. Defendants refused to comply with a request from Senator Charles Grassley to notify FDA employees that they have a right to disclose information to Congress without fear of retaliation.
- 246. Defendants retaliated against Plaintiffs for disclosing information to, and corresponding with, Congress.
- 247. Defendants FDA and Donald St. Pierre recommended the termination of Mr. Hardy in part because of Mr. Hardy's email correspondence with Congress.
- 248. Donald St. Pierre stated explicitly that managers in the FDA did not trust Mr. Paul T. Hardy in part because of email correspondence Mr. Hardy had with Congressional staffers, attorneys and investigators.
- 249. Defendants FDA and Donald St. Pierre and Alberto Gutierrez gave Mr. Hardy negative performance reviews in part because of his communications with Congress.

- 250. Defendants focused their surveillance efforts on Dr. Robert C. Smith. Dr. Smith was the group's liaison to Congress, both individually and as a group. Defendants knew that Dr. Smith was the whistleblower liaison.
- 251. Defendants as a whole retaliated against the whistleblowers for communicating with Dr. Smith *because* he was their Congressional liaison.

### VIII. Defendants' Stated Concerns About Release of Confidential Information Is Pretext

252. The Defendants' stated concerns of release of confidential information are pretextual.

# <u>a.</u> Pretext Is Demonstrated by the Prolonged Surveillance Without Directly Addressing the Matter with the Subjects of the Surveillance

- 253. Pretext is demonstrated by the FDA engaging in years of monitoring without directly informing the whistleblowers to stop communicating with each other or with Congress.
- 254. For over two years Defendants secretly monitored the electronic correspondence of the Plaintiffs and failed to take any direct steps to prevent the disclosure of so-called confidential information.
- 255. For over two years, Defendants monitored the electronic correspondence of the Plaintiffs. During that time, the FDA did not warn the Plaintiffs that they knew of the protected disclosures, or grant them more education on what may or may not be disclosed, or place any of them on a performance improvement plan to address the disclosures.
- 256. Instead, throughout the period of monitoring, Defendants used the information it was obtaining to learn about Plaintiffs' communications (or proposed communications) with Congress, the Office of Inspector General, and other appropriate authorities, and provide

Defendants with the ability to defend and/or discredit the whistleblower in the eyes of the persons to whom the Plaintiffs' were trying to blow the whistle.

- 257. Defendants used this prolonged period of surveillance in an attempt to obtain information that could discredit the whistleblowers or be used by the United States to personally destroy the careers and reputations of distinguished medical doctors and other professionals.
- 258. Defendants engaged in a prolonged effort to try to find any evidence whatsoever that Plaintiff violated a law when they engaged in their whistleblowing activity.
- 259. When Defendants were unable to find evidence that the Plaintiffs had violated laws, they reviewed the contents of the secretly intercepted emails and recommended disciplinary action based on the content and viewpoint expressed in the intercepted emails.
- 260. Defendants viewed the content of emails intercepted from P.J. Hardy and concluded, based on his private opinions and viewpoint expressed in his emails, that he could not be "trusted" and should be terminated.
  - <u>Pretext Demonstrated by Repeated Attempts to Initiate Criminal Investigations</u>
     <u>into Unauthorized Disclosures of Information, Despite Being Repeatedly</u>
     <u>Informed That the Disclosures Are Authorized and Protected by Law</u>
- 261. Pretext is also demonstrated by the FDA's continuous attempts to have other agencies conduct criminal investigations into the whistleblowers, despite being informed on multiple occasions there was nothing illegal about the whistleblowers' communications.
- 262. Senator Grassley informed the FDA that the communications were protected as far back as January 2009.
- 263. On or about January 29, 2009, Defendants intercepted an email from Joanne Royce, Chief Counsel for the House Energy and Commerce Committee, to Plaintiff Hardy. Her email stated that Plaintiffs had committed no crime in releasing information to Congress.

Furthermore, Ms. Royce informed Plaintiff Hardy (and through the intercept, Defendants), that an investigation based on those communications was illegal retaliation.

- 264. On or about May 18, 2010, Special Agent Scott Vantrease of the Office of Inspector General of the Department of Health and Human Services informed Defendants that the disclosures made by the Plaintiffs were not criminal, and were protected under law.
- 265. In May 2011, the FDA cited that series of email correspondence as a reason to terminate Mr. Hardy.
- 266. FDA did not even claim that many of these intercepted emails for which they predicated their request that PHS fire Mr. Hardy contained any confidential information whatsoever.
- 267. Indeed, FDA's rationale for conducting the interceptions changed and shifted, from a focus on so-called confidential information to a focus on the content and viewpoint of the emails themselves.
- 268. FDA selected a small handful of emails obtained from its secret monitoring of Mr. Hardy over a two year period of time, and accused Mr. Hardy of being untrustworthy, in part based on the fact that he raised concerns with Congress and stated private opinions about work and FDA management to his fellow whistleblowers.
- 269. Despite having direct knowledge that the disclosures made by the Plaintiffs were protected under law, Defendants continued to engage in covert surveillance activities.
- 270. On numerous occasions, based on whole or in part on information obtained by the covert surveillance, search, seizure and confiscation activities, Defendants tried to convince federal law enforcement agencies to file criminal charges against one or more of the Plaintiffs, such as HHS OIG, and the DOJ.

- 271. These numerous attempts by Defendants to have the whistleblowers prosecuted for so-called unauthorized disclosures of confidential or Agency information were continuously rejected by appropriate law enforcement officials.
- 272. Defendants completely ignored the warnings that the disclosures were authorized and protected by law. Instead, Defendants continued to conduct their surveillance activities and continued to try to convince law enforcement agencies to charge one or more of the Plaintiffs with a crime.

# IX. Defendants Violated the 5th Amendment Due Process Requirements and Prohibition on Takings Without Just Compensation

- 273. Plaintiffs authored personal correspondences which constitute their property.
- 274. Plaintiffs' correspondence was sent through Private Email Accounts. Alternatively, the Plaintiffs communicated via attachments to their Private Emails.
- 275. Plaintiffs' email correspondence constitutes the personal property of the author ("Proprietary Emails").
  - 276. These Proprietary Emails are afforded full property rights.
- 277. The Proprietary Emails were sent through protected communications from an author's personal email account and sent directly to the recipient's private email account.
- 278. Plaintiffs corresponded on their own time and intended that their Proprietary Emails be private.
- 279. The Proprietary Emails were password protected and communicated via the Internet in an encrypted format using a personal, private, non-Governmental email account.

- 280. Plaintiffs sent and received the Proprietary Emails on their own time, intending these private emails not be read, taken, maintained or copied by HHS and converted into a system of records.
- 281. Defendants without knowledge, consent, or notice of the authors, took the Proprietary Emails and converted them into the property of the Defendants.
- 282. Defendants thereafter stored the Proprietary Emails on a variety of records systems controlled by the Defendants, again without knowledge of, consent of, or notice to the authors.
- 283. Defendants have used and continue to use the Proprietary Emails for their own benefit without consent.
  - 284. At no time were any of the Plaintiffs compensated for their Proprietary Emails.
- 285. Defendants engaged in a wide scale practice of taking Proprietary Emails of the Plaintiffs, making the property part of their databases, and using the documents as if they were the owners, without giving Plaintiffs compensation or Due Process.
- 286. All of the conversions were conducted without any due process or compensation paid to the whistleblowers.

# X. Facts Related to Defendants' Violation of Plaintiff Julian J. Nicholas' First Amendment Rights

- 287. Prior to engaging in protected speech, Plaintiff Nicholas had a pre-existing commercial relationship with the United States as an FDA contract employee.
- 288. The FDA claims that Julian J. Nicholas worked as an independent contractor through an arrangement with the Oak Ridge Institute for Science and Education ("ORISE") from Oct. 10, 2008, until his contract was not renewed on October 30, 2009.

- 289. The FDA has long used ORISE contractors to fill gaps in its expertise. The FDA continues to use ORISE contractors in its operations. ORISE contractors may stay at the FDA and have their contracts renewed regularly for years.
- 290. The FDA claims that Julian J. Nicholas had no status as a Federal employee for the period that he worked under the ORISE contract. FDA considers participants in ORISE short-term contractors. The FDA indicates that such ORISE participants do not have supervisors, and are not subject to performance management plans.
- 291. As an ORISE contractor for the FDA, Dr. Nicholas reviewed medical devices as a scientific expert in gastroenterology for safety and efficacy.
- 292. On or about March 2009, Dr. Nicholas reviewed a CT colonography device for FDA clearance. The device manufacturer wanted to use the CT colonography device for population screening. Dr. Nicholas concluded that the device was neither safe nor effective for population screening.
- 293. Dr. Nicholas noted that a single CT scan was the equivalent of 400 chest X-rays. Because a patient receives two CT scans during a colonoscopy examination, Dr. Nicholas noted that a single CT colonography examination would result in the equivalent radiation dose of 800 chest X-rays.
- 294. Dr. Nicholas concluded that the broad usage of the device on healthy patients would result in significantly increased incidents of induced cancer. Dr. Nicholas estimated that after a single CT colonography examination, a healthy person would have approximately a 1 in 700 to 1 in 1,000 chance of developing cancer. Such induced cancers include colorectal cancers and hematological cancers such as leukemia.

- 295. Dr. Nicholas also found that the most current science on the issue indicated that there is no demonstrable evidence that CT colonography prevents the development of colorectal cancer or reduces colorectal cancer mortality rates when used for population screening.
  - 296. Dr. Nicholas indicated that he would refuse to clear the device.
- 297. On April 13, 2009, despite Dr. Nicholas' finding that the device was neither safe nor effective, FDA managers indicated that they would clear the device anyway.
- 298. On April 26, 2009, Dr. Nicholas requested that Dr. Robert C. Smith independently review the submission.
- 299. On May 5, 2009, Dr. Smith made an independent finding that the device should not be cleared, and that if cleared, it would pose a serious public health risk. Dr. Smith also noted that past CT colonography devices were not cleared for population screening, but prior FDA mistakes led to clearance for population screening. Those devices suffered from the same flaws as the device Drs. Nicholas and Smith were currently reviewing.
- 300. On May 19, 2009, Dr. Nicholas submitted his official clinical review memorandum recommending against FDA clearance.
- 301. On May 29, 2009, Dr. Robert C. Smith submitted his official clinical review memorandum recommending against FDA clearance. Dr. Smith also sent an email to Dr. Joshua Sharfstein, then Principal Deputy Commissioner at FDA, blowing the whistle on FDA managers regarding the review of the GE CT Colonography device.
- 302. On June 11, 2009, Dr. Smith sent an email to the House Energy and Commerce Committee regarding his and Dr. Nicholas's concerns surrounding the GE CT Colonography device.

- 303. On September 24, 2009, a group of FDA whistleblowers, including Dr. Nicholas (via phone) and Dr. Smith, met with members of the House Energy and Commerce Committee and discussed their concerns regarding the CT colonography device under review and related CT colonography devices.
- 304. On September 28, 2009, Dr. Nicholas participated in a joint email to Dr. Jeffrey Shuren with the subject line "Accountability, Transparency, and Enforcement at CDRH." The email outlined the group's concerns about dangers to the public health, safety and welfare. Specifically, Dr. Nicholas and Dr. Smith explained to Dr. Shuren how they tried to prevent the approval of the CT colonography devices. The email provided relevant attachments to support their claims.
- 305. On October 1, 2009, Dr. Nicholas corresponded with Dr. Shuren by email. Dr. Nicholas described his concerns over his management's misconduct and fears that he may be retaliated against.
- 306. On Oct. 6, 2009, Congressman Chris Van Hollen informed Defendant Hamburg that he was "deeply concerned" that Nicholas faced termination as a consequence of bringing forward major concerns. Congressman Van Hollen provided Hamburg with a chronology of Nicholas' whistleblowing that confirmed that Nicholas had gone outside of his chain of command, including but not limited to serious concerns with Office of the Commissioner, FDA Chief Scientist, and Inspector General of HHS.
- 307. On October 14, 2009, Dr. Nicholas was notified that his contract would not be renewed. Though requested, no explanation was given.
- 308. On October 16, 2009, Congressman Van Hollen sent a letter to FDA

  Commissioner Dr. Margaret Hamburg with a detailed chronology explaining Dr. Julian Nicholas

situation. The chronology includes extensive references to the CT colonography device under Dr. Nicholas' review.

309. On Oct. 31, 2009, the FDA let Dr. Nicholas' employment contract expire.

## **FIRST CAUSE OF ACTION**

# (Fifth Amendment- Due Process and Takings Clause)

- 310. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 311. Defendants willfully and intentionally violated the Due Process Clause and the Takings Clause of the Fifth Amendment of the United States Constitution.
- 312. Defendants took Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas,
  Ewa M. Czerska, and Proprietary Emails, memoranda, and
  electronic communications and subsequently converted them into their system of records without
  Due Process of Law.
- 313. Defendants took the Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and Proprietary Emails, memoranda, and electronic communications and subsequently converted them into their system of records without any compensation.
- 314. As authors of these Proprietary Emails, Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and have the right to prevent communication to other persons, and control their use and distribution.
- 315. By unlawfully converting, communicating, controlling, using, and distributing their Proprietary Emails, Defendants violated Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and property rights.

- 316. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and were not compensated for the taking of their Proprietary Emails, memoranda, and other electronic communications.
- 317. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and seek preliminary and permanent injunctive relief in order to cure these violations and to prevent future violations regarding the Plaintiffs and all other similarly situated federal employees, contractors employed through ORISE, and officers of the Public Health Service.
- 318. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, Ewa M. Czerska, and seek a declaratory judgment finding the actions of the Defendants unconstitutional as it concerns themselves and all other similarly situated federal employees, contractors employed through ORISE, and officers of the Public Health Service.
- and other documents were also converted into the property of the United States in violation of the Fifth Amendment and seeks the same relief requested by the other Plaintiffs.
- 320. Plaintiffs seek a declaratory judgment and temporary and permanent injunctive relief, finding the actions of the Defendants unconstitutional at it concerns Plaintiffs' and all whistleblowers who work for or on behalf of the federal government.

#### **SECOND CAUSE OF ACTION**

#### (Fourth Amendment – Unreasonable Initiation of Search & Seizure)

321. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.

- 322. Plaintiffs have a Fourth Amendment right to be free from unreasonable searches and seizures by the Government.
- 323. Plaintiffs had a reasonable expectation of privacy in their private, third-party, non-Governmental, password protected, and encrypted emails accessed from their private offices or personal homes.
- 324. Plaintiffs had a reasonable expectation of privacy in their private, third-party, non-Governmental, password protected, and encrypted emails to representatives of the United States Congress and their own representatives, accessed from their private offices or personal homes
- 325. Defendants violated Plaintiffs Fourth Amendment right to be free from unreasonable search and seizure.
- 326. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected and/or known to have engaged in whistleblower activity.
- 327. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected and/or known to have contacted members of the United States Congress and/or their staffs and raised matters of public concern protected under the First Amendment of the United States Constitution.
- 328. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected and/or known to have raised matters of public concern with President-Elect Obama and the President-Elect's Transition Team.
- 329. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected of having had

constitutionally protected contacts with members of the news media regarding matters of public concern.

- 330. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected and/or known to have engaged in speech protected under the First Amendment of the United States Constitution.
- 331. Defendants initiated searches and seizures of Plaintiffs' private, personal electronic correspondence and files because Plaintiffs were suspected and/or known to have associated with other employees who engaged in protected whistleblowing/First Amendment activity in violation of the association rights protected under the United States Constitution.
- 332. Defendants searched and seized Plaintiffs' private, personal electronic correspondence and files in retaliation for their protected disclosures (or suspected disclosures) under the First Amendment of the United States Constitution and their protected associational rights under the United States Constitution.
- 333. The justification used by Defendants to initiate the searches and seizures at issue in the case will, in fact and *per se*, have a chilling effect on the First Amendment on the Plaintiffs and all other similarly situated federal employees, contractors employed through ORISE, and officers of the Public Health Service.
- 334. The justification used by Defendants to initiate the searches and seizures at issue in the case will, in fact and *per se*, have a chilling effect on the First Amendment rights of members of the public to obtain information concerning government misconduct and significant threats to the public health and safety.
- 335. The justification used by Defendants to initiate the searches and seizures at issue in the case will, in fact and *per se*, have a chilling effect on the First Amendment associational

rights of the Plaintiffs (both in their capacity as citizens and in their capacity as current or former employees of the federal government, government contractors, and/or the Public Health Service) and all other similarly situated members of the public, federal employees, contractors employed through ORISE, and officers of the Public Health Service.

- 336. The Government, by initiating a search and investigation based on allegations of protected activity, engaged in an unreasonable search of Plaintiffs' private, personal, electronic correspondence.
- 337. Plaintiffs seek preliminary and permanent injunctive relief in order to cure these violations and to prevent future violations regarding the Plaintiffs and all other similarly situated federal employees, contractors employed through ORISE, and officers of the Public Health Service.
- 338. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, and Ewa M. Czerska, all of whom are now private citizens and no longer work for the federal government, seek a declaratory judgment and temporary and permanent injunctive relief finding the actions of the Defendants unconstitutional as it concerns their rights of association and their right to engage in speech on matters of public concern.
- 339. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, and Ewa M. Czerska, all of whom are now private citizens and no longer work for the federal government, seek a declaratory judgment and temporary and permanent injunctive relief finding the actions of the Defendants unconstitutional as it concerns the rights of all whistleblowers and all persons who may publish whistleblower-related speech in the United States to be able to freely communicate with current federal employees, contractors and officers of the Public Health Service, without fear that their communications may trigger warrantless searches and seizures of

their private emails and/or the private communications of other persons associated with the federal government for whom they communicate.

- 340. Plaintiffs Paul T. Hardy, Robert C. Smith, Julian J. Nicholas, and Ewa M. Czerska, all of whom are now private citizens and no longer work for the federal government, seek a declaratory judgment and temporary and permanent injunctive relief finding that the actions of the Defendants created an unconstitutional chilling effect on their associational and free speech rights (and the associational and free speech rights of other similarly situated persons who are either private citizens or who work for, or on behalf of the United States) protected under the United States Constitution.
- 341. Plaintiffs seek a declaratory judgment finding the actions of the Defendants unconstitutional at it concerns themselves and all other similarly situated persons, federal employees, contractors employed through ORISE, and officers of the Public Health Service.
- 342. Plaintiffs seek a declaratory judgment and temporary and permanent injunctive relief finding the actions of the Defendants unconstitutional as it concerns all whistleblowers, whether or not they work for, or on behalf of the United States.
- 343. Plaintiffs seek a declaratory judgment and temporary and permanent injunctive relief in order to fully cure the violations of the United States Constitution set forth in this Count.

# **THIRD CAUSE OF ACTION**

# (Fourth Amendment – Unreasonable Scope and Duration of Search & Seizure)

- 344. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 345. Plaintiffs have a Fourth Amendment right to be free from unreasonable searches and seizures by the Government.

- 346. Plaintiffs had a reasonable expectation of privacy in their private, third-party, non-Governmental, password protected, encrypted emails accessed from their private offices or personal homes.
- 347. Defendants stated reason for searching Plaintiffs' private electronic communications was for the purpose of preventing unauthorized disclosures of Agency or confidential information.
  - 348. Defendants searched Plaintiffs' attorney-client privileged communications.
  - 349. Defendants searched Plaintiffs' personal, family, and financial information.
- 350. Defendants searched Plaintiffs' private communications while in the confines of their own homes, while on vacation, or while in a different state, and other locations outside of the regular confines of the workplace.
  - 351. Defendants searched Plaintiffs' private communications with Congress.
- 352. By searching Plaintiffs' attorney-client privileged information, Defendants' exceeded the reasonable scope of their search.
- 353. By searching Plaintiffs' private, family, financial, and otherwise personal, non-FDA-work-related correspondence, Defendants exceeded the reasonable scope of their search.
- 354. By searching all of Plaintiffs' communications, no matter the communication system or the location of Plaintiffs themselves, Defendants exceeded the reasonable scope of their search.
- 355. By searching Plaintiffs' communications with Congress, Defendants exceeded the reasonable scope of their search.
- 356. By searching Plaintiffs' communications for over two years, Defendants exceeded the reasonable duration of their searches.

- 357. By searching Plaintiffs' communications after learning that the information being searched and seized constituted First Amendment protected speech, Defendants exceeded the reasonable duration of their search.
- 358. By failing to narrowly tailor the scope and duration of their searches of Plaintiff's communications, defendants were able to improperly spy on Plaintiffs' private communications and draft communications with various appropriate authorities, such as the United States Congress.

### **FOURTH CAUSE OF ACTION**

# (Violations of the First Amendment Protections of Freedom of Association)

- 359. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
  - 360. The First Amendment protects Freedom of Association.
- 361. Defendants violated Plaintiffs' right to Associate by engaging in surveillance against them.
- 362. The Defendants' secret surveillance is in retaliation for First Amendment protected activity.
- 363. Because the surveillance is retaliation and an implied threat of future adverse employment actions, and because it is secretive and unannounced, even the possibility of surveillance has chilled and continues to chill Plaintiffs' ability to associate, within the group, with people outside the group, and with the public.
- 364. The court should grant injunctive and declaratory judgment on behalf of all Plaintiffs and all other similarly situated employees, finding that PHS and FDA employees are protected when they raise disclosures of matters of public concern, and that such conduct will not

trigger warrantless surveillance and/or to searches and seizures of their Private Emails and that the scope and duration of any such search shall be reasonable and within constitutional proper constitutional boundaries.

365. The court should grant injunctive and declaratory judgment on behalf of the Plaintiffs who no longer work for the United States, in their capacity as citizens and in their capacity as actual and potential publishers of information of public concern regarding public health and safety matters, finding that federal employees and officers of the PHS are protected when they raise disclosures of matters of public concern to these former employees, and that such conduct will not trigger warrantless surveillance and/or to searches and seizures of their Private Emails.

# FIFTH CAUSE OF ACTION

# (Violations of the Mr. Hardy's First Amendment Protections of Freedom of Speech)

- 366. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 367. The First Amendment protects the right of citizens to engage in speech of public concern, to communicate with Congress, and to associate with persons of their choosing.
- 368. Under 5 U.S.C. § 7211 Mr. Hardy had a right to provide information to representatives of the United States Congress.
- 369. Under the First Amendment Mr. Hardy had a right to communicate with counsel of his own choosing, to utilize the services of Dr. Smith as a representative, and to have private communications with persons for whom he was working jointly with in order to blow the whistle to the Congress of the United States and other appropriate agencies.
  - 370. Defendants willfully and intentionally violated all of these rights.

- 371. Mr. Hardy engaged in whistleblower activity by reporting dangers to public health, welfare, and safety to Congress. Mr. Hardy reported flaws in the FDA's device review process and blew the whistle on particular devices that would increase the risk that women with breast cancer would go undiagnosed or suffer a delayed diagnosis.
- 372. On September 9, 2011, Mr. Hardy was informed by Defendant Stevens that his commission would be terminated on October 9, 2011. This resulted in Mr. Hardy's termination from federal service.
- 373. The Office of Special Counsel ("OSC") conducted a preliminary review of the Hardy termination under the Whistleblower Protection Act, a law designed to protect federal civil servant whistleblowers from retaliation.
- 374. The OSC determined that there was sufficient evidence that Hardy had engaged in protected activity and had suffered from illegal retaliation to justify the OSC seeking a "stay" of the negative actions that led to Hardy's removal from the PHS.
- 375. On October 14, 2011, the OSC requested such a "stay" from the Merit Systems Protection Board (MSPB).
- 376. Over the objection of Defendants, the MSPB granted the initial stay on Oct. 14, 2011.
- 377. A "stay" under the rules governing the OSC and MSPB is similar to a preliminary injunction granted by a U.S. District Court.
- 378. OSC continued its investigation into Mr. Hardy's removal and on November 14, 2011, requested an extension of the stay.
- 379. OSC made specific findings that, according to the evidence it reviewed, Mr. Hardy had engaged in speech fully protected under the First Amendment of the United States

Constitution, and furthermore that credible evidence existed that demonstrated illegal retaliation against Mr. Hardy based on that protected speech.

- 380. Defendants opposed the stay, and set forth legal authority which held that officers of the PHS are not federal employees and are not covered under any federal civil service laws.
- 381. The MSPB reviewed these legal authorities and concluded that Mr. Hardy was not a federal employee and thus the MSPB had no jurisdiction over his case.
- 382. Based on a lack of subject matter jurisdiction, the MSPB declined to renew the stay.
- 383. The decision of the MSPB finding that officers of the Commissioned Corps of the PHS have no federal whistleblower rights was publicly published, is widely available on the Internet, and is widely known throughout the PHS.
- 384. Mr. Hardy's termination had a chilling effect on Hardy and similarly situated within FDA and PHS.
- 385. Furthermore, the fact that the MSPB has found no jurisdiction to protect any PHS employee from whistleblower retaliation has had and continues to have a chilling effect on all PHS employees.
- 386. All similarly situated PHS employees have now suffered a chilling effect on their First Amendment right to free speech.
- 387. Similarly situated PHS employees now believe that they have no legal protection if they blow the whistle.
- 388. The fact that PHS employees, by reading the MSPB decision and following media accounts of the Hardy case, and obtaining misinformation from their managers concerning their

right to blow the whistle on issues of public concern, has created a chilling effect on First Amendment freedom of speech for all similarly situated PHS employees.

- 389. The same knowledge interferes with the right of the Public to learn critical health and safety information and other information of public concern from PHS employees and interferes with the ability of Plaintiffs who no longer work for the United States to gain access to important information concerning public health and safety and to publish that information.
- 390. PHS should be ordered immediately to post notice to all employees that they do have a right to raise matters of public concern under the First Amendment, and cannot be lawfully retaliated against for communicating these concerns to appropriate authorities, including the Congress of the United States or to any of the Plaintiffs who are not currently federal employees and who seek access to this information so that they can publish their opinions and views concerning government misconduct and the public health and safety.
- 391. The court should grant a declaratory and injunctive relief on behalf of Mr. Hardy and all other similarly situated employees, finding that PHS employees are protected under the First Amendment when they make disclosures of matters of public concern.
- 392. The court should grant a declaratory and injunctive relief on behalf of Mr. Hardy, all of the Plaintiffs and all other similarly situated federal employees or officers of the PHS, finding that PHS employees have a right to associate with counsel and representatives of their choosing, and cannot be retaliated against for associating with persons who are known to be "whistleblowers."
- 393. Mr. Hardy seeks preliminary and permanent injunctive relief based upon the First Amendment, including but not limited to reinstatement of his position from the effective date of termination.

### SIXTH CAUSE OF ACTION

# (Violations of the Dr. Nicholas' First Amendment Protections of Freedom of Speech)

- 394. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 395. Plaintiff Dr. Nicholas has a Constitutional right to protections of Freedom of Speech and Association, and the right to communicate with Congress under both the First Amendment and 5 U.S.C. § 7211.
- 396. Dr. Nicholas raised matters of public concern protected under the First Amendment and 5 U.S.C. § 7211 when he blew the whistle on FDA efforts to clear ineffective and dangerous CT Colonography devices.
- 397. Dr. Nicholas raised matters of public concern protected under the First Amendment and 5 U.S.C. § 7211 when he associated with the well-known FDA whistleblower Dr. Robert Smith, and used Dr. Smith to act as his representative for the purposes of engaging in constitutionally protected speech.
- 398. Defendants retaliated against Dr. Nicholas based on his association with Dr. Smith.
- 399. Defendants retaliated against Dr. Nicholas based on his speech protected under the U.S. Constitution and 5 U.S.C. § 7211.
- 400. This retaliation by Defendants included, but was not limited to, the refusal of the FDA to renew Dr. Nicholas' contract to work for the United States through the ORISE contracting process. This retaliation by Defendants was intentional and willful.
- 401. Plaintiff Nicholas requests preliminary and permanent injunctive relief based upon the First Amendment, including but not limited to reinstatement of his contract.

402. Plaintiffs request all appropriate injunctive and declaratory relief necessary to cure the chilling effect the termination of Dr. Nicholas' contract had on all federal employees and all persons who work for the United States under a contract with ORISE.

# **SEVENTH CAUSE OF ACTION**

# (Violations of the Lloyd LaFollette Act and Right to Petition Congress)

- 403. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 404. The Lloyd LaFollette Act 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." 5 U.S.C. § 7211.
- 405. The United States Constitution protects the right of every American to communicate with Congress.
- 406. Plaintiffs have provided information to Congress either directly or through their representative Dr. Robert Smith.
  - 407. Plaintiffs have been retaliated against for providing information to Congress.
- 408. Plaintiffs' emails to and from Congress have been intercepted, despite the fact that they were sent privately on third-party, password protected, encrypted Private Email Accounts or other non-FDA accounts.
- 409. Plaintiffs found out about the intercepts of Congressional correspondence on or about December 2011.

- 410. FDA managers have admitted in writing that employees who blow the whistle to Congress "cannot be trusted." Although this quote was directly related to Plaintiff Hardy, it concerned all Plaintiffs and their communications with Congress.
- 411. Additionally, Defendant FDA explicitly pointed to private, third-party email communications with Congress that contain no confidential information whatsoever as evidence that the whistleblowers should be fired from their positions.
- 412. Defendant FDA managers used the intercepted, private, third-party, password protected emails to and from Members of Congress to urge the Public Health Service to take disciplinary action and fire Mr. Paul T. Hardy.
- 413. Defendants' undertook these violations of the U.S. Constitution and the Lloyd-LaFollette Act despite being explicitly being informed by responsible members of Congress of the right of employees to communicate with Congress.
- 414. These responsible members of Congress explicitly informed Defendants of the Lloyd LaFollette Act, of provisions of the criminal code that made it illegal to retaliate against whistleblowers who contact Congress, and provided Defendants with the actual text of the Lloyd-LaFollette Act.
- 415. In addition, responsible Members of Congress warned Defendants not to retaliate against employees who contacted Congress and insisted that Defendants take action to prevent retaliation.
- 416. In May 18, 2010, the OIG informed Defendants that disclosures to Congress are permitted and protected by law. Defendants willfully ignored the law and the warnings from Congress and their own Office of Inspector General.

- 417. Retaliation based on communicating with Congress, whether such communications are undertaken directly by an employee or officer of the Defendants, or is undertaken by a representative of the employees or officers, has had and will have a chilling effect upon Plaintiffs and all similarly situated federal employees, federal contractors, and officers of the PHS.
- 418. Plaintiffs request all appropriate injunctive and declaratory relief, under the First Amendment Right to Petition clause and 5 U.S.C. § 7211.
- 419. Plaintiff Hardy requests an injunction ordering his reinstatement to his position in the PHS.
- 420. Plaintiff Nicholas requests an injunction ordering the reinstatement of his contract with ORISE so he can continue to work for the FDA.
- 421. Plaintiffs request an injunction requiring Defendants to inform all employees/officers and contractors of their rights under the Lloyd LaFollette Act, and ensure that employees will not be subject to any warrantless electronic surveillance because of their communications with Congress, and that their communications with Congress will not trigger surveillance.

# **EIGHTH CAUSE OF ACTION**

# (Violations of Plaintiffs' Right of Association and Counsel)

- 422. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
- 423. The First Amendment protects citizens' right to associate. This right extends to being able to associate in private.

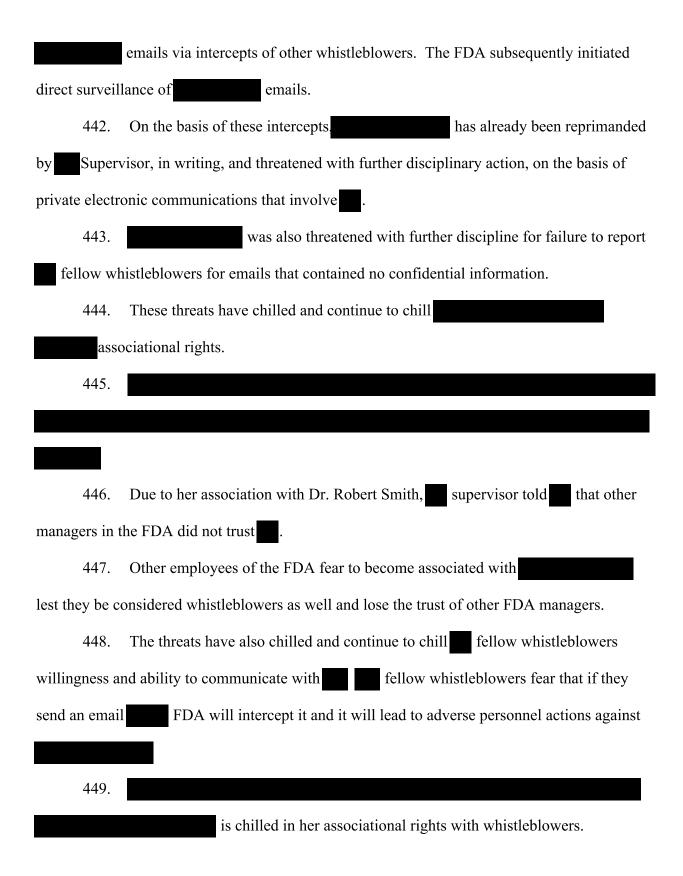
- 424. Plaintiffs and all similarly situated persons have a right to confidential communications with their attorney or their representatives.
- 425. Plaintiffs and all similarly situated persons have a right to associate and communicate with persons who are unpopular with the United States Government, including governmental agencies that may serve as employers to the Plaintiffs and other similarly situated persons.
  - 426. Defendants have violated Plaintiffs' right to freedom of association.
- 427. Defendants have violated Plaintiffs' right to confidential communications with their attorneys.
  - 428. Defendants knew that Dr. Robert C. Smith was an attorney.
  - 429. Defendants knew that Dr. Smith was providing legal advice to whistleblowers.
- 430. Defendants knew that Dr. Smith was helping Plaintiffs file complaints with the Office of Inspector General, the Office of Special Counsel, the President of the United States, and the Congress of the United States.
- 431. While Dr. Smith was providing to whistleblowers legal advice and helping them file complaints to various offices, Defendants targeted Dr. Smith and anyone who communicated with him for surveillance.
  - 432. Other employees within the FDA knew Dr. Smith was an attorney.
- 433. It is now well-known and notorious that Defendants conducted surveillance on Dr. Smith and anyone who communicated with him.
- 434. Plaintiffs seek permanent and preliminary injunctive relief and a declaratory judgment to stop and prevent all warrantless surveillance of FDA/HHS/PHS employees or officers that may be triggered because said employee/officer/contractor communicates with Dr.

Smith or any of the Plaintiffs, any person known to be a whistleblower and/or any person or organization that publishes allegations raised by a whistleblower.

435. Plaintiffs seek an order to have HHS and FDA make a public announcement to their staff that their communications with attorneys are privileged and confidential and are not subject to surveillance.

# **NINTH CAUSE OF ACTION**

The facts contained in the paragraphs above are hereby repeated and re-alleged as 436. set forth above. The First Amendment protects Plaintiffs Freedom of Association. 437. 438. Defendants violated First Amendment Right to Association. 439. associate with the remaining Plaintiffs, including Dr. Robert C. Smith. 440. As a direct consequence of being a member of the whistleblower group, emails have been intercepted, converted, and reviewed. The FDA initially emails via intercepts of other whistleblowers. The FDA obtained subsequently initiated direct surveillance of emails. As a direct consequence of being a member of the whistleblower group, 441. emails have been intercepted, converted, and reviewed. The FDA initially obtained



- 450. The threats have had and continue to have a chilling effect on all other similarly situated employees as well.
- enforcement injunctive relief and a declaratory judgment to cure the chilling effect of these constitutional violations, as they impact directly and other similarly situated federal employees.
- 452. Dr. Smith seeks preliminary and permanent injunctive relief, in his capacity as a member of the public who publishes and seeks to publish information on public concern, based on the violation of his associational and free speech rights and the chilling effect Defendants' conduct has on his (and other whistleblowers') ability to communicate with employees, contractors or officers of the United States.
- 453. All Plaintiffs seek preliminary and permanent injunctive relief, in their capacity as a member of the public who publish, or who have and will seek to publish information on public concern, based on the violation of their associational and free speech rights and the chilling effect Defendants' conduct has on their (and other whistleblowers') ability to communicate with employees, contractors or officers of the United States.
- additional adverse action against them based on their protected First Amendment activity, and seek preliminary and permanent injunctive relief and a declaratory judgment to prevent future adverse action or future threats directed against them (and any similarly situated federal employee/officer or contractor) based on their lawful Private Email communications to whistleblowers (including all of the other Plaintiffs), and their communications with Congress.

- are fearful that Defendants will take additional adverse action against them based on future or continued electronic surveillance of their Private Emails that have been or will be triggered by their protected First Amendment activity (including speech and association), and seek preliminary and permanent injunctive relief and a declaratory judgment to prevent any future warrantless search of their workplace or home electronic communications that may be triggered by their protected speech or right to association with known whistleblowers.
- the Plaintiffs seek this relief on behalf of themselves, and all other similarly situated federal employees, contractors and/or officers.

#### **TENTH CAUSE OF ACTION**

- 457. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
  - 458. The Fourth Amendment protects citizens from unreasonable search and seizures.
- 459. The FDA has violated the Fourth Amendment in conducting unreasonable search and seizures of private email correspondence.
- 460. These unreasonable searches and seizures have had and continue to have a chilling effect on right to freedom of speech.
- and all other similarly situated federal employees (contractors and officers) suffer from these chilling effects.
- seek preliminary and permanent injunctive relief and a declaratory judgment to cure the chilling effect of these violations of their Fourth Amendment rights.

- 463. Defendants' surveillance also chills the right of the Public and Congress to obtain info from FDA employees regarding matters of public concern.
- are fearful that Defendants will take additional adverse action against them based on future or continued electronic surveillance of their Private Emails that have been or will be triggered by their protected First Amendment activity (including speech and association), and seek preliminary and permanent injunctive relief and pre-enforcement preliminary and permanent injunctive relief and a declaratory judgment to prevent any future warrantless search of their workplace or home electronic communications that may be triggered by their protected speech or right to association with known whistleblowers.

### **ELEVENTH CAUSE OF ACTION**

# (Violations of Plaintiff's First Amendment Rights for Viewpoint Based Implementation of Surveillance)

- 465. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.
  - 466. The First Amendment prevents viewpoint-based discrimination.
  - 467. The First Amendment prevents content-based discrimination
  - 468. The First Amendment prevents discrimination based on association.
- 469. The First Amendment protects persons who blow the whistle on government misconduct or threats to the public health and safety.
- 470. Defendants have instituted a policy of conducting electronic surveillance of employees, contractors, and Public Health Service personnel based on the content and/or viewpoint of their speech.

- 471. Defendants have used rules and regulations that are facially neutral in order to trigger and justify viewpoint based monitoring of employee whistleblowers, including the Plaintiffs.
- 472. Defendants have applied facially neutral rules in a manner that target employees/contractors and officers for retaliatory treatment (i.e. highly intrusive electronic monitoring) based on the content of the targets speech, the viewpoint of the target and the persons for whom the target associated.
  - 473. These policies are facially unconstitutional.
- 474. These policies are unconstitutional as applied to the Plaintiffs and other similarly situated employees/contractors/officers.
- 475. These policies violate 5 U.S.C. § 7211 as they target employees/contractors/officers who are known to have, or suspected to have, communicated to the U.S. Congress and provided information critical of the Defendants.
- 476. These policies are unconstitutional as they have a chilling effect on the protected speech of the Plaintiffs and other similarly situated employees/contractors/officers.
- 477. These policies are unconstitutional as they interfere with the ability of members of the public to obtain information on matters of public concern, including information about government misconduct and information regarding important public health and safety matters.

# TWELFTH CAUSE OF ACTION

# (Violations of Former Employees and Members of the Public's Associational and Free Speech Rights)

478. The facts contained in the paragraphs above are hereby repeated and re-alleged as set forth above.

- 479. The members of the public have a First Amendment right to Freedom of Association and Freedom of Speech.
- 480. Defendants have violated the rights of private citizens to obtain information from the Plaintiffs, from similarly situated employees/contractors/officers.
- 481. Defendants' targeting of whistleblowers or people who associate with whistleblowers interferes for extremely intrusive surveillance chills the associational and speech rights of the public.
  - 482. Plaintiffs Dr. Smith and Dr. Nicholas are now private citizens.
- 483. Dr. Smith and Dr. Nicholas are respected medical doctors, with highly respected national and international credentials.
  - 484. Dr. Smith is a published author on medical issues.
  - 485. Dr. Smith and Dr. Nicholas are public speakers on medical related issues.
- 486. Dr. Smith associates with and is a member of public interest organizations that publish on matters of public concern, including government misconduct and health and safety issues.
- 487. These public interest organizations publish information to the general public on medical health and safety issues and issues related to government misconduct.
- 488. Dr. Smith and Dr. Nicholas intend to publish information concerning misconduct by the Defendants and actions taken by the Defendants that threaten the public health and safety.
- 489. It is well known within the agencies managed by Defendants that any employee who associates or communicates with Dr. Smith may be and will be subjected to highly selected and highly intrusive electronic monitoring.

- 490. Association with Dr. Nicholas has a similar stigma, and Dr. Nicholas has specifically noticed that current employees of the FDA are reluctant to communicate with him.
- 491. It is well known within the agencies managed by the Defendants that any employee who associates or communicates with Dr. Smith may be and will be subjected to discipline, including, but not limited to, termination.
- 492. These actions and/or threatened actions by Defendants have a chilling effect on the willingness of any employee/contractor/officer employed by Defendants to communicate or associate with Dr. Smith, Dr. Nicholas and any of the other whistleblowers associated with Dr. Smith and/or any other whistleblower or person who may publish whistleblower-related information.
- 493. The actions of the Defendants interfere with Dr. Smith's and Dr. Nicholas' First Amendment rights to association and to speak and publish information on matters of public concern.
- 494. The actions of the Defendants interfere with all of the Plaintiffs' First Amendment rights to association and to speak and publish information on matters of public concern.
- 495. The actions of the Defendants interfere with the First Amendment rights of association and to speak and publish information on matters of public concern of all similarly situated federal employees/contractors/officers.
- 496. Defendants' actions materially interfere with the ability of Dr. Smith and Dr. Nicholas to obtain information from other employees or whistleblowers who work for Defendants. Defendants' actions materially interfere with Dr. Smith's and Dr. Nicholas' ability to effectively write, speak and publish information on matters of public concern.

- 497. Defendants' actions materially interfere with the ability of all Plaintiffs and all similarly situated employees/contractors/officers to obtain information from other employees or whistleblowers who work for Defendants. Defendants' actions interfere with all Plaintiffs' ability to effectively write, speak and publish information on matters of public concern.
- 498. Defendants' widely known surveillance has a chilling effect on all FDA employees, medical contractors, Public Health Service personnel assigned to the FDA, and any citizen, private or otherwise, who communicates with them. This harms not only the targeted whistleblowers, but private citizens and any potential recipient of a whistleblower disclosure.
  - 499. Plaintiffs seek injunctive and declaratory relief to remedy these violations.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

- (a) Issue a Declaratory Judgment finding that the United States cannot convert the private email and electronic communications of federal employees without due process of law and just compensation and cannot target whistleblowers for searches and seizures without a search warrant or validly issued subpoena that is narrowly tailored and limits the scope of any such search within valid constitutional parameters.
- (b) Issue all appropriate preliminary and permanent injunctive relief prohibiting

  Defendants from converting the private email and electronic communications of
  federal employees without due process of law and just compensation and from
  targeting whistleblowers for searches and seizures without a search warrant or validly
  issued subpoena that is narrowly tailored and limits the scope of any such search
  within valid constitutional parameters.

- (c) Order all Defendants to return the Proprietary Emails to each respective Plaintiff;
- (d) Order all Defendants to delete and expunge any original, copies, excerpts, or summaries of the Proprietary Emails, converted or otherwise, from their system of records;
- (e) Order all Defendants to return Plaintiffs' Proprietary Emails in an expedited fashion;
- (f) Prohibit all Defendants from using the property of Plaintiffs in any manner whatsoever that was obtained without due process or compensation.
- (g) Order all Defendants to inform all third parties to whom Defendants may have provided, sent, communicated, summarized, excerpted or told about the Proprietary Emails that the Proprietary Emails were obtained illegally, and request the third parties delete and expunge the Proprietary Emails and their copies, summaries, or excerpts.
- (h) Order all Defendants to inform all third parties to whom Defendants may have provided, sent, communicated, summarized, excerpted or told about the Proprietary Emails that the Proprietary Emails were obtained illegally, and request the third parties provide the Proprietary Emails to Plaintiffs.
- (i) Order all Defendants to make a complete accounting of all Third Parties provided with the Proprietary Emails, and provide that accounting to Plaintiffs.
- (j) Order all Defendants to make a complete accounting of every record system in which the Proprietary Emails have been stored, and provide that accounting to Plaintiffs.
- (k) Order all Defendants to make a full accounting of all people who received, transmitted, excerpted, summarized or otherwise saw or manipulated the Proprietary Emails.

- (l) Enjoin all Defendants from all such future takings and all future searches and seizures based on the viewpoint expressed by the government employee/contractor or officer;
- (m) Enjoin all Defendants from all such future takings and all future warrantless searches and seizures based on the interception of communications between a government employee/contractor or officer and representatives of the U.S. Congress;
- (n) Order all Defendants to expunge any and all documents for which they used the correspondences in question unless the author voluntarily consents to such use.
- (o) Grant all other equitable, injunctive and declaratory relief permitted under the First,

  Fourth, and Fifth Amendment of the United States Constitution, and the Lloyd

  LaFollette Act;
- Issue a Declaratory Judgment finding that Commissioned Corps Employees of the
   U.S. Public Health Service are protected under the First Amendment of the U.S.
   Constitution when they blow the whistle on matters of public concern.
- (q) Issue a Declaratory Judgment finding that the initiation of a warrantless search of federal employee private electronic communications triggered by protected speech under the First Amendment violates the Fourth Amendment of the U.S. Constitution.
- (r) Issue a Declaratory Judgment finding that the initiation of a warrantless search of federal employee private electronic communications triggered by speech on matters of public concern violates the First Amendment of the U.S. Constitution.
- (s) Issue a Declaratory judgment that the warrantless interception of federal employee private email communications with Congress, including Congressional staff, violates the First Amendment of U.S. Constitution and the Lloyd LaFollette Act.

- (t) Order all injunctive and declaratory relief as required on behalf of Plaintiffs and all similarly situated federal employees, commissioned corp. PHS employees / officers, and employees who work for the federal Government under ORISE contracts to cure and all constitutional violations as set forth in the complaint, and to prevent the future chilling effect caused by these violations.
- (u) Order preliminary and permanent injunctive relief and declaratory relief as appropriate to require that Defendants to reinstate Mr. Hardy into his position with the Public Health Service effective the date of his removal from federal service.
- (v) Order preliminary and permanent injunctive relief and declaratory relief as appropriate to require that Defendants to award an ORISE contract to Dr. Nicolas, and renew such contract consistent with its treatment of other persons who work for FDA under an ORISE contract.
- (w) Issue preliminary and permanent injunctive relief consistent w/ the declaratory judgments issued by the Court.
- (x) Order preliminary and permanent injunctive relief and declaratory relief as appropriate and as requested in this complaint;
- (y) Issue pre-enforcement preliminary and permanent injunctive relief consistent w/ the declaratory judgments issued by the Court.
- (z) Order pre-enforcement preliminary and permanent injunctive relief and declaratory relief as appropriate and as requested in this complaint;
- (aa) Award Plaintiffs their costs and reasonable attorney fees, including costs and fees permissible under the Equal Access to Justice Act; and
- (bb) Grant such other and further relief as the Court may deem just and proper.

# Respectfully submitted,

/s/ Stephen M. Kohn Stephen M. Kohn, Esq. DC Bar #411513 sk@kkc.com

David K. Colapinto DC Bar #416390 dc@kkc.com

Kohn, Kohn & Colapinto, LLP 3233 P Street, NW Washington, DC 20007 202-342-6980 phone 202-342-6984 fax Attorneys for Plaintiff

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