UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL T. HARDY
14905 Dinsdale Drive
Silver Spring, MD 20906,

and

EWA M. CZERSKA
5802 Massachusetts Avenue
Bethesda, MD 20816,

and

ROBERT C. SMITH
14204 Arbor Forest Drive
Rockville, MD 20850,

and

JULIAN J. NICHOLAS
11587 Carowind Lane
San Diego, CA 92131,

and

R. LAKSHMI VISHNUVAJJALA
1130 Betts Trail Way
Rockville, MD 20854,

and

NANCY G. WERSTO
3504 Toddsbury Lane
Olney, MD 20832-1354,

Plaintiffs,

v.

MARGARET A. HAMBURG
Commissioner
U.S. Food and Drug Administration

Case No. 1:11-cv-01739-RLW

SECOND AMENDED COMPLAINT

Filed July 17, 2012

10903 New Hampshire Avenue)
WO-31)
Silver Spring, MD 20993,)
)
and)
)
KATHLEEN SEBELIUS)
Secretary, Department of Health and)
Human Services)
200 Independence Ave. SW, Room 120F)
Washington, DC 20201,)
)
and)
)
REGINA M. BENJAMIN)
Surgeon General)
U.S. Public Health Service)
200 Independence Ave. SW, Rm. 701-H)
Washington, DC 20201,)
)
and)
)
UNITED STATES FOOD AND DRUG)
ADMINISTRATION)
10903 New Hampshire Avenue)
Silver Spring, MD 20993,)
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and)
)
UNITED STATES DEPARTMENT OF)
HEALTH AND HUMAN SERVICES)
200 Independence Avenue SW)
Washington, DC 20201,)
)
and)
)
UNITED STATES PUBLIC HEALTH SERVICE)
U.S. Public Health Service Commissioned Corps)
Tower Building)
Plaza Level 1, Room 100)
1101 Wooton Parkway)
Rockville, MD 20852,)
)
Defendants.)
_____)

INTRODUCTION

Plaintiffs Paul T. Hardy, Ewa M. Czerska, Robert C. Smith, Julian J. Nicholas, R. Lakshmi Vishnuvajjala, and Nancy G. Wersto (collectively "Plaintiffs") bring this action on behalf of themselves and other similarly situated employees, members of the public and contractors, seeking injunctive and declaratory relief against Defendants Margaret Hamburg, Kathleen Sebelius, Regina M. Benjamin, the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Health and Human Services ("HHS"), and the U.S. Public Health Service Commissioned Corps ("PHS") (collectively "Defendants"), in their official capacity, pursuant to the Administrative Procedure Act, the First, Fourth, and Fifth Amendments of the United States Constitution, and the Lloyd-LaFollette Act, 5 U.S.C. § 7211.

In violation of the Fifth Amendment, the Defendants took proprietary e-mails and converted them into government property. In violation of the Fourth Amendment, the Defendants conducted targeted, intrusive warrantless searches and seizures for an investigation of criminal wrongdoing unreasonable in initiation and scope. In violation of the First Amendment, the Defendants interfered with the Plaintiffs' freedom of association and targeted and suppressed individual speakers based on viewpoint. In violation of the Lloyd-LaFollette Act, Defendants interfered with Plaintiffs' ability to petition and furnish information to committees and Members of both Houses of Congress.

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 28 U.S.C. §§ 1331, 1343, 1346, 1361, and 1367.

2. Venue is proper in this District pursuant to the United States Code of Judicial Procedure, 28 U.S.C § 1391.

PARTIES

3. Plaintiff Paul T. Hardy ("Hardy") is a former officer of the PHS, and is a U.S. citizen residing in the State of Maryland. He earned a bachelor of science in biomedical engineering from Marquette University.

4. Plaintiff Ewa M. Czerska ("Czerska"), M.D., Ph.D., is a former employee of the 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.

5. Plaintiff Robert C. Smith ("Smith"), M.D., J.D., is a former employee of the FDA, and is a U.S. citizen residing in the State of Maryland. Between 2006 and 2010, Dr. Smith was a Medical Officer at the FDA, specializing in radiological devices. He received his M.D. from Yale University, and he received his J.D. from Fordham University.

6. Plaintiff Julian J. Nicholas ("Nicholas"), M.D., Ph.D., is a former employee of the FDA, and a former federal contractor working for the FDA through the Oak Ridge Institute for Science and Education ("ORISE") program. As an ORISE contractor, Dr. Nicholas reviewed medical devices for safety and efficacy. 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. in neurosciences from Oxford University.

7. Plaintiff R. Lakshmi Vishnuvajjala ("Vishnuvajjala"), Ph.D., is a current employee of the FDA, and is a U.S. citizen residing in the State of Maryland. She is the Branch

Chief of the Diagnostic Devices Branch in the Division of Biostatistics, Office of Surveillance and Biometrics at CDRH, FDA. She received her Ph.D. in Mathematical Statistics from Florida State University.

8. Plaintiff Nancy G. Wersto ("Wersto"), B.S., M.S., is a current FDA employee and U.S. citizen residing in the State of Maryland.

9. Defendant Margaret Hamburg, Commissioner of the FDA, is a U.S. citizen being sued in her official capacity.

10. Defendant Kathleen Sebelius, the Secretary of HHS, is a U.S. citizen who works in the District of Columbia being sued in her official capacity.

11. Defendant Regina M. Benjamin, the U.S. Surgeon General and head of PHS, is a U.S. citizen being sued in her official capacity.

12. Defendant U.S. Food and Drug Administration is an agency within HHS.

13. Defendant Department of Health and Human Services is a United States government agency.

14. Defendant U.S. Public Health Service Commissioned Corps is an agency within HHS.

FACTS

I. FDA EMPLOYEES AND WORKERS ENGAGED IN PROTECTED WHISTLEBLOWER ACTIVITY

15. In November 2008, Plaintiffs Hardy, Czerska, Smith, and Wersto were among a group of FDA scientists who made well-documented allegations to the House Energy and Commerce Committee about managerial misconduct in the FDA. The scientists disclosed that senior managers in the FDA's Center for Devices and Radiological Health had had "ordered,

intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law."

16. On November 17, 2008, Representatives John Dingell and Bart Stupak, the chairman and ranking member of the House Energy and Commerce Committee at the time, respectively, wrote to high-ranking officials at the FDA describing the allegations. Defendant FDA was aware that Mr. Hardy, Dr. Czerska, Dr. Smith, and Ms. Wersto were among the FDA experts referenced in Dingell's letter.

17. On or about January 7, 2009, nine FDA employees, including scientists, experts, and medical doctors, sent a letter to John Podesta, the co-chairman of President-elect Obama's transition team. Mr. Hardy, Dr. Czerska, Dr. Smith, and Ms. Wersto were among the letter's signatories. The letter raised numerous issues of public concern, including corruption within the FDA's device review process, managerial misconduct, dangers to public health and welfare, and retaliation against whistleblowers. For instance, the letter noted that the FDA had approved "computer-aided detection" devices intended for use with mammograms, despite evidence that the devices were unsafe, ineffective, overly costly, and harmful to large numbers of women. The letter further warned that FDA managers were trying to approve more computer-aided detection devices with similar flaws.

18. The FDA learned of the letter to the Obama transition team shortly after it was sent, and FDA officials began to refer to the letter's nine signatories as the "FDA 9". FDA officials were aware that Mr. Hardy, Dr. Czerska, Dr. Smith, and Ms. Wersto had co-authored the letter to the Obama transition team.

19. The letter to the Obama transition team, and the allegations of misconduct raised therein, were discussed extensively in the national news media. Over the next week, the *New*

York Times, *Wall Street Journal*, and CNN published stories about the "FDA 9" and the FDA's approval of medical devices.

20. On or about January 15, 2009, Senator Charles Grassley wrote to Dr. Andrew C. von Eschenbach, then the Commissioner of the FDA. Senator Grassley expressed concerns about the allegations in the letter to the Obama transition team. Senator Grassley informed Dr. von Eschenbach that FDA employees have a right to communicate confidentially with Congress, free of interference from FDA officials. Senator Grassley stated that FDA officials should assure their employees of their right to speak to Congress. 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."

II. THE FDA INITIATED TARGETED SURVEILLANCE OF THE WHISTLEBLOWERS

21. HHS, FDA, and PHS policy allows and encourages its workers to use government networks and government-issued computers for personal purposes on personal time. These uses include accessing, through government information technology ("IT") resources, e-mail messages sent from and received by a worker's private, third-party, non-governmental, password-protected, encrypted e-mail account, such as Gmail and Yahoo! Mail ("Private E-mail").[1] HHS, FDA, and PHS policies encouraged such use during the work day. The Government also allowed and encouraged its workers and employees to take government-issued laptops home, and permits them to use these computers at home for purely personal purposes.

22. The HHS, FDA, and PHS policy allowed and encouraged personal use to increase workers' familiarity with the government's information technology resources and promote the

[1] Private E-mail accounts are differentiated from government or work e-mail accounts.

efficiency of the Agencies. In line with this policy, Defendants did not block access to Private E-mail accounts. It is common practice within the FDA, HHS, and PHS for employees to use government equipment to access Private E-mail accounts for the purpose of conducting purely personal and private communications through their Private Email.

23. Plaintiffs accessed their Private E-mail accounts from within the FDA from private offices during personal time taken out of the work day. In such cases, Plaintiffs used FDA hardware or the FDA network. For example, Mr. Hardy, Dr. Czerska, Dr. Smith, and Dr. Vishnuvajjala all had private offices with closed doors that could be locked. Dr. Nicholas also had a private office when he worked on-site at the FDA.

24. Plaintiffs also accessed their Private E-mail accounts from home or other private locations, in the evening or at other times such as weekends or non-duty times, using non-government networks, on government laptops and computers. For example, Dr. Nicholas, who is based in California, conducted most of his electronic communications from his private California offices or the privacy of his home.

25. The Plaintiffs' also used their Private E-mail for intimate correspondence with family, friends, and loved ones. The Private E-mail accounts also contained information about personal finances, banking, attorney-client communications, passwords and pass codes, and other private or sensitive personal information.

26. On or before January 29, 2009 (and also on or about April, 2010), Defendant FDA, with the full knowledge and authorization of Defendant HHS, began (or continued or re-started) a covert, targeted and warrantless surveillance operation ("Targeted Surveillance") that intercepted the private communications of Mr. Hardy, Dr. Czerska, Dr. Smith, Ms. Wersto, and

the other members of the "FDA 9," that included surveillance and interception of communications sent to and from Plaintiffs' respective Private E-mail accounts.

27. "Targeted Surveillance" is distinct from "routine" system monitoring of employee emails, for which the FDA and HHS also conduct.

28. "Targeted Surveillance" was conducted on the plaintiffs (and other similarly situated FDA employees) because these employees were identified as whistleblowers, i.e. employees who raised health and safety concerns and allegations of official misconduct that were protected under federal law and the United States Constitution. Employees are selected for Targeted Surveillance based on the viewpoint of their speech, and specifically because these employees have, or are suspected of having, criticized the FDA to Members of Congress, the news media or appropriate law enforcement agencies.

29. "Targeted Surveillance" is also unlike routine system monitoring, as the surveillance if far more intrusive then routine monitoring, as further described in the complaint.

30. The earliest known example of a communication intercepted by the FDA's Targeted Surveillance operation is an e-mail from Ms. Joanne Royce, then-Chief Counsel for the House Energy and Commerce Committee (sent from her government email account), to Mr. Hardy (sent to his Private E-mail account). The Private E-mail is dated January 29, 2009. Ms. Royce's e-mail states that FDA whistleblowers had committed no crime in releasing information to Congress. Furthermore, Ms. Royce informed Mr. Hardy (and, by virtue of the intercept, the FDA) that any investigation based on those communications constituted illegal retaliation.

31. After Plaintiffs Nicholas and Vishnuvajjala began associating with Smith and other members of the FDA 9 whistleblowers, the FDA began Targeted Surveillance of Nicholas and Vishnuvajjala. *See infra* ¶¶ 53, 70.

32. Defendants did not obtain a warrant or a subpoena before conducting the Targeted Surveillance of Plaintiffs or their associates. Defendants did not inform any of the targets that they were under Targeted Surveillance.

33. All six Plaintiffs and all individuals subject to Targeted Surveillance by association with the Plaintiffs were targeted because of their viewpoints as whistleblowers and because of their protected speech to Congress and other appropriate authorities.

34. Pursuant to its Targeted Surveillance operation, the FDA secretly installed or activated spyware on the government-owned computers, hardware, and networks used by the Plaintiffs. The spyware took real-time pictures, or "screen shots" (a.k.a. "snapshot recordings") of the computer screens being used by the Plaintiffs, while the Plaintiffs were using the computers or networks. These screen shots enabled FDA officials to secretly view information that appeared on each of the Plaintiffs' computer screens, even if the information was transitory and not stored within the computer itself.

35. The full capabilities of the Targeted Surveillance program are not known, but at minimum, the surveillance intercepted:

- Private E-mails sent or received from non-governmental Private E-mail accounts;
- the contents of header information of Private E-mails;
- the contents of subject lines of Private E-mails;
- the contents of Private E-mails;
- attachments to Private E-mails and the contents of the attachments;
- Private E-mails sent from the targets' homes;
- Private E-mails sent in the evenings away from work;

- Private E-mails sent on personal time;
- Private E-mails sent on private networks;
- Private E-mails sent on private equipment;
- Private E-mails sent from private offices at work;
- Private E-mails sent to or received from other Private E-mail accounts;
- Private E-mails sent to or received from Congress, the Office of Inspector General, the Department of Justice ("DOJ"), and personal attorneys;
- Private E-mails containing attorney-client privileged information;
- Private E-mails containing draft and final Equal Employment Opportunity and Office of Special Counsel complaints.

36. It is common practice for e-mails to include the contents of any prior e-mails. The result is a single e-mail containing the back-and-forth correspondence leading up the most recent e-mail. Through Targeted Surveillance, the FDA secretly obtained Plaintiffs' private and personal correspondence chains contained within a single e-mail.

37. Through Targeted Surveillance, the FDA secretly learned the names of all files stored on each Plaintiff's computer and files stored on Private E-mail accounts. These files included legally protected documents that were stored in folders with labels such as "For Congress."

38. Through Targeted Surveillance, the FDA seized, viewed on HHS equipment, and converted into government property Plaintiffs' Private E-mails and private documents without providing notice or compensation. The FDA used an internal record keeping system for storing the converted records. This recording system used a folder labeled as "FDA 9," and the system categorized specific e-mails according to the initials of individual whistleblowers. For instance,

"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.

39. Through its Targeted Surveillance the FDA identified and targeted other individuals who associated with the "FDA 9."

40. The FDA also learned through its Targeted Surveillance the confidential and/or privileged work product, tactics and strategy that the Plaintiffs were using or planning to use as a result of FDA intercepting Plaintiffs' Private E-mail communications with Congress, representatives of the *New York Times*, the HHS Office of Inspector General ("OIG"), the Office of Special Counsel ("OSC"), the Equal Employment Opportunity Commission ("EEO"), private attorneys, and other proper authorities.

41. A screen shot obtained through Targeted Surveillance revealed an electronic folder on Dr. Smith's computer or Private E-mail account labeled "OSC," which is widely understood by government employees to stand for the Office of Special Counsel. The OSC has jurisdiction over allegations of official corruption and threats to the public health and safety. Dr. Smith was using that folder to store confidential work product and information he and the other Plaintiffs planned to use in a confidential filing with the OSC. The "OSC" folder contained subfolders labeled with each of the Plaintiff's names and the names of other whistleblowers. Other subfolders contained signed OSC draft filing documents and evidence to be submitted to the Office of Special Counsel.

42. The FDA intercepted Private E-mails that were composed during the work day, on personal time, from private offices, on government networks and government laptops.

43. The FDA also intercepted Private E-mails that were composed during non-work hours, from home, on personal networks, and on government laptops. For example, the FDA intercepted Private E-mails composed by Mr. Paul Hardy between the hours of 10pm and 2am.

44. The FDA intercepted Private E-mails that were composed during non-work hours, from home, on personal networks and non-government computers. Such Private E-mails were part of an e-mail chain or written to someone subject to Targeted Surveillance. For example, the Targeted Surveillance intercepted Private E-mails written by Dr. Nicholas from California on his non-government issued personal computer.

45. Defendants never informed any of the Plaintiffs that their Private E-mails and private documents would be subject to Targeted Surveillance, interception, or seizure.

III. DR. NICHOLAS AND CT COLONOGRAPHY

46. In or around March 2009, Dr. Nicholas reviewed a computed tomography ("CT") colonography device for possible FDA clearance. General Electric, the device's manufacturer, wanted to use the device for population screening of asymptomatic patients.

47. Dr. Nicholas concluded that the device should not be cleared because the device was neither safe nor effective for population screening. The science indicated no demonstrable evidence that CT colonography prevents the development of colorectal cancer or reduces colorectal cancer mortality rates when used for population screening. Meanwhile, a single CT colonography examination results in a radiation dose equivalent to 800 chest X-rays. Dr. Nicholas concluded that the broad usage of this device on healthy patients would significantly and unnecessarily increase incidence of radiation-induced cancer, and result in missed cancers and unnecessary additional testing, among other serious concerns.

48. On April 13, 2009, FDA managers indicated that they would clear the device over Dr. Nicholas' objections.

49. On April 26, 2009, Dr. Nicholas requested that Dr. Smith independently review the device. At the time, Dr. Smith was the FDA's sole radiologist working in the Radiological Devices Branch and was FDA's expert clinical reviewer of radiological devices.

50. On May 5, 2009, Dr. Smith independently found that the device should not be cleared, and that if cleared, it would pose a serious public health risk. Dr. Smith also noted that prior FDA mistakes had resulted in erroneous clearance of other CT colonography devices for population screening. Those devices suffered from the same flaws as the device that Dr. Nicholas and Dr. Smith were currently reviewing. Dr. Smith concluded that clearance of CT colonography devices for population screening of asymptomatic patients was a major public health issue and that there was insufficient data to demonstrate that the benefits outweighed the risks.

51. On May 19, 2009, Dr. Nicholas submitted his official clinical review memorandum recommending against FDA clearance.

52. On May 29, 2009, Dr. Smith submitted his official clinical review memorandum recommending against FDA clearance. Dr. Smith also sent an e-mail to Dr. Joshua Sharfstein, then Principal Deputy Commissioner of FDA, alleging FDA mismanagement and abuse of authority regarding the review of CT colonography devices.

53. Based on Dr. Nicholas's association with Dr. Smith and other whistleblowers, the FDA targeted Dr. Nicholas for electronic surveillance.

54. On June 11, 2009, Dr. Smith sent an e-mail to the House Energy and Commerce Committee regarding his and Dr. Nicholas's concerns surrounding CT colonography devices.

55. In or about June 2009, Dr. Nicholas appealed to the then CDRH Director, Dan Schultz. Dr. Nicholas explained that clearance of the CT colonography device for population screening was unsafe and would "expose a number of Americans to a risk of radiation that is unwarranted and may lead to instances of solid organ abdominal cancer."

56. On or about July 17, 2009, Dr. Nicholas alleged to then CDRH Director, Dan Schultz, that the same managers who sought to clear the CT colonography device for population screening had inserted a memorandum into the Administrative File containing false and misleading statements. Dr. Nicholas and Dr. Smith requested an investigation into these allegations.

57. In or around September 2009, FDA managers inquired into what rights Dr. Nicholas had as an ORISE contractor. The FDA managers concluded that Dr. Nicholas did not have any employment rights as an ORISE contractor.

58. On September 24, 2009, a group of FDA whistleblowers, including Dr. Nicholas (via phone) and Dr. Smith, spoke 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.

59. On October 1, 2009, Dr. Nicholas exchanged more e-mails with Dr. Shuren. Dr. Nicholas described his fears that FDA managers would retaliate against him for raising safety concerns about colonography devices.

60. On Oct. 6, 2009, Representative Chris Van Hollen informed Defendant Hamburg that he was "deeply concerned" that Dr. Nicholas faced termination as a consequence of bringing forward major health and safety concerns. Representative Van Hollen provided Dr. Hamburg with a chronology of Nicholas's whistleblowing that confirmed that Nicholas had raised

concerns with the Office of the FDA Commissioner, the FDA Chief Scientist, and the HHS Inspector General.

61. Prior to his association with Dr. Smith, Dr. Nicholas was not a whistleblower. Prior to his association with Dr. Smith, Dr. Nicholas received exemplary performance evaluations and had no trouble maintaining his ORISE contract with the FDA.

62. On October 14, 2009, Dr. Nicholas was notified that his ORISE contract would not be renewed.

63. Upon hearing that Dr. Nicholas' ORISE contract would not be renewed, numerous professionals who worked with Dr. Nicholas at the FDA petitioned for a renewal of his contract. The professionals noted that no other medical doctor working for the FDA was able to provide the same services to the United States that Dr. Nicholas provided.

64. On October 31, 2009, the FDA let Dr. Nicholas's employment contract expire.

65. The FDA gave Dr. Nicholas no explanation for the non-renewal of his contract.

66. After October 2009, Dr. Nicholas, as a private citizen, continued to communicate with Congress and other appropriate authorities about matters of public concern regarding the FDA.

67. To this day, Dr. Nicholas is committed to speaking, writing, and publishing information regarding government misconduct and threats to the public health and safety based on the improper approval of devices by the FDA. Dr. Nicholas has made public statements about this issue in national media outlets such as ABC News and the *New York Times.*

IV. DR. VISHNUVAJJALA

68. In or around August 2009, Dr. Vishnuvajjala became associated with Dr. Smith and the other members of the whistleblower group.

69. Like other Plaintiffs, Dr. Vishnuvajjala had serious concerns regarding government misconduct and threats to the public health and safety based on actions by FDA managers.

70. As a direct consequence of her association with the whistleblower group, the FDA targeted Dr. Vishnuvajjala by monitoring and intercepting her private communications.

71. Initially, the FDA obtained Dr. Vishnuvajjala's Private E-mails via intercepts or surveillance of other whistleblowers' e-mails. The FDA subsequently initiated Targeted Surveillance of Dr. Vishnuvajjala as a result of her association with the other Plaintiffs and her viewpoint on matters of public concern that supported the viewpoint of the other Plaintiffs.

V. A MARCH 2010 *NEW YORK TIMES* ARTICLE TRIGGERS AN INTERNAL FDA CRIMINAL INVESTIGATION OF NAMED WHISTLEBLOWERS, INCLUDING THE USE OF WARRANTLESS SURVEILLANCE

72. On March 28, 2010, the *New York Times* published a front-page article entitled "Scientists Say F.D.A. Ignored Radiation Warnings." The article states that FDA experts were warning that the FDA was trying to approve ineffective and dangerous devices and ignoring or suppressing the concerns of its own scientists. The article quoted Dr. Smith, Dr. Nicholas, and FDA manager Dr. Gutierrez.

73. On April 16, 2010, the FDA received a letter from a 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 identify any information the release of which would have been prohibited by law.

74. After Dr. Smith, Dr. Nicholas and Dr. Gutierrez were quoted in the *New York Times* HHS and FDA officials initiated Targeted Surveillance of Dr. Smith, but did not initiate

Targeted Surveillance on Dr. Gutierrez (Dr. Nicholas no longer worked for FDA, whereas both Smith and Gutierrez worked for the agency).

75. In the *New York Times* article, Smith expressed a viewpoint unfavorable to FDA, while Gutierrez expressed a viewpoint favorable to the agency. Gutierrez also made a statement to the *New York Times* that could reasonably have been interpreted as releasing confidential information to the press.

76. On or about April 28, 2010, the FDA made a criminal referral against Dr. Smith (and, most likely, other Plaintiffs), based on the allegation that confidential information may have been disclosed to the *New York Times*, to the Office of Internal Affairs. FDA did not make such a referral concerning Dr. Gutierrez.

77. On or about May 17, 2010, the FDA made a criminal referral against Dr. Smith (and, most likely, the other Plaintiffs) to the Office of Inspector General based on the allegation that confidential information may have been disclosed to the *New York Times*. In making the referral, FDA provided the OIG with a copy of the letter sent by General Electric's attorneys.

78. No such referral was made against Dr. Gutierrez.

79. The FDA had no direct evidence that Dr. Smith, or any of the Plaintiffs, had violated any law in providing information to the *New York Times*.

80. The FDA conducted its warrantless Targeted Surveillance for the purpose of investigating the Plaintiffs for potential criminal charges.

81. On May 18, 2010, Mr. Scott A. Vantrease, Assistant Special Agent in Charge in the Office of Inspector General, responded to the FDA's referral. He noted the 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.

82. Despite the letter from the Office of Inspector General indicating that all the allegations were of protected whistleblower activity, the FDA continued its Targeted Surveillance of the Plaintiffs. The FDA expanded the Targeted Surveillance to include the Plaintiffs' associates, none of whom was even accused of leaking confidential information.

83. By May 21, 2010, the FDA had intercepted Private E-mails of Mr. Hardy, Dr. Czerska, Dr. Smith, Dr. Nicholas, and Dr. Vishnuvajjala. The intercepted Private E-mails included privileged attorney-client information, which the FDA summarized for HHS attorneys.

84. In early 2010 and going forward, Dr. Smith, who is a licensed attorney, was acting as counsel for and provided confidential legal advice to several FDA employees. Among other actions, Dr. Smith was working with Mr. Hardy, Dr. Czerska, Dr. Nicholas, Dr. Vishnuvajjala, and Ms. Wersto to prepare a complaint of FDA misconduct with the Office of Special Counsel. Dr. Smith also acted as a representative and / or liaison to Congress for the whistleblower group and other employees and former employees of the FDA and PHS.

85. On or about June 28, 2010, Dr. Shuren filed a second criminal referral to the Office of Inspector General against Dr. Smith, Dr. Czerska, Mr. Hardy, and potentially other Plaintiffs. Attached to this request were documents, computer screen shots of at least one of the Plaintiffs' computer, and intercepted e-mails from one or more Plaintiffs' Private E-Mail accounts that the FDA obtained or intercepted, without a warrant, for the purpose of making a criminal referral. The central document in the request was a draft document called the "Optasia Chronology," which had been prepared by the whistleblowers as part of a formal complaint alleging government misconduct that Dr. Czerska intended to file with the Office of Special Counsel and other appropriate authorities.

86. Dr. Shuren, who made the second criminal referral to the OIG, knew that the FDA whistleblowers, including the Plaintiffs, were planning to make a filing with either the Office of Inspector General, the Office of Special Counsel, or the Department of Justice, and that the Plaintiffs planned to accuse Dr. Shuren of official misconduct. Dr. Shuren was able to learn of the Plaintiffs' planned activities through his access to the FDA's Targeted Surveillance program, which revealed the Plaintiffs' Private E-mail communications, their private and confidential work product, their privileged communications, and draft legal filings.

87. On or about July 7, 2010 the FDA placed Dr. Smith on paid administrative leave.

88. On or about July 7 or 8, 2010, Mr. Donald J. St. Pierre (St. Pierre), a deputy director in the FDA, issued a memo to Dr. Smith in which Mr. St. Pierre ordered Dr. Smith "not to conduct, transact or speak to any FDA employees and others about FDA business matters" during Dr. Smith's period of administrative leave. Dr. Smith was threatened with disciplinary action if he disobeyed this instruction.

89. On or about July 7 or 8, 2010, Mr. St. Pierre directed that no one within the FDA communicate with Dr. Smith regarding the FDA.

90. Throughout his employment at the FDA, Dr. Smith was never questioned or interviewed by FDA or HHS managers about the release of any confidential information. Dr. Smith was never disciplined or reprimanded about any improper release of government information. Dr. Smith was never formally charged by any government official with having improperly leaked any information to any person.

91. On July 31, 2010, the FDA did not renew Dr. Smith's employment contract, and Dr. Smith's employment for the United States ended.

92. Dr. Smith's removal from the agency, and statement made by FDA regarding Dr. Smith, had a chilling effect on the willingness of employees at HHS, PHS, FDA (and contractors working for FDA) to lawfully communicate to Dr. Smith regarding matters of public concern, including, the safety of various medical devices and misconduct within the FDA.

93. As employees working at HHS, PHS and FDA learned more about the Targeted Monitoring program, this chilling effect increased.

94. After July 31, 2010, Dr. Smith, as a private citizen and an attorney, continued to act as a representative for, and provide legal advice to employees of HHS, FDA, and PHS, including the Plaintiffs, who wanted to raise matters of public concern with Congress and other appropriate authorities. Dr. Smith's activities included meeting with representatives from various Congressional committees both on behalf of himself and on behalf of other FDA employees.

95. Since July 31, 2010, and continuing to the present, Dr. Smith, as a private citizen, has spoken publicly and published information regarding government misconduct and threats to the public health and safety based on the improper approval of devices by the FDA.

96. Dr. Smith is an internationally renowned expert and a prolific publisher and speaker in the field of radiology. Dr. Smith also has extensive contacts with public interest organizations that seek to disseminate information on matters of public concern, including issues of government misconduct and issues of health and safety. Dr. Smith possesses the professional credentials and ability to publish and comment on health issues as a private citizen-publisher and to communicate concerns based on his expertise in the area of public health to members of Congress, the news media and public interest organizations.

97. Some time after Dr. Smith was removed from the FDA in or about July 7, 2010, it became widely known and notorious within the FDA that Dr. Smith was likely a primary target of intrusive surveillance.

98. Some time after Dr. Smith was removed from the FDA in or about July 7, 2010, FDA managers informed current employees that associating with Dr. Smith was not permitted and that doing so would harm their careers.

99. FDA's Targeted Surveillance has reasonably created, and continues to create, fear amongst similarly situated employees within FDA, HHS and PHS and contractor employees that associating with Dr. Smith (and other plaintiffs/whistleblowers) will result in being placed under Targeted Surveillance. Such surveillance could result in the FDA learning about whistleblowing activities, protected speech, future or current litigation, accusations against the FDA, or simply expressing dissent. Furthermore, such surveillance by FDA could reveal embarrassing information, statements, or e-mails that could be used as pretext for termination or blacklisting against similarly situated employees.

100. The FDA's continued surveillance, and the fear it reasonably engenders among FDA, HHS and PHS employees or contractor employees, chills the willingness of federal employees and contractors to communicate or associate with Dr. Smith.

101. The FDA's surveillance, and the fear it engenders, directly and indirectly impedes Dr. Smith's ability to access and publish lawful information regarding threats to public health and safety. As a result of the FDA's actions, the public is likewise prevented from learning critical information on matters of extraordinary public concern.

102. On or about November 15, 2010, the HHS Office of Inspector General again declined to take action against any of the Plaintiffs based on information provided by the FDA,

including numerous intercepted e-mails and documents. In its closing letter to the FDA, the Office of Inspector General noted that the Department of Justice had also declined prosecution of any of the Plaintiffs or other whistleblowers.

VI. RETALIATION AGAINST THE OTHER WHISTLEBLOWERS

103. On or about Dec. 6, 2010, the FDA proposed the termination of Dr. Czerska's 23-year career at the FDA based entirely on Private E-mails intercepted through the FDA's Targeted Surveillance program.

104. On or about February 25, 2011, Dr. Vishnuvajjala received a warning letter from her FDA supervisor. The letter warns Dr. Vishnuvajjala that the FDA had intercepted Private E-mails sent to Dr. Vishnuvajjala, and that Dr. Vishnuvajjala should have reported those conversations to FDA management. The Private E-mails in question contained no confidential information.

105. Dr. Vishnuvajjala's supervisor, Dr. Gregory Campbell, personally informed Dr. Vishnuvajjala that other FDA managers did not trust her because of her association with Dr. Smith.

106. Other employees of the FDA fear becoming associated with Dr. Vishnuvajjala, lest they be considered whistleblowers as well, lose the trust of FDA managers, and become subject to Targeted Surveillance.

107. In May 2011, the FDA cited Private E-mail correspondence between Mr. Hardy and Congress as a reason that Mr. Hardy should be fired from Defendant PHS.

108. On September 9, 2011, Mr. Hardy was informed by Capt. Gregory A. Stevens, the deputy director of the PHS Commissioned Corps, that Mr. Hardy's commission would be terminated on October 9, 2011. Mr. Hardy was subsequently removed from federal service.

109. The Office of Special Counsel conducted a preliminary review of the Hardy termination under the Whistleblower Protection Act, a law designed to protect federal civil servant whistleblowers from retaliation.

110. The OSC determined that there was sufficient evidence that Mr. Hardy had engaged in protected activity and had suffered illegal retaliation; the OSC thus sought a "stay" of the negative actions that led to Mr. Hardy's removal from the PHS.

111. On October 14, 2011, the OSC requested such a stay from the Merit Systems Protection Board ("MSPB"). Over the objection of the Defendants, the MSPB granted the initial stay on Oct. 14, 2011. An MSPB stay is similar to a preliminary injunction ordered by a court for the purpose of reinstating a wrongfully terminated employee.

112. The OSC continued its investigation into Mr. Hardy's removal and on November 14, 2011, requested an extension of the stay. The OSC made specific findings that, according to the evidence it reviewed, Mr. Hardy had engaged in speech fully protected under the First Amendment and had suffered illegal retaliation based on that protected speech.

113. Defendants opposed the stay on jurisdictional grounds, 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.

114. The MSPB reviewed these legal authorities and agreed with the Defendants' arguments, concluding that Mr. Hardy was not a federal employee covered by the Civil Service Reform Act. The MSPB declined to renew Mr. Hardy's stay for lack of subject matter jurisdiction.

115. As a result of the FDA, HHS and PHS actions taken against Mr. Hardy, there continues to be a chilling effect on FDA, HHS and PHS employees who wish to raise issues of public concern.

116. In or around December 2011, Mr. Hardy learned that his private, confidential communications with Congress had been monitored by both the FDA and HHS. Representatives from the PHS told Mr. Hardy that FDA and HHS officials believed Mr. Hardy could not be "trusted." This belief was based on covert surveillance of Private E-Mail communications between Mr. Hardy and staff members of the House Energy and Commerce Committee and the Senate Finance Committee.

117. None of the Plaintiffs' Private E-Mail communications disrupted in any way the efficiency of the FDA workplace or the operations of the government.

VII. INTERFERENCE WITH NON-GOVERNFMENT SPEECH CONCERNING THE SAFETY OF CT COLONOGRAPHY DEVICES AND THE CARESTREAM DEVISE

118. Prior to his termination from the Public Health Service, Mr. Hardy was the lead reviewer on a device under review by the FDA known as CARESTREAM. Prior to his termination from the FDA, Dr. Smith was a medical officer also assigned to review the safety of the CARESTREAM device.

119. Prior to being terminated from his job as a contractor for ORISE, Dr. Nicholas was a medical reviewer for the CT Colonography device discussed in this complaint, and had direct knowledge of other CT Colonography devices that had been approved by FDA.

120. After their terminations from government service, plaintiffs Dr. Smith, Dr. Nicholas and Mr. Hardy have engaged in constitutionally protected speech regarding the safety

of CT Colonography devices and CARESTREAM. This has included statements made to members of the news media.

121. On May 31, 2012 the "Disclosure Unit" of the United States Office of Special Counsel ("OSC") completed its investigation of information provided by plaintiffs concerning FDA misconduct regarding these two devices, and the safety of these two devices.

122. After completing its review, the OSC made the following finding related to the merits of the concerns raised by Dr. Smith (on behalf of himself and other plaintiffs): " . . . OSC has concluded that there is a substantial likelihood that the information you provided discloses a violation of law, rule or regulation, gross mismanagement, and a substantial and specific danger to public safety."

123. Under the provisions of 5 U.S.C. § 1213, this finding triggers a number of additional review procedures, which will ultimately provide Dr. Smith (with the support and cooperation from other plaintiffs) a window of opportunity to directly comment on the FDA's review of the OSC's findings. Dr. Smith's comments would thereafter be referred by OSC to the President of the United States.

124. There are very strict time limits for public participation in this review process.

125. Without access to information from current FDA employees, the ability of Dr. Smith, Dr. Nicholas and Mr. Hardy to participate in the public debate on the safety of these two devices, and public debate concerning the misconduct at FDA, will be severely prejudiced.

126. The Targeted Surveillance program conducted by the FDA, along with the other retaliatory actions described in this complaint, have created a chilling effect on plaintiffs and other similarly situated employees/contractors, and prejudices the ability of Dr. Smith, Dr. Nicholas and Mr. Hardy to participate as private citizens in the public debate concerning the

OSC findings, and further prejudices the ability of Dr. Smith to directly participate in the debate over these matters that will be referred to the President of the United States.

FIRST CAUSE OF ACTION

(Fifth Amendment: Violations of the Due Process and Takings Clauses)

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

128. Defendant FDA willfully and intentionally violated the Due Process Clause and the Takings Clause of the Fifth Amendment of the United States Constitution.

129. Defendant FDA took Plaintiffs' proprietary electronic communications and documents and converted them into a system of government records, without compensation or Due Process of Law.

130. Defendant FDA violated Plaintiffs' right to Due Process by conducting Targeted Surveillance that intercepted confidential communications with private counsel and others.

SECOND CAUSE OF ACTION

(Fourth Amendment: Unreasonable Searches and Seizures)

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

132. In initiating and conducting the Targeted Surveillance, Defendant HHS and FDA violated the Fourth Amendment's prohibition on unreasonable searches and seizures.

133. The Targeted Surveillance was conducted in a manner that violated federal law.

134. Plaintiffs had a reasonable expectation of privacy in their personal, password-protected, encrypted, third-party, non-Government e-mails ("Private E-mails"), sent from home

or off-site, through private networks, on private and government computers and networks, during personal time, by permission.

135. Plaintiffs had a reasonable expectation of privacy in their Private E-mails sent from private FDA offices, during personal time, by permission.

136. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails pursuant to criminal and administrative investigations violated the Fourth Amendment's prohibition on unreasonable search and seizures.

137. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails, sent from home or off-site, through private networks, on private or government computers, during personal time, by permission, violated the Fourth Amendment's prohibition on unreasonable search and seizures.

138. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails, sent from private HHS, FDA, or PHS offices, during personal time, on HHS, FDA, or PHS networks, by permission, violated the Fourth Amendment's prohibition on unreasonable search and seizures.

139. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails was unreasonable in its initiation because it was initiated based on allegations of First Amendment-protected communications with Congress, President-elect Obama's transition team, and the news media.

140. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails was unreasonable in its initiation because it was continued or re-initiated based on allegations of First Amendment-protected communications with the news media in or about March or April 2010.

141. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails was unreasonable in its scope because it continued after the OIG informed the FDA on May 18, 2010, that the alleged wrongdoing was protected by law.

142. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails was unreasonable in its scope because it captured statutorily protected communications with Congress, the OIG, the DOJ, and the Office of Special Counsel.

143. Defendants HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails was unreasonable in its scope because it captured private communications with family, loved ones, personal financial information, passwords and pass codes, and other private information unrelated to the FDA's purported interest of preventing release of confidential information.

144. Defendant HHS and FDA's warrantless search-and-seizure of Plaintiffs' Private E-mails is unreasonable in its scope because it lasted for at least seven months, and potentially for over two years, and may be still ongoing, despite failing to produce evidence of unlawful conduct, and exposing constitutionally and statutorily protected information.

THIRD CAUSE OF ACTION

(First Amendment: Violations of the Freedom of Association of All Plaintiffs)

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

146. Defendant FDA violated the Plaintiffs' First Amendment right to Freedom of Association by secretly discovering protected associations, retaliating against Plaintiffs' associates for their association with Plaintiffs, and chilling Plaintiffs' ability to freely association with FDA employees and contractors.

147. Defendant HHS and FDA conducts and threatens Targeted Surveillance against any employee or contractor who associates with suspected whistleblowers. This conduct has chilled and continues to chill all Plaintiffs' ability to freely associate with FDA employees and contractors.

148. Defendant FDA violated the association rights of Dr. Czerska, Mr. Hardy, Dr. Nicholas, Dr. Vishnuvajjala, and Ms. Wersto, because each was targeted for punitive Targeted Surveillance based on their associations, interactions, and communications with Dr. Smith or other suspected whistleblowers.

149. Defendant FDA violated the association rights of Dr. Vishnuvajjala by threatening her with disciplinary action because she received Private E-mails from whistleblowers. Because of these threats, Dr. Vishnuvajjala fears future disciplinary actions, and her ability to associate freely with persons of her choice is substantially chilled.

150. Defendant FDA violated the association rights of all Plaintiffs by violating their right to communicate confidentially with private counsel and by obtaining Plaintiffs' attorney-client work product and privileged communications.

151. Defendant FDA violated the association rights of all Plaintiffs by using the Targeted Surveillance to undermine the confidentiality of their private associations with persons who supported their whistleblowing and/or who wanted to provide more information to the whistleblower group without FDA managers learning their identity.

152. Defendant FDA's systematic targeting of communications with Dr. Smith, an attorney who was representing and advising the other Plaintiffs, and by obtaining Plaintiffs' attorney-client work product and other privileged communications, violated Plaintiffs' right to associate and communicate with counsel.

FOURTH CAUSE OF ACTION

(First Amendment: Violations of the Freedom of Speech of All Plaintiffs)

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

154. Plaintiffs' communications involved matters of public concern and were protected by the rights to freedom of speech under the First Amendment.

155. Defendant FDA violated the Plaintiffs' First Amendment rights to freedom of speech by targeting the Plaintiffs for Targeted Surveillance because of their status as whistleblowers and due to the content of the views expressed by Plaintiffs on matters of public concern. This constitutes viewpoint- and content-based discrimination.

FIFTH CAUSE OF ACTION

(First Amendment: Wrongful Discharge of Mr. Hardy Based on His Protected First Amendment Activities)

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

157. Defendants FDA and PHS and violated Mr. Hardy's rights under the First Amendment, including his freedom of speech, freedom of association, right to privacy, and right to petition Congress.

158. Defendant FDA conducted Targeted Surveillance of Mr. Hardy in retaliation for engaging in protected speech and associating with whistleblowers. This speech included communications in which Mr. Hardy, speaking as a private citizen, disclosed to Congress serious dangers to the public health and safety, including flaws in FDA's review process for "computer-aided detection" devices used with mammograms. Mr. Hardy also associated with Plaintiff

Smith, who was a known whistleblower within the FDA. Also in retaliation for Mr. Hardy's speech on matters of public concern, Mr. Donald St. Pierre and Dr. Alberto Gutierrez, Mr. Hardy's first- and second-line supervisors, respectively, gave Mr. Hardy an extremely negative performance review.

159. None of Mr. Hardy's speech disrupted the workplace operations of the PHS, FDA, or U.S. government.

160. Defendant FDA informed Defendant PHS of Mr. Hardy's protected communications and requested that Defendant PHS terminate Mr. Hardy. Defendant PHS subsequently removed Mr. Hardy from public employment based on the FDA's retaliatory actions.

161. The termination of Mr. Hardy by Defendants PHS and FDA had a chilling effect on the exercise of First Amendment rights by other similarly situated federal employees, contractors, and officers.

SIXTH CAUSE OF ACTION

(First Amendment: Wrongful Discharge of Dr. Smith Based on His Protected First Amendment Activities)

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

163. Defendant FDA violated Dr. Smith's rights under the First Amendment, including his freedom of speech, freedom of association, right to privacy, and right to petition Congress.

164. Defendant FDA fired Dr. Smith from public employment in retaliation for his speech on matters of public concern. This speech included communications in which Dr. Smith, speaking as a private citizen, disclosed to Congress and the media serious dangers to the public

health and safety. Dr. Smith's disclosures included repeated attempts to blow the whistle on safety risks in a CT colonography device. None of Dr. Smith's speech disrupted the workplace operations of the FDA or U.S. government.

165. Defendant FDA fired Dr. Smith from public employment in retaliation for his association with other suspected whistleblowers.

166. The termination of Dr. Smith by Defendant FDA had a chilling effect on the exercise of First Amendment rights by other similarly situated federal employees, contractors, and officers.

SEVENTH CAUSE OF ACTION

(First Amendment: Wrongful Discharge of Dr. Nicholas Based on His Protected First Amendment Activities)

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

168. Defendant FDA violated Dr. Nicholas's First Amendment rights under the First Amendment, including his freedom of speech, freedom of association, right to privacy, and right to petition Congress.

169. Defendant FDA terminated Dr. Nicholas from public employment in retaliation for his speech on matters of public concern. This speech included communications in which Dr. Nicholas, speaking as a private citizen, disclosed serious dangers to the public health and safety. Dr. Nicholas's disclosures included repeated attempts to blow the whistle on safety risks in a CT colonography device. None of Dr. Nicholas's speech disrupted the workplace operations of the FDA or U.S. government.

170. Defendant FDA caused Dr. Nicholas to be fired from his position as an employee for FDA-contractor ORISE in retaliation for his association with other suspected whistleblowers and for engaging in speech protected under the U.S. Constitution.

171. The termination of Dr. Nicholas by Defendant FDA had a chilling effect on the exercise of First Amendment rights by other similarly situated federal employees, contractors, and officers.

EIGHTH CAUSE OF ACTION

(First Amendment: Violations of the Free Speech and Association Rights of Dr. Vishnuvajjala and Ms. Wersto)

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

173. Defendant FDA violated, and continues to violate, the First Amendment rights of Dr. Vishnuvajjala and Ms. Wersto.

174. The targeted surveillance of Dr. Vishnuvajjala and Ms. Wersto, and the threats of disciplinary action against them, significantly chill their ability to freely engage in speech protected under the U.S. Constitution, as private citizens, and creates a chilling effect on other similarly situated employees.

175. The targeted surveillance of Dr. Vishnuvajjala and Ms. Wersto, and the threats of disciplinary action against them, significantly chills their ability (and the ability of other similarly situated employees) to associate freely with persons of their choosing.

176. The targeted surveillance of Dr. Vishnuvajjala and Ms. Wersto, and the threats of disciplinary action against them, significantly chill their ability (and the ability of other similarly situated employees) to lawfully provide information related to the safety of medical devices,

misconduct within FDA and other matters of public concern, to whistleblowers, such as plaintiffs Smith, Hardy and Nicholas.

177. Plaintiffs Dr. Vishnuvajjala and Ms. Wersto seek pre-enforcement injunctive relief to stop the chilling effect caused by FDA's targeted surveillance, FDA's prohibition on communications with Dr. Smith and FDA violations of the First and Fourth Amendments of the United States Constitution.

NINTH CAUSE OF ACTION

(First Amendment: Violations of the Free Speech Rights of Mr. Hardy, Dr. Smith, and Dr. Nicholas, as Private Citizens and Publishers)

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

179. Defendant FDA violated, and continues to violate, the First Amendment rights of Mr. Hardy, Dr. Smith, and Dr. Nicholas, as private citizens, to freely publish information, ideas, and viewpoints.

180. Defendant FDA's targeted surveillance and its intimidation of government employees and contractors based upon their association with plaintiffs (or based upon their providing information to plaintiffs on matters of public concern) chills those employees (or contractors) speaking and associating with Mr. Hardy, Dr. Smith, and Dr. Nicholas. This chilling effect impedes the ability of Mr. Hardy, Dr. Smith, and Dr. Nicholas to access lawful information and disseminate information, ideas, and viewpoints as citizen publishers.

181. Defendant FDA's Targeted Surveillance program, and the threat that an employee may be subjected to Targeted Surveillance due to his or her association with plaintiffs (or based upon their providing information to plaintiffs on matters of public concern) chills those

employees (or contractors) speaking and associating with Mr. Hardy, Dr. Smith, and Dr. Nicholas in a manner that directly interferes with their ability to properly and fully participate in the public debate on the safety of the CARESTREAM device and CT Colonography, on misconduct and wrongdoing within FDA and the overall public debate triggered by the Office of Special Counsel's letter of May 31, 2012. This chilling effect impedes the ability of Mr. Hardy, Dr. Smith, and Dr. Nicholas to access lawful information and disseminate information, ideas, and viewpoints concerning these matters.

182. Defendant FDA's Targeted Surveillance program, and the threat that an employee may be subjected to Targeted Surveillance due to his or her association with Dr. Smith (or based upon their providing information to Dr. Smith on matters of public concern) chills those employees (or contractors) speaking and associating Dr. Smith in a manner that directly interferes with his ability to properly and fully participate in the public debate that will be undertaken by the President of the United States on the issues raised by the Office of Special Counsel's letter of May 31, 2012. This chilling effect impedes the ability of Dr. Smith to access lawful information and use that information in the deliberations that will be conducted by the President of the United States.

183. Defendant FDA's warning to FDA employees that they are not permitted to speak with Dr. Smith, and that doing so will harm their careers, violates the First Amendment rights of Dr. Smith to access and publish lawful information as a private citizen and the associational rights of Dr. Smith and all employees who work for the defendants.

184. The chilling effect caused by this instruction violates Dr. Smith's rights under the Constitution of the United States, and the rights of all other employees who are denied the

opportunity to associate with Dr. Smith due to the chilling effect caused by FDA's instructions.

TENTH CAUSE OF ACTION

(First Amendment: Violations of the Free Speech and Association Rights of Dr. Smith)

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

186. Defendant FDA's July 7, 2010 memo to Dr. Smith, which ordered him "not to . . . speak to any FDA employees and others about FDA business matters" violated Dr. Smith's First Amendment rights to free speech and association.

187. Defendant FDA's order to its employees on or about July 8, 2010, to not communicate with Dr. Smith violates Plaintiffs Vishnuvajjala and Wersto's First Amendment rights to association and freedom of speech and creates a chilling effect on all other similarly situated employees.

ELEVENTH CAUSE OF ACTION

(First Amendment: Violations of the Public's Speech and Association Rights)

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

189. Members of the public have First Amendment rights to freedom of speech and freedom of association.

190. Defendant FDA violated the First Amendment because its over-inclusive surveillance chills the ability of all federal employees and members of the public to associate with, and speak to, Dr. Smith and the other Plaintiffs.

191. The suppressive policies of Defendant FDA violate the right of the public to access critical information about the operations of their government and about the public health and welfare.

192. Defendant FDA violated the First Amendment because its electronic surveillance program, targeted at suspected whistleblowers, suppresses an enormous amount of potential speech by thousands of public employees, including the Plaintiffs. While suppressing potential speech by public employees, the surveillance program also consequently interferes with the right of the public to learn information about matters of public concern.

TWELFTH CAUSE OF ACTION

(Lloyd-LaFollette Act: Violations of the Right to Petition Congress)

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

194. 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.

195. Defendant FDA violated the Lloyd-LaFollette Act by using intrusive surveillance to interfere with and spy upon Plaintiffs' communications to Congress, either directly or through their representative Dr. Smith and created a chilling effect on the willingness of all similarly situated employees to communicate with Congress.

196. Defendant FDA violated the Lloyd-LaFollette Act by retaliating against Plaintiffs for communicating with Congress, either directly or through their representative Dr. Smith.

197. Defendant FDA willfully ignored statements from Congress and from the HHS Office of Inspector General making clear that public employees' disclosures to Congress are permitted and protected by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

(a) Grant Plaintiffs all declaratory relief, as appropriate, on behalf of themselves and all other similarly situated employees or contractors;

(b) Grant Plaintiffs all preliminary and permanent injunctive relief, as appropriate, on behalf of themselves and all other similarly situated employees or contractors;

(c) Issue a Declaratory Judgment finding that no agency or officer of the United States government may confiscate Private E-mail and other personal, private electronic communications of federal employees without Due Process of Law and just compensation;

(d) Issue a Declaratory Judgment finding that no agency or officer of the United States government may target Private E-mail and other personal, private electronic communications 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;

(e) Order all Defendants to inform all their workers and employees that they cannot be subject to surveillance pursuant to a criminal investigation without a valid warrant;

(f) Issue all appropriate preliminary and permanent injunctive relief prohibiting the Defendants from converting the Private E-mail and other personal, private

electronic communications of federal employees without Due Process of Law and just compensation;

(g) Issue all appropriate preliminary and permanent injunctive or declaratory relief necessary to prohibit the Defendants from violating the First or Fourth Amendments when they conduct surveillance or Targeted Surveillance of any person;

(h) Issue all appropriate preliminary and permanent injunctive or declaratory relief necessary to prohibit the Defendants from conducting surveillance or Targeted Surveillance of any person based on the viewpoint of the target, or the fact that the target is a whistleblower, associates with whistleblowers or lawfully engages in public speech;

(i) Order all Defendants to return all proprietary e-mails to each respective Plaintiff;

(j) Order all Defendants to delete and expunge any originals, copies, excerpts, or summaries of the Plaintiffs' Private E-mail and other personal, private electronic communications, converted or otherwise, from their system of records;

(k) Order all Defendants to return Plaintiffs' Private E-mail and other personal, private electronic communications in an expedited fashion;

(l) Prohibit all Defendants from using, in any manner whatsoever, Plaintiffs' property that was obtained without Due Process and just compensation;

(m) Order all Defendants to inform all third parties to whom Defendants may have provided, sent, communicated, summarized, excerpted, or told about the Plaintiffs' Private E-mail and other personal, private electronic communications

that such records were obtained illegally, and request that the third parties delete and expunge the proprietary e-mails and their copies, summaries, or excerpts;

(n) Order all Defendants to make a complete accounting of all third parties who were provided with Plaintiffs' Private E-mail and other personal, private electronic communications, and provide that accounting to Plaintiffs;

(o) Order all Defendants to make a complete accounting of every record system in which the Plaintiffs' Private E-mail and other personal, private electronic communications have been stored, and provide that accounting to Plaintiffs;

(p) Order all Defendants to make a full accounting of all persons or entities that received, transmitted, excerpted, summarized, or otherwise saw or manipulated the Plaintiffs' Private E-mail and other personal, private electronic communications;

(q) 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;

(r) Enjoin all Defendants from all such future takings and all future warrantless searches and seizures of communications between government employees, contractors, or officers and representatives of the United States Congress;

(s) Grant all other equitable, injunctive, and declaratory relief permitted under the First, Fourth, and Fifth Amendments of the United States Constitution, and the Lloyd-LaFollette Act;

(t) Issue a Declaratory Judgment finding that the initiation of a warrantless search of a federal employee's private electronic communications violates the Fourth and

First Amendments if that search was triggered or motivated by the employee's constitutionally protected speech;

(u) Issue a Declaratory Judgment finding that the warrantless interception of federal employees' private communications with Congress, including congressional staff, violates the First Amendment and the Lloyd-LaFollette Act;

(v) Order all injunctive and declaratory relief, on behalf of Plaintiffs and all similarly situated federal employees, PHS officers, and ORISE government contractors, as required to cure all constitutional violations as set forth in this Complaint, and to prevent the future chilling effect caused by the violations set forth herein;

(w) Order preliminary and permanent injunctive relief and declaratory relief, as appropriate, to require that Defendants reinstate Mr. Hardy into his position with PHS, effective the date of his removal from federal service;

(x) Order preliminary and permanent injunctive relief and declaratory relief, as appropriate, to require that Defendants reinstate Dr. Smith into his position with the FDA, effective the date of his removal from federal service;

(y) Order preliminary and permanent injunctive relief and declaratory relief, as appropriate, to require that Defendants award a new ORISE contract to Dr. Nicholas, and renew such contract consistent with its treatment of other persons who work for FDA under ORISE contracts;

(z) Award Plaintiffs Hardy, Nicholas and Smith, all equitable relief, including restoration of back pay and benefits and reinstatement of employment;

(aa) Award Plaintiffs their costs and reasonable attorneys' 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,

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