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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Danville Division

The United States of America, ex rel. Joseph M. Thomas, Bringing this Action on Behalf of the United States of America,

Plaintiff,

v.

Duke University,
Duke University Health System, Inc.
William M. Foster, Ph.D.,
and
Erin N. Potts-Kant,

Defendants.

[Note: This is now case No. 1:17-cv-256 in the U.S. D.C. M.D. N.C.]

Civil Action No. 4:13-cv-00017

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

Amended Complaint

1. Relator Joseph M. Thomas brings this action on behalf of the United States of America under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, against Defendants Duke University, Duke University Health System, Inc. ("DUHS"), William M. Foster, Ph.D. ("Foster"), and Erin N. Potts-Kant ("Potts-Kant") to recover losses sustained by the Public Health Service ("PHS"), the National Institutes of Health ("NIH"), the Environmental Protection Agency ("EPA"), and other Federal agencies responsible for administering scientific research grants.

I. Introduction

2. Medical research seeks to improve public health and medical treatment. Because it advances the public good, much of medical research is funded by the United States government (the "Government"). Public research dollars, however, are scarce, and the grant process is highly competitive. Public grants can only be awarded to the most deserving research

projects. And once received, public grant funds must be spent responsibly.

3. Defendants have abused the public trust. They have engaged in systematic research misconduct and fraud, and failed to comply with the terms, conditions, and assurances of their grant awards. Between 2006 and the present, the Defendants used false and/or fabricated research results to obtain millions of dollars in medical research grants from the NIH, the EPA and other federal agencies, and the Defendants used grant funds to generate false and/or fabricated research results. After March 2013, Duke University, DUHS and Foster attempted to conceal and minimize the extent of the wrongdoing.

4. These research results were false, fabricated, and/or fraudulent because they were: (i) simply made up; (ii) reported data that had been knowingly manipulated; or (iii) based on experiments that had been knowingly done incorrectly. Duke University also made numerous certifications—including certifications of accuracy and completeness of the grant documents and certifications of compliance with its policies and federal regulations governing research misconduct—to obtain and maintain the grant funding. These certifications were false when made.

5. The fraudulent research was conducted by Potts-Kant, working under the primary supervision of Foster. Its scope was vast, in part because Foster runs a laboratory which functions as an experimental hub for research across Duke University and for researchers at other institutions.

6. The research misconduct and fraud perpetuated itself. During the relevant years, researchers at Duke University—including, most prominently, Foster and Potts-Kant—authored numerous scientific publications based on fraudulent research funded by public grants. These publications were used to justify future grant awards, money which would then be spent on more fraudulent research.

7. During these years, Defendants Foster, Duke University, and DUHS received

warnings and allegations that the research results reported by Potts-Kant and the airway physiology laboratory supervised by Defendant Foster were the result of research misconduct. Nothing was done to address the situation, until Potts-Kant's embezzlement of Duke University dollars (a wholly separate fraud), sparked an internal review of Potts-Kant's reported research results in March 2013.

8. After March 2013, Defendants intentionally concealed the full extent of the research fraud. Defendants withheld information from the government, as well as from other researchers and scientific journals. Duke University continued to submit grant applications and progress reports that included false, fabricated, and/or fraudulent research results.

9. The grant fraud perpetrated by the Defendants has substantially damaged the integrity of the NIH grant process and the grant processes of other federal agencies. The Defendants' improper acts have also damaged the scientific community through the continued diversion of scarce grant funds away from universities performing honest research and through the publication of fraudulent research. The Defendants' actions since March 2013 seeking to conceal their fraud have caused these negative impacts to ripple and worsen, as this fraudulent research continues to be cited and, relying upon this fraudulent research, other scientists have embarked down fruitless avenues of study.

10. Under the FCA, Defendants are liable to the United States for the ill-gotten and misspent grant funds, trebled, as well as other damages and civil penalties.

II. Jurisdiction and Venue

11. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732 and 3730(b).

12. This Court has personal jurisdiction of the Defendants under 31 U.S.C. § 3732(a) because Defendants Duke University and DUHS both can be found in and transact business in the Western District of Virginia. Among other things, Duke University solicited and enrolled

students from the District, advertised in the District, participated in academic activities in the District, and participated in athletic activities in the District during all times relevant hereto. Likewise, DUHS transacted business at its Cardiovascular Surgery of Danville clinic in Danville, Virginia.

13. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) because, at all times material and relevant hereto, Defendants Duke University and DUHS transacted business in the Western District of Virginia.

14. Thomas's claims and this Amended Complaint are not based on allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

15. To the extent that there has been a public disclosure unknown to Thomas, he is the "original source" and meets the requirements of 31 U.S.C. § 3730(e)(4)(B). Thomas has direct and independent knowledge of the information upon which the allegations are based, and he has voluntarily provided this information to the government, prior to filing this action under seal, as required by 31 U.S.C. § 3730(b)(2), before publicly proceeding with this action.

III. Parties and Other Key Players

A. Joseph M. Thomas

16. Thomas is a resident of North Carolina. At all times relevant hereto, he was an employee of Duke University.

17. From August 2008 until February 2012, Thomas worked in the Cell Biology Department of the Duke University Medical Center.

18. In February 2012, Thomas moved to the laboratory of Dr. Monica Kraft in the Pulmonary, Asthma and Critical Care Division (the "Pulmonary Division"). By that point, Thomas was employed as a Laboratory Research Analyst II. In that capacity, he developed, designed, and conducted experiments for the Pulmonary Division.

B. Duke University

19. Defendant Duke University is a private university located in Durham, North Carolina. Duke University holds itself out as one of the premier research institutions in the United States. It annually receives hundreds of millions of dollars in grant funding from the federal government.

C. DUHS

20. Defendant DUHS is a health-care-services company located in Durham, North Carolina. DUHS is a subsidiary of Duke University, and it runs the Duke University Medical Center.

21. Employees of Duke University and DUHS share cross-appointments, employment duties, and employment activities between Duke University and DUHS.

D. Erin N. Potts-Kant

22. Defendant Potts-Kant was an employee of Duke University and/or DUHS. She was hired in or about 2005 and worked with Defendant Foster in his Airway Physiology Laboratory (the "Foster Lab"). Potts-Kant was approximately 25 years old when she began working for Duke University.

23. Potts-Kant subsequently served as the Clinical Research Coordinator II in the Pulmonary Division. The Job Description for this position is attached as **Exhibit A**. Among other things, it called for the Clinical Research Coordinator II to:

a. "coordinate and participate in a variety of complex activities involved in the collection, compilation, documentation and analysis of clinical research data."

b. "[e]nsure compliance with protocol guidelines and requirements of regulatory agencies; identify problems and/or inconsistencies."

c. "[e]valuate and interpret collected clinical data in conjunction with principal investigator(s) as appropriate; prepare oral presentations or written reports and

analyses setting forth progress, trends and appropriate recommendations or conclusions."

d. supervise and train more junior personnel, and "[p]rovide guidance to lower level personnel involved in planning, implementation and evaluation of clinical studies."

E. William Michael Foster, Ph.D.

24. Defendant Foster is a Research Professor of Medicine in the Pulmonary Division. Foster was Potts-Kant's direct supervisor, including for Potts-Kant's work in the Foster Lab. Foster is an employee of Duke University, and may have a cross-appointment with DUHS.

25. Duke University, DUHS, and Foster himself all held Foster out as a leading authority on research into factors that affect airway inflammation, including the design of experiments to evaluate respiratory resistance in mice; the conduct of such experiments; the proper methods of delivering inflammatory agents; and the interpretation of the resulting data.

F. Other Key Players

(i) The Foster Lab

26. The Foster Lab primarily studied the effects of pathogens, chemicals, medications, and environmental factors on the airways of laboratory mice, with the ultimate goal of treating human pulmonary diseases.

27. The Foster Lab operated as a "core laboratory" for Duke University, meaning that many other laboratories and researchers, both internally within Duke University and from fellow research institutions, would submit experiments to the Foster Lab to conduct on their behalf.

28. In turn, researchers in the Foster Lab asked to be credited as co-authors on the publications stemming from their work, and, in some instances, to receive funding from fellow researchers' grants.

(ii) The Pulmonary Division

29. The Pulmonary Division is within the Department of Medicine, and made up of several researchers who possess either a Ph.D. or an M.D, or both. These researchers are called "Principal Investigators," because they direct, manage, and supervise the research performed in the laboratories at Duke University. Principal Investigators are also the agents by which Duke University applies for and receives federal grant funding.

30. The Foster Lab's research misconduct and fraud directly affected research conducted for Principal Investigators within the Pulmonary Division. The institutional chart attached as **Exhibit A-1** sets out the relationships among Duke University, DUHS, and the relevant employees within the Pulmonary Division. Many of these individuals and relationships are also addressed below.

31. Foster is a Principal Investigator for the Pulmonary Division.

32. Dr. Monica Kraft was a Principal Investigator for the Pulmonary Division, and became Division Chief in late 2012.

33. Dr. Paul W. Noble was a Principal Investigator for the Pulmonary Division, and was Division Chief until leaving the Division in late 2012.

34. Dr. John W. Hollingsworth was a Principal Investigator for the Pulmonary Division, and worked closely with Foster and Potts-Kant. Dr. Hollingsworth supervised Potts-Kant on significant research projects.

35. Dr. Loretta G. Que is a Principal Investigator for the Pulmonary Division, and worked closely with Foster and Potts-Kant.

36. Dr. Jerry Eu was a Principal Investigator for the Pulmonary Division.

37. Dr. Julia K. Walker was a Principal Investigator for the Pulmonary Division.

38. Dr. Julie G. Ledford was an Assistant Research Professor, who worked for Dr. Kraft.

39. Dr. Jennifer Ingram is an Assistant Research Professor, who worked for Dr. Kraft.

40. Dr. David M. Brass was an Assistant Research Professor in the Pediatric Department who worked primarily with Dr. Hollingsworth.

41. Barbara S. Theriot worked in the laboratory of Dr. Walker. She was Potts-Kant's peer in terms of job responsibilities and experience, and also her successor in the Foster Lab.

42. Dave Francisco was a lab analyst, who functioned as Dr. Kraft's lab manager.

43. Charles Giamberandino was a Lab Research Analyst.

(iii) Other Researchers

44. The Pulmonary Division and the Foster Lab also conducted research in conjunction with other laboratories, physicians, scientists, and researchers outside of the Pulmonary Division.

45. The Foster Lab's research fraud directly affected research conducted for Principal Investigators outside of the Pulmonary Division.

46. Among these other Principal Investigators were: Dr. Soman Abraham (Department of Immunology, Pathology, and Molecular Genetics and Microbiology); Dr. Jo Rae Wright (Department of Cell Biology);[1] Dr. Mary Sunday (Department of Pathology); Dr. Michael "Dee" Gunn (Department of Medicine, Cardiology). Dr. Richard L. Auten (Department of Pediatrics); Donald N. Cook (Department of Immunology); Njira L. Lugogo (Assistant Professor of Medicine); and Amy M. Pastva (Assistant Professor of Orthopaedic Surgery).

IV. Legal Framework

A. The FCA

47. The FCA provides, in part, that any person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

[1] Dr. Wright passed away in 2012.

(a)(1)(B) knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim;

[or]

(a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990,[2] plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.[3]

48. For purposes of the FCA, the terms "knowing" and "knowingly" "mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). No proof of a specific intent to defraud is required to show knowledge. 31 U.S.C. § 3729(b)(1)(B).[4]

49. In relevant part, for purposes of the FCA, the term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—(i) is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2).

50. For purposes of the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4)).

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[2] The civil penalty range has been increased to $5,500 to $11,000.

[3] On May 20, 2009, the FCA was amended pursuant to the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Public Law 111-21. To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include applicable violations of the Federal False Claims Act prior to the 2009 amendments.

[4] Unless otherwise specified, use of "know," "knew," "knowing," "knowingly," or "knowledge" in this Amended Complaint refers to this statutory definition, and thus one or more of the ways to establish knowledge under the FCA.

51. For purposes of the FCA, the term "obligation" means "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3).

B. NIH Grants

(i) The relationship among NIH, PHS, and HHS.

52. The PHS is a division of the Department of Health and Human Services ("HHS"), and works to administer HHS programs.

53. The NIH is an HHS agency division and component of the PHS.

54. The NIH is made up of multiple institutes and centers, each with a specific research agenda. NIH institutes include the National Cancer Institute ("NCI"), the National Heart, Lung, and Blood Institute ("NHLBI"), the National Institute of Allergy and Infectious Diseases ("NIAID"), the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD"), the National Institute of Environmental Health Sciences ("NIEHS"), and the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK").

(ii) The purpose of NIH grants.

55. The NIH invests over $30 billion annually for medical research on behalf of the American people.

56. Through a competitive application process, the NIH awards grants to research institutions like Duke University.

57. In addition to directly funding scientific research in grants, NIH includes a substantial "indirect cost" amount within grant awards to reimburse institutions for administering the grants. Among the indirect costs are the costs of complying with PHS regulations, including fostering an environment of research integrity and dealing forthrightly with allegations of research misconduct as required under 42 C.F.R. Part 93.

58. The NIH "is the steward of medical and behavioral research" for the United States. (NIH Grants Policy Statement (2013), Part I, § 2, "The National Institutes of Health as a Grant-Making Organization" p. I-28.)[5]

59. The NIH seeks to "ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee organizations." (NIH Grants Policy Statement, Part I, § 2.1, "Roles and Responsibilities," p. I-28.)

(iii) Grantee institutions must foster research integrity, protect against research misconduct, and safeguard public funds.

60. "NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Grantees are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain." (NIH Grants Policy Statement, Part II, § 4, "Public Policy Requirements, Objectives and Other Appropriation Mandates" p. IIA-3.)

61. No NIH grant funds can be used to disseminate information that is deliberately false or misleading. (NIH Grants Policy Statement, Part II, § 4.2.3, "Dissemination of False or Deliberately Misleading Information, p. IIA-43.)

62. "The grantee is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project." (NIH Grants Policy Statement, Part II, § 4.1.27, "Research Misconduct" p. IIA-40.)

63. NIH grant programs are subject to the HHS, Public Health Service Policies on

[5] Citations are made to the current NIH Grants Policy Statement, effective October 1, 2013. Upon information and belief, the NIH Grants Policy Statements effective at other relevant times are substantively the same.

Research Misconduct, 42 C.F.R. Part 93 (the "Regulations"). (NIH Grants Policy Statement, Part II § 4.1.27, "Research Misconduct," p. IIA-40-41.)[6]

64. The Regulations define "research misconduct" as:

> fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

42 C.F.R. § 93.103.

65. "Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds." 42 C.F.R. § 93.100(a).

66. The Regulations establish an institution's "affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct." 42 C.F.R. § 93.100(b) (emphasis added).

67. The Regulations further require that institutions "foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research." 42 C.F.R. § 93.412(a)). See also 42 C.F.R. §

[6] The Regulations apply to "any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support." 42 C.F.R. § 93.102(a)(2).

93.300(c). In the context of this regulation, the directive in Sec. 93.300(c) to foster an environment that promotes the responsible conduct of research means an environment that promotes competent, ethical research that is free of misconduct. This is directly related to the purposes of the regulation to establish the responsibilities of institutions in responding to research misconduct issues and to promote the integrity of PHS supported research and the research process." Public Health Service Policies on Research Misconduct, Final Rule, 70 Fed. Reg. 28378 (May 17, 2005) (amending 42 C.F.R. pts. 50 and 93).

(iv) Grantee institutions must maintain an assurance of compliance to receive funds.

68. An assurance is necessary for a grantee institution to be eligible to receive PHS funding. (NIH Grants Policy Statement, Part II, § 4.1.27, "Research Misconduct," p. IIA-40; *see also* 42 C.F.R. § 93.101(d) (grantee institutions must "provid[e] HHS with the assurances necessary to permit the institutions to participate in PHS supported research"); 42 C.F.R. § 93.301(a) (PHS grant funds may be paid "only to institutions that have approved assurances and required renewals on file with ORI").

69. An institution establishes an assurance when it signs a grant application or a separate assurance form. (NIH Grants Policy Statement, Part II, § 4.1.27, "Research Misconduct," p. IIA-40).

70. To be in compliance under the Regulations, an institution must:

> (a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;
>
> (b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;
>
> (c) Foster a research environment that promotes the responsible

> conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
>
> ...
>
> (i) Have an active assurance of compliance.

42 C.F.R. § 93.300.

71. An institution must also provide an assurance that it: "(1) [h]as written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) [c]omplies with its own policies and procedures and the requirements of this part." 42 C.F.R. § 93.301(b).

72. An institution can only comply with its assurance if it:

> (1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;
>
> (2) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including—
>
> > (i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and
> >
> > (ii) Complies with its policies and procedures and each specific provision of this part.

42 C.F.R. § 93.302(a).

73. Each year, a grantee institution must file an Institutional Assurance and Annual Report on Possible Research Misconduct ("Institutional Assurance and Annual Report") with the

Office of Research Integrity ("ORI").[7] 42 C.F.R. § 93.302(b).

74. A grantee institution maintains its assurance status by filing the Institutional Assurance and Annual Report, and by otherwise complying with the Regulations. (NIH Grants Policy Statement, Part II, § 4.1.27, "Research Misconduct," p. IIA-40).

(v) Grantee institutions must report and respond to allegations of possible research misconduct.

75. The Regulations impose specific obligations on grantee institutions to investigate allegations of research misconduct and to make certain disclosures to ORI under specific circumstances.[8]

76. In the Institutional Assurance and Annual Report, the institution must disclose to ORI any allegations made during the preceding calendar year of possible research misconduct. (Form PHS-6349.) All inquiries or investigations launched or continued in the preceding calendar year must be reported to ORI in the Institutional Assurance and Annual Report. (Form PHS-6349 §II(B).)

77. The institution must conduct an "inquiry" if an allegation falls within the definition of research misconduct and is "sufficiently credible and specific so that potential evidence of research misconduct may be identified." 42 C.F.R. § 93.307(a). "The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation." 42 C.F.R. § 93.307(b).

78. Upon completing an inquiry, the institution must prepare a written inquiry report, 42 C.F.R. § 93.307(e), including the name and position of the respondent, a description of the allegations of research misconduct, and the PHS support affected. 42 C.F.R. § 93.309(a). The

[7] The Office of Research Integrity is part of the HHS. It oversees and directs PHS research integrity on behalf of the Secretary of Health and Human Services.

[8] The Regulations define an "allegation" as a disclosure of possible research misconduct through any means of communication, including written and oral statements. 42 C.F.R. § 93.201.

inquiry report must specifically set forth all grant numbers, applications, and publications listing PHS support that may be affected by the research misconduct. 42 C.F.R. § 93.309(a)(3).

79. The institution must provide ORI with a written inquiry report upon finding that an investigation is warranted. 42 C.F.R. § 93.309. The institution must then conduct an investigation, which entails reviewing the research record, conducting interviews, and pursuing all leads that are relevant to resolving the merits of the allegation and any additional instances of research misconduct. *See* 42 C.F.R. § 93.310.

80. Upon the completion of the investigation, the institution must submit, in writing, a final institutional investigation report which includes: (a) information of the allegations of research misconduct; (b) the PHS support including any grant numbers, grant applications, contracts and publications listing PHS support; (c) a summary of the research records and evidence reviewed; and a statement of findings for each separate allegation of research misconduct identified during the investigation. 42 C.F.R. § 93.313(a)-(f).

81. The statement of findings must also: (a) identify the nature of the research misconduct and whether it was intentional, knowing or in reckless disregard; (b) summarize the facts and analysis which support the conclusion; (c) identify the specific PHS support; (d) identify whether any publications need correction or retraction; and (e) identify the persons responsible for the misconduct; and list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies. 42 C.F.R. § 93.313(f).

82. An institution must notify ORI "immediately" if it has reason to believe that any one of seven conditions exist, including:

(i) HHS resources or interests are threatened;

(ii) There is a reasonable indication of possible violations of civil or criminal law; or

(iii) The research community or public should be informed.

42 C.F.R. § 93.318(b), (d), and (g).

83. Once notified of an allegation, ORI does not need to wait for a grantee institution to conduct an inquiry or investigation before taking action. Rather, "ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter." 42 C.F.R. § 93.400(a); *see also* 42 C.F.R. § 93.402.

84. Once notified, ORI has broad powers to address an allegation of research misconduct:

> The ORI response may include, but is not limited to—
>
> (1) Conducting allegation assessments;
>
> (2) Determining independently if jurisdiction exists under this part in any matter;
>
> (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
>
> (4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;
>
> (5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
>
> (6) Reviewing an institution's findings and process;
>
> (7) Making a finding of research misconduct; and
>
> (8) Proposing administrative actions to HHS.

42 C.F.R. § 93.400(a); *see also* 42 C.F.R. § 93.402.

85. In any research misconduct proceeding, ORI can review a grantee's institutional assurances and compliance with the Regulations. 42 C.F.R. §§ 93.400(e)-(f).

(vi) Grantee institutions must comply with all terms and conditions of the grant award.

86. Applicants approved for grant funding receive a "Notice of Award," a legally binding document signed by an NIH Grants Management Officer that contains or references all the terms and conditions of the grant. Among the terms and conditions is the NIH Grants Policy Statement and the Notice of Award. (NIH Grants Policy Statement, Part II, § 3, "Overview of Terms and Conditions," p. IIA-1.)

87. Accordingly, acceptance of an award from the NIH obligates the grantee to know and comply with the terms and conditions of the award.

(vii) Institutional certifications relating to grant awards.

88. In connection with grant funding, an institution makes certifications related to its request for, and proposed use of, federal funds.

89. For example, by its signature on the grant application, the grantee institution certifies to the NIH that it has "the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application." (NIH Grants Policy Statement, Part I, § 2.3.6, "Legal Implications of Applications," p. I-36.)

90. By its signature on the grant application, the grantee institution also certifies that it "complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions." (NIH Grants Policy Statement, Part II, § 4, "Public Policy Requirements, and Objectives" p. IIA-3.)

91. The NIH grant application form (PHS 398) includes an express certification that reads:

> APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true,

> complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

92. Over the time period at issue, the NIH transitioned from the PHS 398 Grant Application Form to the SF 424 (R&R) Grant Application Form, which allows for the electronic submission of grant applications. Similar to form PHS 398, the SF 424 Form includes an express certification which provides:

> By signing this application, I certify (1) to the statements contained in the list of certifications[], and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001).

93. The "list of certifications" and the "required assurances" referenced in the SF 424 form are set forth in the U.S. Department of Health and Human Services, Public Health Service, Supplemental Grant Instructions For All Competing Applications and Progress Reports (the "Supplemental Grant Instructions"). Section 2.7 of the Supplemental Grant Instructions provides:

> Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by 42 C.F.R. Part 93, "Public Health Service Policies on Research Misconduct."
>
> The signature of the official signing for the applicant organization on the Face Page of the application (or for electronic applications, checking the "I agree box on line 17 of the SF 424 (R&R) (Cover Form) serves as certification that:
>
> 1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible research misconduct under 42 C.F.R. Part 93;
>
> 2. The institution has established policies and procedures

> incorporating the provisions set forth in 42 C.F.R. Part 93;
>
> 3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
>
> 4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

94. The NIH requires that grantees periodically submit financial and progress reports. Progress reports inform the NIH of the grantee's accomplishments, including publications and inventions resulting from the award, personnel and location changes, budget updates, and other information pertaining to the grantee's use of funds. (NIH Grants Policy Statement, Part II, § 8.4.1, "Reporting," pp. IIA-107 – IIA-111.)

95. For multiyear funded awards, progress reports serve as the basis for the NIH's continued support for subsequent budget periods:

> Grantees are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (*see* Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support.

(NIH Grants Policy Statement, Part II, § 5.3, "Funding," pp. IIA-48; *see also* NIH Grants Policy Statement, Part II, § 8.4.1.3, "Progress Reports for Multiyear Funded Awards," p. IIA-111.)

96. In submitting a progress report, the grantee institution certifies compliance with the terms and conditions of the grant award, and verifies the accuracy and validity of all administrative, fiscal, and scientific information in the progress report. The grantee institution further certifies its accountability for the appropriate use of any funds awarded and for the

performance of the grant-supported project or activities resulting from the progress report. (NIH Grants Policy Statement, Part II, § 8.4.1, "Reporting," pp. IIA-107 – IIA-111.)

97. At the conclusion of a funded project, the grantee is also required to submit certain closeout documents to the NIH, including a final progress report, final invention statements and certifications, and a final financial status report. Again, the grantee institution certifies compliance with the terms and conditions of the Notice of Award and verifies the accuracy and validity of all information contained in the final reports. (NIH Grants Policy Statement, Part II § 8.6, "Closeout," p. IIA-120 – IIA-122).

98. At closeout, final progress reports summarize the grantee's accomplishments, identify significant results (positive or negative), and list publications resulting from the grant. Again, the grantee institution certifies compliance with the terms and conditions of the Notice of Award and verifies the accuracy and validity of all information contained in the final reports. (NIH Grants Policy Statement, Part II § 8.6.2, "Final Progress Report," p. IIA-121.)

99. Each grant progress report (PHS 2590) includes an express certification that reads:

> APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

100. Section V of the Institutional Assurance and Annual Report also contains a certification. By making this certification, the grantee institution certifies that its Institutional Assurance and Annual Report is accurate, as well as the institution's compliance with the Regulations. 42 C.F.R. § 93.302(b); Form PHS 6349.

101. Under the controlling NIH policies and the Regulations, as reviewed above, the grantee institution's certifications are a condition of grant approval and grant funding.

(viii) Grantee institutions are required to identify publications and research results in grant applications and grant progress reports, and to make published research funded by NIH grants publicly available.

102. In a grant application, the institution must provide a bibliography of any references cited in the "Research Plan" and/or "Project Narrative" section. (HHS, PHS, Grant Application (PHS 398), Part I, § 5.5.5, "Bibliography and References Cited/Progress Report Publication List," p. I-48; SF 424 (R&R); Application Guide for NIH and Other PHS Agencies, Part I, § 4.4 "Other Project Information Form," pp. 58, 63.)[9]

103. In a grant progress report, the grantee institution must provide complete references to the publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. (HHS, PHS, Grant Application (PHS 398), Part I, § 5.5.5, "Bibliography and References Cited/Progress Report Publication List," p. I-48; SF 424 (R&R); Application Guide for NIH and Other PHS Agencies, Part I, § 5.5 "PHS 398 Research Plan Form," p. 114.)

104. For non-competing continuation progress reports, the grantee institution must report publications resulting directly from the grant. If the grantee has no publications to report, it must include such a statement. (HHS, PHS, Non-Competing Continuation Progress Report (PHS 2590), § 2.6(E) "Publications," p. 16.)[10]

105. In a final progress report, the grantee institution must include a list of significant results (positive or negative), and a list of resulting publications. (HHS, PHS, Final Progress Report Instructions, § B "Instructions for All Final Progress Reports (exclusive of SBIR/STTR Phase II Final Progress Reports)," p. 1.)[11]

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[9] Citation to these instructions are to the current version. Upon information and belief, instructions effective at other relevant times are substantively the same.

[10] Citation is to the current instruction document; upon information and belief, instructions effective at other relevant times are substantively the same.

[11] Citation is to the current instruction document; upon information and belief, instructions effective at other relevant times are substantively the same.

106. All research results that are funded by the NIH and accepted for publication by a peer-reviewed journal must be made available to the public no later than 12 months after publication. (NIH Public Access Policy Details.) This public access requirement is in place to help advance science and improve public health, and has been an NIH requirement since at least April 2008.

(ix) Enforcement actions and other remedies for research misconduct, the failure to foster an appropriate research environment, and the misuse of NIH grant funds.

107. "If a grant is awarded on the basis of false or misrepresented information, or if a grantee does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies." NIH Grants Policy Statement, Part II, § 4, "Public Policy Requirements, Objectives and Other Appropriation Mandates" p. IIA-4 (emphasis added).)

108. Among the legal remedies available to the United States for fraud, waste, or abuse of NIH grant funds are FCA actions. (NIH Grants Policy Statement, Part I, § 2, "Fraud, Waste and Abuse of NIH Grant Funds" p. I-47.)

109. In connection with a finding of research misconduct, HHS "may seek to recover PHS funds spent in support of activities that involved research misconduct." 42 C.F.R. § 93.407(b).

110. ORI can also determine that a grantee institution has not complied with its institutional obligations under the Regulations, including its obligation to "foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research." 42 C.F.R. § 93.412(a).

111. Accordingly, "ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the

requirements of this part and its assurance." 42 C.F.R. § 93.412(b). In making a determination of institutional noncompliance:

> ORI may consider, but is not limited to the following factors—
>
> (1) Failure to establish and comply with policies and procedures under this part;
>
> (2) Failure to respond appropriately when allegations of research misconduct arise;
>
> (3) Failure to report to ORI all investigations and findings of research misconduct under this part;
>
> (4) Failure to cooperate with ORI's review of research misconduct proceedings; or
>
> (5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

42 C.F.R. § 93.412(b).

112. Should a grantee institution fail to comply with its assurance and its obligations under the Regulations, HHS may bring an enforcement action that results in debarment, suspension or any other appropriate action. 42 C.F.R. § 93.413(c).

113. If a grantee's "actions constitute a substantial or recurrent failure to comply with this part, ORI may also revoke the institution's assurance under §§ 93.301 or 93.303." 42 C.F.R. § 93.413(d).

C. EPA Grants

114. The EPA has established a process by which grants are paid to private research institutions. The EPA grant process is governed by 40 C.F.R. Part 40.

(i) Certifications Relating to EPA Grant Awards

115. To obtain EPA grant funding, an institution makes certifications related to its request for, and proposed use of, federal funds.

116. The EPA grant application form (Form SF 424) includes an express certification

that reads:

> By signing this application, I certify (1) to the statements contained in the list of certifications[] and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances[] and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

117. The EPA issues a Notice of Award if an institution's grant application is successful. A Grant Agreement and Affirmation of Award are enclosed with the Notice Award, and must be signed and returned to the EPA by the grantee institution. These documents contain instructions regarding the submission of a payment request form.

118. To receive payment of the grant funds, the grantee institution must submit an EPA Payment Request form.

119. Once a grant has been awarded, the EPA requires that grantees periodically submit financial and progress reports. Grantees receiving a multiyear award must submit an annual progress report and may be required to submit additional monthly or quarterly reports. 40 C.F.R. § 40.160-1. The grantee's progress reports inform the EPA of the grantee's accomplishments, including publications resulting from the award, personnel and location changes, budget updates, and other information pertaining to the grantee's use of funds. 40 C.F.R. § 40.160-1.

120. At the conclusion of a funded project, the grantee is also required to submit certain closeout documents to the EPA, including a final report, a final invention report, an equipment report, and a financial status report. 40 C.F.R. § 40.160-2 *et seq.* The grantee must report all publications resulting from grant funds in an Executive Summary that is attached to the final report.

(ii) Grantee institutions are required to identify publications and research results in grant progress reports.

121. In grant annual progress reports, the grantee institution must report all publications resulting from the grant funded project. The grantee institution must provide copies of all publications that have not previously been submitted to the EPA. (EPA Research and Related Terms and Conditions, § 8(A)(7)). The grantee institution must also prepare an Annual Report Summary for display on the EPA website, which contains a list of all publications and presentations arising out of that grant. (EPA Research and Related Terms and Conditions, § 8(A)(8).)

122. At the close of the funding period, the grantee institution must submit an Executive Summary to the EPA as a part of its final report. The grantee must report all publications resulting from the grant in that Executive Summary.

(iii) EPA policy requires reporting and responding to allegations of research misconduct.

123. In 2003, the EPA established its Policy and Procedures for Addressing Research Misconduct ("EPA Research Misconduct Policy").

124. The EPA Research Misconduct Policy "applies to all research conducted, sponsored or funded, in whole or in part, by EPA and to research proposals submitted to EPA. It thus applies to research . . . funded by EPA and performed at research institutions, including universities . . . ." (EPA Research Misconduct Policy § 3; *see also* EPA Research Misconduct Policy § 5(G) (defining research institutions).)

125. The EPA Research Misconduct Policy defines "research misconduct" as "fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results . . . or ordering, advising or suggesting that subordinates engage in research misconduct." (EPA Research Misconduct Policy § 5(A).)

126. "Fabrication is making up data or results and recording or reporting them." (EPA

Research Misconduct Policy § 5(C).)

127. "Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record." (EPA Research Misconduct Policy § 5(D).)

128. Paralleling the NIH Regulations, a research institution must "immediately" notify the EPA Office of Inspector General ("OIG") if "any allegation of research misconduct" involves any one of seven factors, including:

(i) Agency resources or interests are threatened;

(ii) There is a reasonable indication of possible violations of civil or criminal law; or

(iii) Circumstances where the research community or public should be informed.

(EPA Research Misconduct Policy § 7(B), (D), and (G); *see also* EPA Research Misconduct Policy § 9(C)(i)(a); 65 Fed. Reg. 76263(III).)

129. If an allegation of research misconduct falls outside of these categories, the research institution need not immediately notify the EPA. In such instances, the research institution must conduct its own inquiry into the allegation and must notify the EPA if it has "determined that there is sufficient evidence to proceed with an investigation." (EPA Research Misconduct Policy § 9(C)(i)(b); *see also* 65 Fed. Reg. 76263(III).)

130. The EPA has the "ultimate oversight authority for Federally funded research." 65 Fed. Reg. 76263(III). "[A]t any time, the [EPA] may proceed with its own inquiry or investigation." 65 Fed. Reg. 76263(III).

V. Factual Allegations

A. The purpose of medical research and the potential pitfalls in its pursuit.

131. Quality medical research is an ongoing endeavor. Today's research leads to the research of tomorrow, and, ultimately, to improved public health and medical treatment.

132. Research results must therefore be communicated to the medical and scientific community. Typically, this is done through journal publications.

133. In addition to serving the public interest, medical research can also advance and benefit the researchers and institutions that conduct it.

134. This advancement and benefit can take many forms. Tangibly, researchers and institutions can receive monetary benefit, directly and indirectly, from research efforts. For example, grants fund the costs of research, including salaries and institutional support and infrastructure. Further, medical research can lead to the development of lucrative patents for researchers and institutions.

135. Medical research can also have many intangible benefits. For researchers, medical research can lead to promotion and advancement. For both researchers and institutions, medical research can increase professional esteem, prestige and reputations.

136. Journal publications are a primary conduit to achieve this advancement and benefit, for both researchers and their institutions. The more publications, and the more noteworthy the results, the more advancement and benefit.

137. There is a risk of research fraud, misconduct and abuse because grant funding for medical research furthers the individual and organizational interests of the investigators and the institution.

138. In an effort to address these pitfalls, NIH, PHS, HHS and EPA have created policies, procedures, and regulations to maintain research integrity. Some of these have been referenced above.

B. Duke University's Policy

139. Research institutions themselves recognize the risk presented by these pitfalls. For this reason—and because of the requirements to receive grant funds under the Regulations—research institutions have policies and procedures directed towards research misconduct.

140. Effective November 1995 and revised in January 2007, Duke University issued the Duke University Policy and Procedures Governing Misconduct in Research (the "Duke Policy"). The Duke Policy is currently part of the Duke Faculty Handbook Appendix P: Policies Related to Research ("Duke Faculty Handbook") (available at http://provost.duke.edu/wp-content/uploads/FHB_App_Ppdf.).

141. The Duke Policy states that "Duke University strives to foster an atmosphere of honesty and trust in which pursuit of knowledge can occur. Integrity of research forms the foundation of respect among scholars and students and between the academic world and the public. All members of the university community share responsibility for maintaining this climate of trust." (Duke Faculty Handbook, p. 33 (emphasis added).)

142. Although any research misconduct is unacceptable, the Duke Policy states that it "is especially serious in collaborative research, where the reputations of several researchers pursuing different components of an integrated project may be damaged by the actions of one or more partners. (Duke Faculty Handbook, p. 33).

143. According to the Duke Policy, responsibility to prevent research misconduct and ensure research integrity is shared: "Principal investigators must bear primary responsibility for ensuring the integrity of collaborative research performed under their supervision whether by faculty or non-faculty. Investigators, department and division chairpersons, and center directors are expected to make periodic and reasonable inquiries concerning the integrity of the activities conducted under their supervision." (Duke Faculty Handbook, p. 33 (emphasis added).)

144. Duke's Policy provides that any individual having reason to believe that a researcher has committed misconduct in research should report the matter in writing to the researcher's department or division chairperson, division chief, dean or appropriate Misconduct Review Officer. (Duke Faculty Handbook, p. 35).

145. Similar to the Regulations and EPA Research Misconduct Policy, under the Duke

Policy, external research sponsors must be notified in writing "at any stage" of an inquiry or investigation if certain conditions exist. One such condition is if there is a reasonable indication of possible violations of civil or criminal law—in which case notifications within twenty-four (24) hours of obtaining the information is required. (Duke Faculty Handbook, p. 40, ¶ 6).

146. Duke adopted this Policy to comply with the Regulations (42 C.F.R. Part 93) and thereby maintain its assurance status required as a condition of payment for NIH grant awards.

C. The Foster Lab engaged in systematic research misconduct and fraud.

147. Potts-Kant's work with the Foster Lab involved operating several machines that measured and assessed pulmonary physiology, along with performing laboratory assays. The machines that Potts-Kant operated included devices known as the "*flexi*Vent" and the "Bio-Plex."

148. The *flexi*Vent measures pulmonary function by force-ventilating a mouse and measuring the total amount of lung resistance and is capable of measuring a number of other physiological measurements, such as elastance, compliance, Newtonian resistance, tissue dampening, and pressure-volume loops.

149. The Bio-Plex analyzes samples of biological material, and identifies the presence of specific proteins, and quantifies the amount of those proteins within the samples. The Foster Lab used the Bio-Plex machine to quantify cytokines, small cell signaling proteins, implicated in airway inflammation. In some of the exhibits to this Amended Complaint, the Bio-Plex is referred to as the "Luminex" or "multiplex" machine.

150. The airway physiology and inflammation data resulting from experiments performed on the *flexi*Vent and multiplex machines is fundamental in current pulmonary research studies. It is unlikely that the NIH would award any significant grant funding for pulmonology research that does not include preliminary studies based on *flexi*Vent and/or multiplex experiments.

151. The Pulmonary Division coordinated the purchase of the *flexi*Vent machine for the Foster Lab around the time that Potts-Kant was hired in or about 2005. Before that, Duke University researchers had obtained a similar type of physiological measurement using an APTI machine.

152. When Potts-Kant began operating the *flexi*Vent machine, she obtained results that were inconsistent with the previous results from the APTI machine.

153. Foster and the Pulmonary Division dismissed this discrepancy.

154. Throughout her employment with Duke University and/or DUHS, Potts-Kant committed research misconduct and fraud on nearly every experiment or project with which she was involved.

155. This research misconduct and fraud was funded, in large part, by grants from the NIH, the EPA and other federal agencies.

156. As discussed below, this misconduct and fraud took several forms. Sometimes, Potts-Kant did not even run the experiments that she was purporting to conduct in the first place, deliberately failing to run the *flexi*Vent and multiplex machines or failing to expose the mice to the appropriate chemical, medical, or environmental conditions. Instead, she simply made up data.

157. On other occasions, Potts-Kant was more subtle. She sometimes actually ran the experiments, but later altered the resulting data to make it conform to the Principal Investigator's preconceived hypothesis or to increase its statistical significance. To fabricate the data, Potts-Kant downloaded source experimental data from the *flexi*Vent or multiplex machines, then imported it into an Excel spreadsheet. Once in Excel, Potts-Kant altered the data before forwarding it to the relevant Principal Investigator.

158. As a result, Potts-Kant was able to generate fraudulent research results that: (i) supported researchers' hypotheses; (ii) were statistically significant; and/or (iii) purported to

have been consistently "replicated." This was to her personal advancement and benefit, as well as that of Foster, Duke University, DUHS, and the Principal Investigators.

D. Based on false, fabricated, and fraudulent research results, Potts-Kant and Foster quickly co-authored dozens of publications in scientific journals.

159. Collaborating with a variety of Duke University faculty, DUHS appointees, and others, between 2007 and 2013, Potts-Kant used the fraudulent research results to co-author over 38 scientific papers and journal articles. Potts-Kant was 32 years old in 2013. These publications are attached in **Exhibit B**, which is incorporated by reference. Each of these publications report false and/or fabricated research data.

160. Collaborating with a variety of Duke University faculty, DUHS appointees, and others, Foster used the fraudulent research results to co-author over 38 scientific papers and journal articles.

161. Some of these publications are discussed in more detail below.

(i) PMID 17993584—*Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase*

162. In 2007, Potts-Kant and Foster performed experiments that contributed to the paper entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47 Subunit of NAD(P)H Oxidase*. (**Ex. B**, at Relator_000029.)

163. Potts-Kant falsified and/or fabricated data that went into Figures 9A and 9B of this paper. To the extent that raw data exists, it does not support the reported research results.

164. This paper was published in January 2008 in the American Journal of Physiology. Before it was published, a portion of the work contained in the paper was presented to the American Thoracic Society.

165. This scientific article, premised upon fraudulent research, cites the financial support from NIH grants HL067021, HL075307 and HL67281.

(ii) PMID 21684833—*The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury*

166. Potts-Kant and Foster co-authored a paper entitled *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury*. (**Ex. B**, at Relator_000447.)

167. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent and multiplex machines. The data supposedly produced by these experiments are contained in Figure 1 (*flexi*Vent), Figure 3 (multiplex), Figure 4 (*flexi*Vent), and Figure 6 (multiplex) of the paper. Potts-Kant also claimed to perform the lipopolysaccharide ("LPS") and ozone exposures reported in the paper. Other researchers were unable to repeat the Foster Lab's results and observed results that were contrary to the published results.

168. Potts-Kant did not actually perform the experiments at all, but rather falsified and/or fabricated the data in the paper.

169. This scientific paper was accepted for publication on June 17, 2011, by the scientific journal Environmental Health Perspectives.

170. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES020426, ES016347 and HL081825.

(iii) PMID 21037098—*Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide*

171. Potts-Kant and Foster co-authored a scientific paper entitled *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide*. (**Ex. B**, at Relator_000169.)

172. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent machine. The data supposedly produced by these experiments are contained in Figures 1C, Figure 2C, Figure 4C and Figure 5C (*flexi*Vent) of the paper. Potts-Kant also claimed to

perform the ozone and hyaluronan ("HA") exposures reported in the paper.

173. Potts-Kant falsified and/or fabricated the data in the paper.

174. Another researcher later tried to repeat the Foster Lab's results but was unsuccessful and observed results that were contrary to the published results.

175. This scientific paper was accepted for publication on September 21, 2010, by the Journal of Immunology.

176. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126, ES016659, ES016347, AI064789 and AI081672.

(iv) PMID 19494306—*SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice*

177. Potts-Kant and Foster co-authored a scientific paper entitled *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice*. (**Ex. B,** at Relator_000437.)

178. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent machine. The data supposedly produced by these experiments are contained in Figures 1, 5A, and 5B (*flexi*Vent) of the paper.

179. Potts-Kant falsified and/or fabricated the data in the paper.

180. One of the paper's co-authors, Dr. Ledford, has stated that the data in this publication is false, and that she will have to retract the paper.

181. This scientific paper was accepted for publication on April 20, 2009, by the Journal of Immunology.

182. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants F32HL091642, ES011961, PHL073907 and HL084917.

(v) PMID 18818374—*The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace*

183. Potts-Kant and Foster co-authored a scientific paper entitled *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace*. (**Ex. B**, at Relator_000120.)

184. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent and multiplex machines. The data supposedly produced by these experiments are contained in Figure 1B, 1C and 1D (*flexi*Vent), Figure 2 (multiplex), and Figure 4C (multiplex) of the paper. Potts-Kant also claimed to perform the ovalbumin ("OVA") exposures reported in the paper.

185. Potts-Kant falsified and/or fabricated the data in the paper.

186. This scientific paper was accepted for publication on September 3, 2008, by the Journal of Leukocyte Biology.

187. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES11961, ES12496, ES16126 and National Heart, Lung and Blood Institute grant HL91335.

(vi) PMID 17878331—*Ambient Ozone Primes Pulmonary Innate Immunity in Mice*

188. Potts-Kant and Foster co-authored a scientific paper entitled *Ambient Ozone Primes Pulmonary Innate Immunity in Mice*. (**Ex. B**, at Relator_000052.)

189. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent machine. The data supposedly produced by these experiments are contained within Figure 1 (*flexi*Vent) of the paper. Potts-Kant also claimed to perform the ozone exposures reported in the paper.

190. Another researcher tried to re-run this experiment and observed results that were the opposite of the Foster Lab's published results.

191. Potts-Kant falsified and/or fabricated the data in the paper.

192. This scientific paper was accepted for publication on July 18, 2007, by the Journal of Immunology.

193. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES12717, ES11961, National Institute of Allergy and Infectious Disease grant AI58161 and National Heart, Lung and Blood Institute grant HL91335.

(vii) PMID 22073274—*Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP*

194. Potts-Kant and Foster co-authored a scientific paper entitled *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP*. (**Ex. B**, at Relator_000177.)

195. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent and multiplex machines. The data supposedly produced by these experiments are contained in Figure 1 (*flexi*Vent), Figure 3 (multiplex), Figure 6 (*flexi*Vent), and Figure 8 (multiplex) of the paper. Potts-Kant also claimed to perform the ozone and HA exposures described in the paper.

196. One Duke University researcher later found that the data in this publication was manipulated, and another was unable to repeat the Foster Lab's reported results.

197. Potts-Kant falsified and/or fabricated the data in the paper.

198. This scientific paper was accepted for publication on October 11, 2011, by the scientific journal Free Radical Biology & Medicine.

199. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants ES016126 and ES020426.

(viii) PMID 22773729—*Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype*

200. Potts-Kant co-authored a scientific paper entitled *Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype*. (**Ex. B**, at Relator_000523.)

201. In contributing to this paper, Potts-Kant claimed to perform experiments on the multiplex machine. The data supposedly produced by these experiments are contained in Table 3 (multiplex) of the paper.

202. A Duke University researcher re-ran the multiplex experiments and could not repeat the Foster Lab's reported results. He also identified manipulated data and missing multiplex plate keys.

203. Potts-Kant falsified and/or fabricated the data in the paper.

204. This scientific paper was accepted for publication in final form on May 27, 2012, by the American Journal of Respiratory and Critical Care Medicine.

205. This scientific paper, premised upon fraudulent research, cites financial support from American Thoracic Society Grant 07 012, and NIH grants P50-HL-084917, HL-05-009, HL086887, ES016126, and AI081672.

(ix) PMID 22502799—*Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice*

206. Potts-Kant and Foster co-authored a scientific paper entitled *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice*. (**Ex. B.**, Relator_00202.)

207. In contributing to this paper, Potts-Kant claimed to perform experiments on the *flexi*Vent machine. The data supposedly produced by these experiments are contained in Figures 3A and 3B, Figure 4C, and Figure 6A (*flexi*Vent) of the paper.

208. Dr. Ledford, one of the co-authors of this publication, observed that its data looked "too clean" because the baseline response was too consistent for the number of animals used. Dr. Ledford has stated that she will have to retract this paper.

209. Potts-Kant falsified and/or fabricated the data contained within the paper.

210. This scientific paper was accepted for publication on January 17, 2013, by the scientific Journal of Allergy and Clinical Immunology.

211. This scientific paper, premised upon fraudulent research, cites financial support from NIH grants F32-HL091642 and PO1-AI81672.

(x) Additional Publications

212. In addition to these publications listed above, other publications co-authored by Foster and/or Potts-Kant were based on false and/or fabricated research data. Additional examples of these publications are listed on **Exhibit E.**

(xi) Potts-Kant and Foster used false and/or fabricated research results to publish scientific papers – EPA grant funding.

213. Collaborating with a variety of Duke University faculty, DUHS appointees, and others, Potts-Kant and/or Foster used false and/or fraudulent research results to co-author scientific papers and journal articles funded by an EPA grant. Two of these publications are described in **Exhibit E** at ¶¶ 1 through 5 and 70 through 74. Each of these publications report false and/or fabricated research data.

E. The defendants used the false and/or fabricated research results, as well as the fraudulent publications, to secure grant funding.

214. Defendants' fraud went beyond using federal grant money to publish scientific research papers based on false and fabricated research. Duke University also used the false and fabricated research results to seek payment through the NIH and EPA grant systems.

215. As discussed above, the publication of articles and papers is central to the NIH and EPA grant systems. A single NIH or EPA grant (and particularly a multiyear grant) can pay

for research that results in multiple publications over several years.

216. The NIH and the EPA fund medical research to advance the public good. To help achieve this goal, the dissemination of NIH and EPA funded research results is required, and all publications that include funded research must be made available to the public. In turn, these publications identify the grants that financially supported the reported research. In addition, research results and resulting publications must be identified in grant progress reports. The NIH and the EPA rely on this information in deciding whether to fund multiyear grants.

217. Grantee institutions are required to identify relevant publications in grant applications and progress reports for several reasons. First, the publications may support the need for proposed research. Second, the publications may establish the expertise and capabilities of the researchers identified in the application. And third, the publications may provide the basis for continued or additional grant funding.

218. The interaction among grant applications, grant progress reports, and publications establish that Duke University made the same false reports of research results to the NIH and the EPA as were made in the publications funded by NIH and EPA grants. The sequence and required content of grant progress reports required that Duke University report its claimed research results each year and identify to the NIH and the EPA the publications that were funded by the grants. The false research results reported in Potts-Kant's and Foster's publications, therefore, in many cases, were also reported to the NIH and the EPA in Duke University's grant progress reports.

219. Due to the sequence of grant applications, grant progress reports, and publications, Duke University made the same reports of false and/or fabricated research results to the NIH, in grant applications and progress reports, described in paragraphs **(162, 166, 171, 177, 183, 188, 194, 200, 206)** above and as described in paragraphs **(1, 6, 11, 17, 23, 28, 31, 36, 41, 47, 52, 60, 65, 72, 77, 82, 87, 92, 97, 102, 107, 112, 118, 123, 128, 133, 138)** of **Exhibit E** as

were made in the publications funded by those NIH grants, that are listed in **Exhibits C** and **C-1**.

220. For example, in 2013, Potts-Kant and Foster published false reports of research results in PMID 22502799, *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice* (described above). This publication reports that the research was funded by NIH Grant P01-AI081672.[12] The NIH requires Duke University to report research results funded by Grant P01-AI081672 in its grant progress reports. Duke University, therefore, reported the same false research results to the NIH as were reported in PMID 22502799, results that provided a basis for additional funding.

221. Another example, in 2009, Potts-Kant and Foster published false reports of research results in PMID: 19762564, *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice*. This publication reports that the research was funded by EPA Grant RD83329301. The EPA requires Duke University to report research results funded by RD83329301 in its grant progress reports. Duke University, therefore, reported the same false research results to the EPA as were reported in PMID 19762564.

222. Duke University applied for and received at least 49 grants, totalling over $82,776,000 that were directly premised on and/or arose from the research misconduct and fraud of Potts-Kant and/or the Foster Lab, including false reports of research results in grant progress reports, as described below. These grants are identified in the attached as **Exhibit C.**

223. In addition to those grants made to Duke University listed in **Exhibit C**, the NIH made 15 multi-year grants to grantee institutions other than Duke University, totalling over $120,910,000, which were premised on and/or arose from the research misconduct and fraud of Potts-Kant and/or the Foster Lab. These grants are identified in the attached **Exhibit C-1**. In many instances, the grantee institutions assigned experimental work to be performed at Duke

[12] NIH Grant P01-AI081672 is the "SP-A Grant," discussed in more detail below.

University funded by these grants. In those instances, the grant applications and grant progress reports submitted by the grantee institutions necessarily included the same reports of false and/or fabricated research results that are stated in the publications in **Exhibit B** as described above and in **Exhibit E.**

F. Duke University made false certifications.

224. Certifications—express and/or implied—in the applications and progress reports for the grants identified in **Exhibit C** were false when made. Duke University was not complying and did not comply with the terms and conditions of the grant awards. For example, Duke University had knowledge of false claims, statements, and records included and/or referenced in the grant applications and progress reports. In addition, Duke University failed to comply with its affirmative duty to protect grant funds from misuse, failed to ensure the integrity of work supported by grant funds, and failed to comply with its notifications duties and policies.

225. Duke University failed to foster a research environment that discourages research misconduct, and failed to deal forthrightly with possible research misconduct as required by the Regulations (42 C.F.R. §§ 93.300(c) and 93.412(a)).

226. Certifications—express and/or implied—in Duke University's Institutional Assurance and Annual Report were false when made. For example, Duke University was not complying and did not comply with its assurances under the Regulations. Upon information and belief, Duke University also failed to report allegations of research misconduct concerning Potts-Kant and the Foster Lab (discussed below) on its Institutional Assurance and Annual Reports, rendering these false when made.

G. Beginning in March 2013, the Pulmonary Division reviewed the Foster Lab's data and found it to be false and/or fabricated.

227. In addition to committing widespread research misconduct and fraud, Potts-Kant embezzled funds from Duke University to make personal purchases over a four-year period from

2008 to 2012. In furtherance of this scheme, she produced false invoices for scientific equipment and supplies for reimbursement. Upon information and belief, Potts-Kant embezzled more than $14,000.

228. Sometime between November 2012 and March 2013, the Pulmonary Division discovered Potts-Kant's embezzlement.

229. Duke University and/or DUHS placed Potts-Kant on leave in early March 2013. The Durham Police Department charged her with felony embezzlement on March 31, 2013.

230. After Duke University and/or DUHS placed Potts-Kant on leave, the Pulmonary Division initiated a review of the Foster Lab data that had been reported in grant applications, grant progress reports, and publications. This review included analyzing the raw data, trying to recalculate the Foster Lab's results using the raw data, re-running the experiments in an attempt to repeat the reported results, and comparing the results of the re-run experiments with the published results.

231. The review of Foster Lab data involved senior administrators within Duke University and/or DUHS, including: Donna Cookmeyer, Ph.D., the Research Integrity Officer; Sally A. Kornbluth, Ph.D., the Vice Dean for Basic Science; Mary E. Klotman, M.D., the Chair of the Department of Medicine; and Nancy Andrews, M.D., Ph.D., Dean of the School of Medicine.

232. Foster, Dr. Que, Dr. Ledford, Dr. Ingram, Dr. Brass, Ms. Theriot, Mr. Francisco, Thomas, and others participated in this review effort.

233. Thomas has discussed this review with Dr. Ledford, Dr. Que and other Pulmonary Division personnel. These individuals have explained to Thomas that upon review of Potts-Kant's research, all such research is either non-existent, falsified, manipulated, unreliable, and/or fraudulent in some manner. Based upon their statements to him, Thomas understands that all work completed by Potts-Kant is false, fabricated, and/or fraudulent in some way. A more

detailed description of the fraudulent data follows below.

(i) No raw data exists to support many of the Foster Lab's reported results.

234. For example, researchers found that the raw data for many of the Foster Lab experiments did not exist.

235. Ms. Theriot noted that only a few raw data files existed for the Foster Lab's *flexi*Vent experiments. Dr. Ledford found that there was no raw data at all for the Foster Lab *flexi*Vent experiments from before 2009. She found no raw data files for Dr. Hollingsworth's study of ozone and diesel exhaust exposure.

236. Mr. Francisco also noted that raw data files did not exist for two of the six multiplex experiments that he reviewed, and that original data could not be located for the publication designated PMID 22773729.

237. In addition to this missing raw data, Dr. Que found that some of Potts-Kant's records did not include "plate keys" for the experiments she had run. Plate keys are records of multiplex experiments that allow other researchers to confirm and compare reported values. Mr. Francisco also noticed that plate keys were missing.

238. The reviewers could not find raw data to support the results reported in PMID 21930959, PMID 22073274, PMID 22773729, PMID 21684833, PMID 21037098, PMID 17993584, and PMID 17878331. The lack of raw data establishes that the results reported in those publications were fabricated and false.

239. These publications state that the reported research was funded by Grants AI 081672, AI 064789, AI 58161, ES 016126, ES 020426, ES 016166, ES 016347, ES02046, ES016659, ES 11961, ES12717, HL 05009, HL 086887, HL 081825, HL 067021, HL 075307, HL 67281, HL 91335, HL 77291, P50-HL084917, ATS 07-012.

(ii) In some cases, the Foster Lab did not run the reported experiments.

240. In some cases, the Pulmonary Division reviewers concluded that the Foster Lab had never even run the experiments it reported in the first place—Potts-Kant had simply made up the results.

241. Dr. Que reached this conclusion. So, too, did Dr. Ledford, who observed that the data reported for Dr. Hollingsworth's epigenetic work involving maternal diesel exposure was entirely made up. Dr. Ledford also noted that Duke University had withdrawn a pending grant application because the underlying data was false.

242. Mr. Francisco identified fabricated multiplex and *flexi*Vent data in connection with the publication PMID 22773729.

243. Ms. Theriot observed that two parts of Figure 2 (the cytokines IL-6 and KC results) in PMID 20543006 were simply "made up."

244. These facts establish that the research results reported in the publications designated PMID 22773729 and PMID 20543006 were fabricated and/or false.

245. Those publications state that the reported research was funded by NIH Grants HL82504, HL81763, HL36982, ES16347, AI81672, HL05009, HL086887, and ES016126.

(iii) The Foster Lab conducted experiments differently than was reported.

246. In other cases, the review showed that Potts-Kant and the Foster Lab failed to conduct experiments as reported in the grant applications, grant progress reports, and publications.

247. For example, when Dr. Ledford tried to re-run certain experiments, she observed that the mice died after being administered an antigen but before the experiments could be performed. This shows that administering antigens at the dosage called for and reported by Potts-Kant killed the mice before they could be tested and that any reported results were, therefore,

fabricated.

248. As a result of Potts-Kant's actions, hundreds, if not thousands, of laboratory mice were killed for no purpose.

249. Dr. Ledford also found that Potts-Kant had administered the wrong ozone dose in some of her experiments, and that the data from experiments involving LMP-420, an inhibitor of tumor necrosis factor α ("TNF-α"), for some of her experiments was fraudulent.

250. Dr. Ingram noted that Potts-Kant had not exposed mice to the proper antigens for some studies.

251. These facts establish that the research results reported in PMID 22073274, PMID 21930959, PMID 21684833, PMID 21037098, PMID 17878331, and PMID 19494306 were fabricated and/or false.

252. These publications state that the reported research was funded by NIH Grants ES016126, ES020426, ES016347, HL081825, AI0081672, ES016659, AI064789, AI58161, ES11961, ES12717, HL91335, F-32-HL0911642, PHL073907, and HL084917.

(iv) Potts-Kant manipulated the results of those experiments that she did run.

253. The reviewers also determined that Potts-Kant had altered or manipulated the results of the experiments that she did run.

254. Dr. Que observed that Potts-Kant's multiplex data was likely false.

255. Dr. Ledford identified data that Potts-Kant had falsified. Among other things, Potts-Kant had lowered the reported resistance values in the "LPS/NOS" project.

256. Mr. Francisco identified data that Potts-Kant had manipulated in the interleukin 8 ("IL-8") and TNF-α cytokines results that were significant to the conclusions in PMID 22773729.

257. Ms. Theriot found that the Foster Lab's airway hyperresponsiveness ("AHR") results in the diesel particle experiments were "all bad."

258. Ms. Theriot also found that all of the calculations in publication PMID 20348208 were incorrect.

259. These facts are additional evidence that the research results reported in PMID 19762564, PMID 22052876, PMID 22773729, PMID 20543006, and PMID 20348208 were fabricated and/or false.

260. These publications state that the reported research was funded by Grants AI068822, AI081672, ES011961, ES016347, ES016126, HL05009, HL086887, HL82504, HL81763, HL36982, HL084917, HL068072, HL058795, HL084123, HL081285, HL079915, ATS 07-12, and EPA RD 83329301.

(v) Reviewers cannot repeat the Foster Lab's results.

261. Duke and/or DUHS re-ran experiments in an attempt to repeat the results reported in grant applications, grant progress reports and publications. Dr. Ledford, Ms. Theriot, Thomas, and Mr. Francisco participated in this effort.

262. Mr. Francisco re-ran certain multiplex experiments and was unable to repeat the published results. Thomas assisted in re-running these experiments.

263. Ms. Theriot re-ran certain experiments related to Dr. Hollingsworth's work as published in PMID 17878331. Not only was she unable to repeat the published results, she observed results that were exactly the opposite of the published results. Likewise, when Ms. Theriot re-ran the Foster Lab's LPS experiments, she observed results that were the opposite of those that the Foster Lab published.

264. Ms. Theriot was similarly unable to get the Hollingsworth Lab's HA experiments to repeat.

265. Dr. Ingram described efforts to re-run HA experiments, and stated that the observed results were the opposite of the published results.

266. Ms. Theriot also re-ran the *flexi*Vent experiments reported in PMID 20007931.

She found that the data were inconsistent and did not correspond to the published results.

267. Ms. Theriot re-ran experiments related to Dr. Hollingsworth's "mindin" gene project and observed results that contradicted the published results.

268. Ms. Theriot re-ran experiments using Nlrp3 mice and observed results that did not correspond to those that were published.

269. These facts establish that the research results reported in PMID 22773729, PMID 17878331, PMID 20007931, PMID 20348208, PMID 23560245, PMID 21684833, PMID 18818374, and PMID 23010656 were fabricated and/or false.

270. These publications state that the reported research was funded by NIH Grants AI081672, AI58161, AI068822, AI089756, ES016126, ES11961, ES12717, ES16347, ES16659, ES020426, ES12496, ES020350, HL05009, HL086887, HL91335, HL084917, HL068072, HL058795, HL084123, HL079915, HL081285, HL77291, HL91335, P50-HL084917.

(vi) Dr. Ledford identifies specific "manipulated" data.

271. The documents attached as **Exhibit D** (Relator_000114 – 000119) identify several specific examples of false data created by Potts-Kant and the Foster Lab.[13]

272. Dr. Ledford created these documents attached as **Exhibit D** in April 2013. They are copies of notes and spreadsheets that she made while reviewing Potts-Kant's data. The experiments referenced in **Exhibit D** were conducted to understand the interaction between of TNF-α, a cytokine involved in lung inflammation, and mast cells, myeloid-derived cells involved in the immune system. The *flexi*Vent data was important in this context because, if accurate, it would have presented compelling evidence of a novel paradigm in the lung's response to bacterial infection whereby TNF-α binds the surface of mast cells via the TNF receptor.

[13] Thomas has seen additional documents similar to those in **Exhibit D** that demonstrate the discrepancies between actual raw data and the fraudulent data produced by Potts-Kant and used by Duke University and/or DUHS. Because he does not presently have access to these documents, **Exhibit D** is provided as a representative sample.

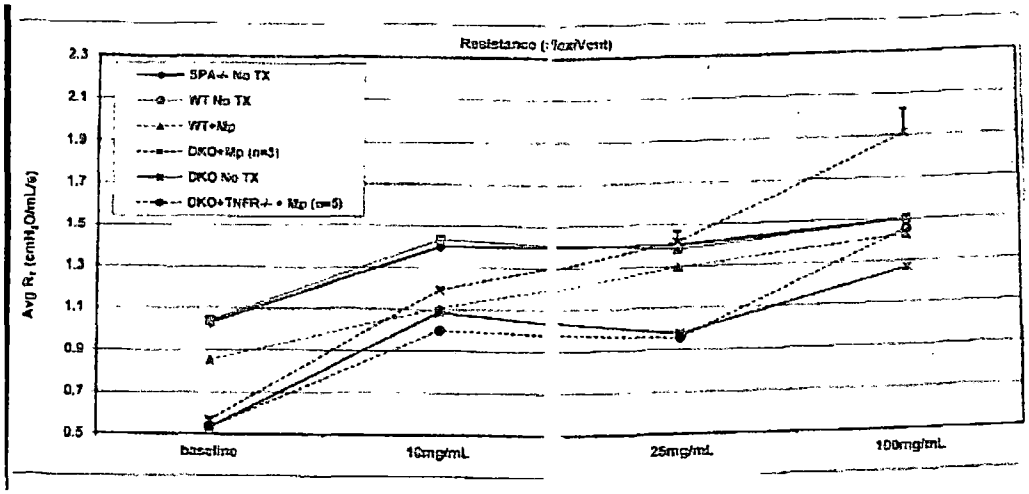
273. At pages 1-3 (Relator_000114 – 116), **Exhibit D** compares raw data with the Foster Lab's manipulated data. Exhibit D states that Potts-Kant conducted the experiments on November 3, 2009; January 29, 2010; and March 2, 2011. The column "Actual Numbers" on each page contains raw data from the *flexi*Vent machine. Dr. Ledford compared these values with the values in the "R" column. "R" stands for Resistance, which is an important standard of measurement in the context of this experiment. As Dr. Ledford notes on the margins of her page, the R values have been "Manipulated."

274. This manipulated data was reported in Figure 6A of PMID 22502799, *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice*. (**Ex. B**, at Relator_000202 (discussed above).)

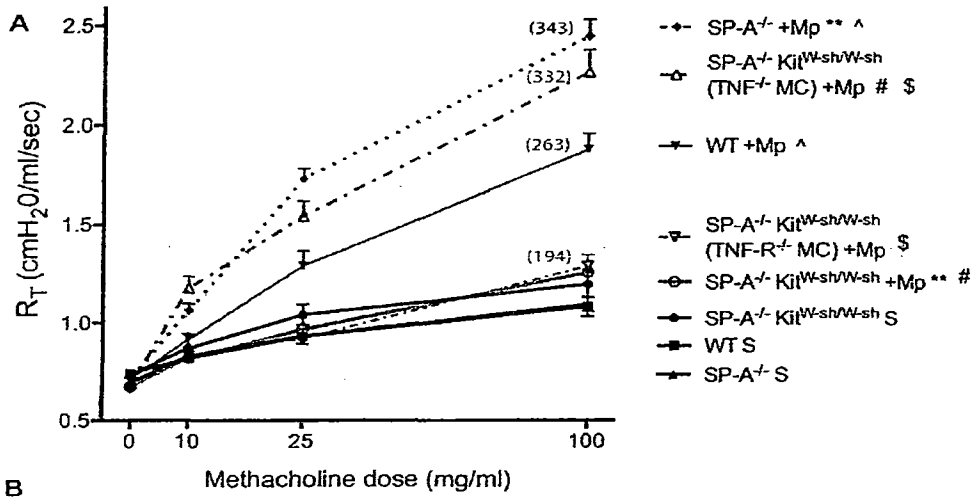
275. At page 4 (Relator_000117), **Exhibit D** contains a graph showing airway resistance at varying levels of methacholine administration, which is reproduced as Graph A below. Graph A is the raw data from the experiment performed on March 2, 2011.

276. Upon information and belief, Figure 6A of PMID 22502799 contains the manipulated data produced by Potts-Kant. It is reproduced as Graph B below.

Graph A: Actual Data



Graph B: Published Manipulated Data



277. Graph A, based on the actual data, shows a high degree of variability in the results, and the absence of any statistically significant difference between the various experimental groups of mice. Graph B, based on the Foster Lab's manipulated data (and as reported as Figure 6A in PMID 22502799), shows a low degree of variability between mice, as evidenced by very small error bars and a high degree of significance between different genotypes and treatments of mice. Furthermore, this data presents clear evidence that airway hyperresponsiveness does not implicate mast cell endogenous TNF-α, but rather through exogenous TNF-α via the TNF receptor.

278. Dr. Ledford and Ms. Theriot re-ran the *Mycoplasma* treatment experiments reported in PMID 22502799, which includes Graph B, and they could not repeat the published results. Theriot observed results that were the opposite of what was published. This is additional evidence that the research results reported in grant progress reports for Grant AI081672 and in PMID 22502799 were fabricated and/or false.

H. After March 2013, Duke failed to disclose what it knew about the research fraud from other researchers and the Government.

279. During its review of the Foster Lab's reported research results, the priority for

Foster, Duke University, and/or DUHS was to conceal the Foster Lab's research misconduct, rather than make complete and timely disclosures. These Defendants chose not to fully report their knowledge of research misconduct and fraud, and instead withheld and concealed information from the government and researchers outside of the Pulmonary Division.

280. Senior managers at Duke University and/or DUHS had actual and specific knowledge of research misconduct involving Potts-Kant and the Foster Lab from at least March 2013.

281. Duke and/or DUHS assigned Foster a leadership role in this review—even though the allegations of research misconduct questioned work done under his direct supervision, on experiments he had designed, and challenged the accuracy of publications he had co-authored.

282. In April 2013, the Pulmonary Division held a laboratory meeting. Dr. Kraft told the assembled researchers that widespread research misconduct and fraud was suspected on Potts-Kant's experiments, but that they should communicate about the research misconduct and fraud only in person or over the phone, in order to avoid creating a "paper trail."

283. On or about May 7, 2013, Duke's Office of Research Administration told the Pulmonary Division that if the "trends" reported in the publications held up that no retractions would have to be issued and that the Office of Research Administration did not want the issue to "snowball".

284. Foster, Duke University, and/or DUHS repeated experiments and recalculated raw machine data in an attempt to replicate the results that had been reported to the NIH, EPA and in publications. The Defendants took these steps when they had actual and specific knowledge that the results reported by Potts-Kant and the Foster Lab were false and/or fraudulent, in the hopes of avoiding such disclosures to the NIH, EPA, and publications.

(i) Duke University and/or DUHS misleadingly described the Potts-Kant situation as an "employment issue".

285. In April or May 2013, a "script" was circulated with instructions on how to communicate the research fraud situation outside of Duke, *i.e.*, to co-authors of scientific papers. The script misleadingly stated that Potts-Kant was involved an employment situation and that Duke was currently reviewing the situation. The script did not provide accurate information about the Foster Lab's research misconduct fraud.

(ii) Foster, Duke University and/or DUHS delayed retracting publications.

286. Journal articles affected by Potts-Kant's research misconduct and fraud must be retracted. Duke University researchers acknowledged the need for retractions during their review of Potts-Kant's work.

287. These actions, as described above, violate Duke University's obligations under the Regulations (42 C.F.R. §§ 93.300(c), 93.318, and 93.412(a)) and establish Duke University's failure to foster an environment that promotes the responsible conduct of research and respond promptly and forthrightly with allegations of research misconduct.

(iii) In Fall 2013, Duke University resubmitted its SP-A grant, using data that it knew to be false and/or fabricated.

288. In 2008, the NIH awarded Duke University a five-year grant to investigate the role of surfactant protein A ("SP-A") in the lung, Grant ID P01AI081672 (the "SP-A Grant").

289. The NIH funded the SP-A Grant in fiscal years 2009 through 2014.

290. Potts-Kant and the Foster Lab performed experiments between 2009 and 2013 using the SP-A Grant funding.

291. Potts-Kant and Foster reported the results of experiments funded by the SP-A Grant in publications listed in **Exhibit B** and identified as: PMID 20543006; PMID 21037098; PMID 21285515; PMID 21252304; PMID 21960548; PMID 22241062; PMID 24273688; PMID 22502799; PMID 22773729; PMID 22815821; PMID 23029172; and PMID 23010656.

292. Duke University submitted a grant progress report on the SP-A Grant in June 2013 that included research reports based on experiments performed by Potts-Kant and the Foster Lab. This was done intentionally, months after Potts-Kant was placed on leave, with actual knowledge that none of her work was reliable.

293. Duke University and/or DUHS decided to seek renewal of the SP-A project in order to obtain an additional five years of grant funding.

294. Duke University submitted its competing renewal grant application for the SP-A project in the fall of 2013.

295. In its grant application for renewed funding of the SP-A project, Duke University included research results based on the "recalculation" of data produced by Potts-Kant.

296. The "recalculated" results that Duke reported in fall 2013 were inconsistent with the results that Ms. Theriot had obtained when she tried to repeat the Foster Lab's experiments earlier in 2013.

(iv) Duke's primary interest—in particular the Pulmonary Division—has been self-preservation.

297. Possessing actual knowledge of Potts-Kant's research fraud and misconduct in March 2013, as described above, Foster, Duke University, and/or DUHS sought to protect their institutional and personal interests. This mindset was exemplified by a statement Dr. Kraft made over a year later.

298. On May 17, 2014, after a lab-sponsored dinner, Dr. Kraft discussed the Potts-Kant research misconduct issue with Thomas and others within the Pulmonary Division. In reference to the existence of a "whistleblower," Dr. Kraft stated that while the Pulmonary Division had experienced setbacks, "nobody is going to take us down."

299. Since March 2013, Dr. Kraft, Dr. Hollingsworth, Dr. Ledford, and Mr. Francisco have left the Pulmonary Division, resigning their employment with Duke University and/or

DUHS.

I. The Foster Lab research fraud and misconduct did not occur in a vacuum.

300. At times that overlapped with and preceded the Foster Lab events described above, Duke University and/or DUHS were involved in other significant incidents of research misconduct. This experience should have made Foster, other Principal Investigators, and other researchers sensitive to the prevention, detection, and reporting of any possible research misconduct. Duke University's and DUHS' failure to prevent or detect the Foster Lab research fraud demonstrates a systemic failure by Duke University to foster an environment conducive to responsible research. In fact, Duke University and/or DUHS maintained a "toxic environment" in which it pushed its researchers for more grants and more publications while ignoring credible warnings of ongoing and serious research fraud.

301. Dr. Anil Potti was formerly a Duke University medical researcher, focusing on cancer genomics. Dr. Potti resigned from Duke University in November 2010.

302. Published reports have accused Dr. Potti of falsifying data published in journal articles, results that purported to show advances for personalized cancer treatment. This allegedly false data was first published in 2006.

303. The Potti scandal has received widespread attention, both within the scientific community and in the media.

304. For example, the events surrounding Dr. Potti's work at Duke University were the catalyst to the Institute of Medicine's formation of a committee, which then published a 300 page report titled *Evolution of Translational Omics: Lessons Learned and the Path Forward.*

305. By way of other examples, on September 10, 2011, The Economist published an article about the Potti scandal titled *Misconduct in science: An array of errors*; on February 12, 2012, 60 Minutes ran a story on the Potti scandal titled "Deception at Duke."

306. In The Economist article, Duke University's Vice-Chancellor in Charge of

Clinical Research, is quoted as saying, "[a]s we evaluated the issues, we had the chance to review our systems and we believe we have identified, and are implementing, an improved approach."

307. On January 26, 2015, Dr. Califf—who has taken a leave of absence from Duke University to serve as Deputy Commissioner for Medical Products and Tobacco at the U.S. Food and Drug Administration—was quoted in the Triangle Business Journal on the Potti scandal. Dr. Califf said that "[t]here were systems that were not adequate, as we stated. . . . That was a tough one, I think, for the whole institution."

308. Dr. Califf is also quoted in the Triangle Business Journal article as stating that Duke University had "learned the importance of high-quality evidence, and not just taking somebody's word for it."

309. The Pulmonary Division was also faced with a separate instance of research misconduct during the relevant time period.

310. On October 14, 2011, HHS issued a finding of research misconduct against Dr. Shamarendra Sanyal, a former postdoctoral scholar within the Pulmonary Division. Dr. Sanyal worked under the supervision of Dr. Eu.

311. The Office of Research Integrity found that Dr. Sanyal engaged in research misconduct by falsifying data in a grant applications submitted to the NIH as well as another federal agency.

312. The circumstances surrounding the research misconduct of Dr. Sanyal further evidence Duke University's failure to comply with its assurances under the Regulations (42 C.F.R. §§ 93.300(c) and 93.412(a)) to foster an environment that promotes the responsible conduct of research.

J. The Defendants' acts and omissions occurred knowingly.

313. At all relevant times, Potts-Kant and Foster were employees and/or agents of

Duke University and/or DUHS, and acting in the course and scope of their employment and/or agency.

314. At all relevant times, other Principal Investigators and researchers at Duke University (both within and outside of the Pulmonary Division) were employees and/or agents of Duke University and/or DUHS, and acting in the course and scope of their employment and/or agency.

315. Defendants each knew that research results and related publications were fundamental to the grant system, and reported in grant applications and progress reports to secure grant funding.

316. Potts-Kant knew that the reported research results in question were false and/or fabricated, having generated the results herself.

317. Foster, Duke University, and DUHS knew that the reported research results in question were false and/or fabricated, for the reasons explained below.

(i) Foster, Duke University, and DUHS ignored repeated warnings and about the Foster Lab's research misconduct.

318. When Potts-Kant presented a paper she had co-authored, Dr. Wayne Mitzner, Director of the Respiratory Biology/Lung Disease Program at Johns Hopkins University, questioned the validity of the Foster Lab's data. Due to the low statistical error of the data despite the low sample sizes, Dr. Mitzner believed the data to be manipulated or doctored. Upon information and belief, without checking the raw data, Foster vigorously defended Potts-Kant and his laboratory.

319. Dr. Jamie Cyphert, a researcher with the NIEHS, also questioned the Foster Lab's data. Dr. Cyphert was unable to reproduce their results. She then requested a copy of the experiment's "script" for the *flexi*Vent machine to try to replicate the experiment and confirm the results. The Foster Lab refused to provide the requested script to Dr. Cyphert.

320. In fact, Foster, Potts-Kant, and the Foster Lab refused to share *flexi*Vent scripts with anyone.

321. In 2010 or 2011, Dr. Eu advised Foster and Dr. Hollingsworth that he suspected Potts-Kant of falsifying results. Dr. Eu "blinded" Potts-Kant to an experiment and confirmed his suspicions, and then told Foster and Dr. Hollingsworth what he had found and they ignored his concerns.

322. On information and belief, Mr. Giamberardino raised concerns of possible research misconduct involving Potts-Kant and the Foster Lab during the period between 2010 and 2012. Mr. Giamberardino stated that Potts-Kant should have been "blinded" from aspects of experiments.

323. Accordingly, Principal Investigators within the Pulmonary Division were both warned and gave warnings about Potts-Kant's and the Foster Lab's fraudulent research results. In addition, Dr. Eu confirmed his suspicions and reported that information to other Principal Investigators within the Pulmonary Division.

324. Under the Regulations, these warnings constituted allegations of possible research misconduct that were required to be reported on Duke University's Institutional Assurance and Annual Report.

325. In addition, Duke University had actual knowledge of research misconduct by Potts-Kant in March 2013.

(ii) There were obvious red flags about Potts-Kant's methods.

326. The facts surrounding Potts-Kant's work indicate that Foster and others within the Pulmonary Division knew that Potts-Kant was engaging in research misconduct and fraud.

327. Potts-Kant's method of processing mice through the machines grossly deviated from acceptable scientific standards and research protocols.

328. For example, there were only two *flexi*Vent machines in the Pulmonary Division:

one in the Foster Lab, in one in the laboratory of Dr. Walker. Ms. Theriot operated the flexiVent machine in Dr. Walker's lab.

329. Potts-Kant and Ms. Theriot were equally experienced with the *flexi*Vent machine.

330. It took Potts-Kant about three minutes to process a mouse through the *flexi*Vent machine. The same work took her counterpart, Ms. Theriot, about 20 minutes per mouse. There is no reasonable basis to believe that Potts-Kant could have correctly processed mice so quickly.

331. Foster would become defensive and refuse to cooperate with anyone who was also collaborating with Dr. Walker's lab or Ms. Theriot.

332. The large number of publications Potts-Kant co-authored was unusual in light of her relative youth and inexperience. Further, the number of publications that Foster himself co-authored increased dramatically after Potts-Kant was hired in 2005.

333. The false and fabricated data reported by Potts-Kant was also "too good to be true," in that, in too many instances, they supported the stated hypotheses and desired outcome, and/or were statistically significant.

(iii) Foster recklessly disregarded the truth or falsity of Potts-Kant's research results.

334. Foster was responsible for supervising Potts-Kant's work and he failed to do so. His supervision of her was, at best, reckless. Foster was purportedly one of the world's leading experts in his field. Potts-Kant was a young, junior employee.

335. During the time that Potts-Kant worked in the Pulmonary Division, Foster either: (i) failed to review Potts-Kant's data for accuracy; (ii) failed to compare her reported data with the raw data produced and stored by the machines; (iii) failed to appropriately review Potts-Kant's data; or (iv) reviewed Potts-Kant's data and, therefore, would have understood that it was false and/or fabricated.

336. Likewise, other Principal Investigators and researchers either: (i) failed to review

Potts-Kant's data for accuracy; (ii) failed to compare her reported data with the raw data produced and stored by the machines; (iii) failed to appropriately review Potts-Kant's data; or (iv) reviewed Potts-Kant's data and, therefore, would have understood that it was false and/or fabricated.

337. As explained above, the failure to supervise Potts-Kant occurred during a time period when (among other things): (i) warnings about Potts-Kant's work had been made and received within the Pulmonary Division; (ii) the significant Potti research misconduct scandal was unfolding, which purportedly caused Duke University to review its systems, implement an improved approach, and have "learned the importance of high-quality evidence, and not just taking somebody's word for it;" and (iii) another researcher in the Pulmonary Division had been found to have engaged in research misconduct.

338. The failures described above establish Duke University's failure to foster an environment that promotes the responsible conduct of research, discourage research misconduct, and deal promptly with allegations or evidence of research misconduct as required in 42 C.F.R. §§ 93.300(c) and 93.412(a) and in violation of Duke University's assurances of compliance with the Regulations.

(iv) Summary of knowledge/scienter that the reported research results were false and/or fabricated for Foster, Duke, and DUHS.

339. Foster knew that the reported research results were false and/or fabricated for reasons that include, but are not limited, to the following:

a. Foster was responsible for designing experiments Potts-Kant conducted, supervising Potts-Kant's actual performance of the experiments, and interpreting the results.

b. The sheer scope, duration, and differing types of Potts-Kant's activities in creating the false data over a period of years indicates that her direct

supervisor was involved. These activities included Potts-Kant's failure to perform certain experiments, failure to preserve the raw data from many of the those experiments that she did perform, failure to follow experimental protocols, fabrication of certain research results, and alteration of other research results.

c. The false research results reported in grant applications and grant progress reports, and reported in the publications funded by the grants, were too complex and required too much expertise for Potts-Kant to have developed on her own, given her limited experience and training.

d. Foster failed to supervise Potts-Kant.

e. Raw data did not exist to support some of the reported research results.

f. Foster received warnings about Potts-Kant's work. His failure to follow-up indicates either that: (i) he already understood that the work was fraudulent; or (ii) he acted with reckless disregard and/or was deliberately ignorant to the truth or falsity of Potts Kant's work.

g. The large number of publications that Potts-Kant co-authored.

h. The number of publications that Foster himself co-authored increased dramatically after Potts-Kant was hired.

i. The data reported by Potts-Kant was "too good to be true."

j. Foster refused to provide other researchers with the raw data or *flexi*Vent scripts that would allow other researchers to attempt to replicate or verify the Foster Lab's results when those researchers requested such information.

340. Other Duke University and/or DUHS Principal Investigators, executives and managers had actual and specific knowledge that Potts-Kant's reported research results in

question were false and/or fabricated by no later than March 2013 after Potts-Kant left Duke University.

341. Even before that, other Duke University and/or DUHS Principal Investigators, executives, and managers knew that Potts-Kant and Foster Lab research results were false and/or fabricated for reasons that include, but are not limited, to the following:

a. Principal Investigators were responsible for designing experiments that Potts-Kant conducted, supervising Potts-Kant's actual performance of the experiments, and interpreting the results.

b. Principal Investigators failed to supervise Potts-Kant.

c. Raw data did not exist to support some of the reported research results.

d. Employees in the Pulmonary Division knew that results reported by Potts-Kant and the Foster Lab were not reliable.

e. Warnings about Potts-Kant's work had been given and received.

f. Dr. Eu had confirmed his suspicions that Potts-Kant was falsifying and/or fabricating data and reported that confirmation to other Principal Investigators within the Pulmonary Division.

g. The data reported by Potts-Kant was "too good to be true."

h. After becoming concerned that Potts-Kant may have falsified and/or fabricated data in March 2013, the review team created by Duke University put affected researchers—such as Foster—in leadership roles. These appointments violated Duke University' obligations under 42 C.F.R. § 93.300(b).

i. Duke University continued to use the false and/or fabricated data in grant applications and grant activities after March 2013. For example, Duke University had actual knowledge that the research results reported in the

grant application for the SP-A project in the fall of 2013 were fabricated and/or false when it submitted the application.

j. Duke University and/or DUHS refused to disclose to other researchers or the government known problems with the research results reported by Potts-Kant and the Foster Lab.

K. The Defendants' acts and omissions were material.

342. The previously identified false statements and records made and used by the Defendants were material, because they had a natural tendency to influence, or be capable of influencing, the NIH's and EPA's payment of grant funds. For example, such false statements and records were material because:

a. They were made in the grant applications, progress reports, and the Institutional Assurance and Annual Report.

b. They were required to be included in the grant applications, progress reports, and the Institutional Assurance and Annual Report.

c. They related to the provision of preliminary data, other research results, and experiments that had allegedly been performed as the basis for supporting the proposed research, and therefore were likely to affect the NIH's and the EPA's funding decisions. Defendants knew that the report of false and/or fabricated preliminary data and other data would cause the applications to receive artificially high priority rankings, and be more likely to cause the NIH and the EPA to award the grant.

d. They falsely reported results of experiments that would, if accurate, prove and/or support research hypotheses.

e. The physiological phenomenon that were the subject of the Foster Lab's false and fabricated research results were central to hypotheses asserted in

grant applications and discussed in the grant progress reports. These reported physiological results were convincing—but false and fraudulent—evidence that the asserted hypotheses had been proven by properly designed and conducted experiments with observed, documented, and reproducible results.

f. They falsely reported results of experiments that would, if accurate, support the need for additional research using additional grant funding.

343. Defendant Duke University has knowingly made false statements and representations to the Government by virtue of (1) providing false reports and summaries of research results in grant applications and grant progress reports; (2) by citing fraudulent scientific papers in support of its grant funding and by representing that the results reported in the publications had been funded by NIH grants; (3) by falsely certifying compliance with its assurances and 42 C.F.R. Parts 50 and 93 or 40 C.F.R. Part 40, the NIH Grants Policy Statement, or the EPA Research and Related Terms and Conditions, and all Federal laws and regulations; and (4) by fraudulently and wrongfully retaining grant funds after discovering the fraud and lack of compliance with the grant terms and conditions.

L. Failure to Disclose and Concealment.

344. Duke University, DUHS, and Foster acted to conceal and withhold their actual knowledge of widespread research fraud, grant fraud, and their obligations to repay grant funds to NIH and EPA. In addition, Duke University, DUHS, and Foster knowingly and improperly sought to avoid or decrease their obligations to pay money to the Government.

345. These actions establish Duke University's failure to foster an environment that promotes the responsible conduct of research, discourage research misconduct, and deal promptly with allegations or evidence of research misconduct as required under 42 C.F.R. §§ 93.300(c) and 93.412(a) and Duke University's assurances of compliance with the Regulations.

VI. Causes of Action

Count One: False or Fraudulent Claims in Grant Applications and Grant Progress Reports (All Defendants), 31 U.S.C. § 3729(a)(1)(A)

346. Thomas incorporates paragraphs 1-345 as if fully set forth in Count One.

347. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

348. From 2006-2013, Potts-Kant knowingly caused to be presented, false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to grants listed in **Exhibit C**.

349. From 2006-2013, Potts-Kant knowingly caused to be presented, false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to grants listed in **Exhibit C-1**.

350. From 2006-2014, Foster knowingly caused to be presented, false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to grants listed in **Exhibit C**.

351. From 2006-2014, Foster knowingly caused to be presented, false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to grants listed in **Exhibit C-1**.

352. As a result of Defendants' research misconduct and fraud, as well as their other actions and omissions, Duke University knowingly presented false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to the grants listed in **Exhibit C**.

353. As a result of Defendants' research misconduct and fraud, as well as their other

actions and omissions, Duke University knowingly caused to be presented false or fraudulent claims for grant payments in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to the grants listed in **Exhibit C-1**.

354. These claims were false or fraudulent because they were: (i) based on false, fabricated, and/or fraudulent statements of research results; (ii) based on publications that included false, fabricated, and/or fraudulent statements of research results; and/or (iii) included false certifications.

355. The false or fraudulent statements of research results, publications that included false, fabricated, and/or fraudulent statements of research results, and false certifications were material to the grant-making agencies' decision to fund the grants.

356. As a result of the false or fraudulent claims, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid to Duke University on the grants identified in **Exhibit C**. These damages include, at a minimum, the total costs of the grants identified in **Exhibit C**, in an amount exceeding $82,000,000.

357. As a result of the false or fraudulent claims, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid on the grants identified in **Exhibit C-1**. These damages include, at a minimum, the total costs of the grants identified in **Exhibit C-1**, in an amount exceeding $120,000,000.

358. The false or fraudulent claims proximately caused additional damages, deprived other researchers of access to scarce NIH funds and EPA funds, and misled other scientists to obtain federal funds for studies that otherwise would not have been pursued.

359. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

Count Two: False Records or Statements in Grant Applications, Grant Progress Reports, and Institutional Assurance and Annual Reports (All Defendants); 31 U.S.C. § 3729(a)(1)(B)

360. Thomas incorporates paragraphs 1-359 as if fully set forth in Count Two.

361. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

362. Defendants knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claims for grant payments, that were made in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to the grants listed in **Exhibit C**.

363. Defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims for grant payments, that were made in applications and progress reports submitted to the NIH, the EPA, and other United States grant-making agencies, with respect to the grants listed in **Exhibit C-1**.

364. The false records or statements include: (i) false statements of research results made in grant applications or grant progress reports; (ii) false publications reported in the grant applications and progress reports; (iii) false certifications in the grant applications and progress reports; (iv) the grant applications and progress reports, as false records; and (v) false certifications in the Institutional Assurance and Annual Reports.

365. The false records or statements were material to the grant-making agencies' decision to fund the grants.

366. As a result of the false records or statements, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid to Duke University on the grants identified in **Exhibit C**. These damages include, at a minimum, the total costs of the grants identified in **Exhibit C**, in an amount exceeding $82,000,000.

367. As a result of the false records or statements, the United States sustained direct

and substantial monetary damages, in the amount of the federal funds paid on the grants identified in **Exhibit C-1**. These damages include, at a minimum, the total costs of the grants identified in **Exhibit C-1**, in an amount exceeding $120,000,000.

368. The false records or statements proximately caused additional damages, deprived other researchers of access to scarce NIH funds and EPA funds, and misled other scientists to obtain federal funds for studies that otherwise would not have been pursued.

369. By reason of the false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

Count Three: Reverse False Claims (All Defendants); 31 U.S.C. § 3729(a)(1)(G)

370. Thomas incorporates by reference paragraphs 1 through 369 above as if fully set forth in Count Three.

371. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

372. Duke University has an obligation to repay grant funds: (i) when Duke University failed to comply with the terms and conditions of the grant award; (ii) that were spent in support of activities that involved research misconduct; or (iii) that were used to disseminate deliberately false or misleading information.

373. For the grants identified in **Exhibit C**, Duke University failed to comply with the terms and conditions of the grant awards.

374. Defendants engaged in wide-spread research misconduct, misconduct that was supported by grants identified in **Exhibit C**.

375. Using grants identified in **Exhibit C**, Defendants disseminated deliberately false or misleading information in publications, grant applications, and grant progress reports.

376. Defendants have knowingly made or used false records and statements material to

Duke University's obligation to repay grant funds.

377. Defendants have also knowingly concealed or knowingly and improperly attempted to avoid or decrease Duke University's obligation to repay grant funds.

378. Duke University has wrongfully withheld repayment of grant funds.

379. By reason of Defendants' actions and omissions, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

Count Four: False or Fraudulent Claims in Grant Applications and Grant Progress Reports with Respect to Duke's Assurance Status (Duke University and DUHS); 31 U.S.C. § 3729(a)(1)(A)

380. Thomas incorporates paragraphs 1-379 as if fully set forth in Count Four.

381. The United States seeks relief against Duke University and DUHS under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

382. Duke University falsely certified its compliance with its assurances to the Government with respect to the Regulations for some or all of the calendar years from 2007 to 2015. Duke University made the false certifications knowingly.

383. During those years, Duke University knowingly failed to report to ORI allegations of possible research misconduct, and failed to conduct warranted and timely inquiries and investigations into the allegations.

384. During those years, Duke University knowingly failed to foster an appropriate research environment.

385. During those years, Duke University knowingly failed to otherwise comply with the Regulations.

386. During those years, Duke University knowingly failed to forthrightly deal with possible research misconduct.

387. As a result, Duke University knowingly made false or fraudulent claims for grant

payments in all grant applications and all grant progress reports submitted to the NIH after the date on which Duke University failed to comply with its assurances to the Government with respect to the Regulations.

388. All such claims during those years were false or fraudulent because they included false certifications that Duke University: (i) complies with PHS regulations concerning reporting possible research misconduct; (ii) fosters an appropriate research environment; (iii) deals forthrightly with possible research misconduct; and (iv) otherwise complies with the Regulations.

389. The false or fraudulent certifications were material to the NIH's decision to fund each grant paid to Duke University during some or all of the calendar years from 2007 to 2015.

390. As a result of the false or fraudulent claims, the United States sustained direct and substantial monetary damages, in the amount of all federal funds paid to Duke University for NIH grants during some or all of the calendar years from 2007 to 2015.

391. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

Count Five: False Records or Statements with Respect to Duke's Assurance Status (Duke University and DUHS); 31 U.S.C. § 3729(a)(1)(B)

392. Thomas incorporates paragraphs 1-391 as if fully set forth in Count Five.

393. The United States seeks relief against Duke University and DUHS under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

394. Duke University and DUHS knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims for grant payments, that were made in applications and progress reports submitted to the NIH.

395. The false records or statements include the false certifications in Duke

University's Institutional Assurance and Annual Reports, submitted to ORI with respect to some or all of the calendar years from 2007 to 2015.

396. The false records or statements also include the false certifications in all Duke University's grant applications and grant progress reports for all NIH grants submitted after the date on which Duke University knowingly failed to comply with its assurances to the Government with respect to the Regulations.

397. Duke University's false certifications in the Institutional Assurance and Annual Reports were made knowingly.

398. Duke University's false certifications in grant applications and grant progress reports were made knowingly.

399. The false certifications in Duke University's Institutional Assurance and Annual Reports were material. Based on the false certifications for all or some of the calendar years 2007 through 2015, Duke University maintained its assurance status, which was required for Duke University to receive NIH grant funding.

400. The false certifications in Duke University's NIH grant applications and grant progress reports were material to the NIH's decision to fund each grant paid to Duke University during some or all of the calendar years from 2007 to 2015.

401. As a result of the false records or statements, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid to Duke University for all NIH grants during some or all the calendar years 2007 through 2015.

402. By reason of the false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

VII. Prayer for Relief

WHEREFORE, Relator, on behalf of the United States, prays that judgment be entered in

their favor and against Defendants as follows:

1. That Defendants pay the United States triple the amount of its damages to be determined, plus civil penalties of up to $11,000 for each false claim, statement, or record;

2. That the Relator be awarded all reasonable attorneys' fees and costs, pursuant to 31 U.S.C. §§ 3730(d)(1) and/or (d)(2);

3. That in the event the United States proceeds with this action, the Relator, for bringing this action, be awarded an amount of at least 15 percent but not more than 25 percent of the proceeds of any award or the settlement of the claims;

4. That in the event the United States does not proceed with this action, the Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall be not less than 25 percent nor more than 30 percent of the proceeds of any award or settlement;

5. That the Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

6. That the Relator be awarded pre-judgment and post-judgment interest; and

7. The Court award such other and further relief as is just, equitable and proper;

Relator requests a jury on all issues so triable.

Filed Under Seal Pursuant