

**UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA  
GREENSBORO**

THE UNITED STATES OF AMERICA,	)	
ex rel. JOSEPH M. THOMAS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
DUKE UNIVERSITY,	)	Case No.: 1:17-cv-00276-CCE-JLW
DUKE UNIVERSITY HEALTH	)	
SYSTEM, INC.,	)	
WILLIAM M. FOSTER, Ph.D.,	)	
and	)	
ERIN N. POTTS-KANT	)	
	)	
Defendants.	)	
	)	

**DEFENDANTS’ ANSWER TO RELATOR’S  
FIRST AMENDED COMPLAINT**

Defendants Duke University (“Duke”) and Duke University Health System, Inc. (“DUHS”) (collectively, “Defendants”), through their undersigned counsel, answer the First Amended Complaint (“Complaint”) of Relator Joseph Thomas (“Relator”) as follows:

1. Defendants admit that 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, DUHS, William M. Foster, Ph.D. (“Foster”), and Erin N. Potts-Kant (“Potts-Kant”). Defendants deny any remaining allegations contained in Paragraph 1.

## I. Introduction<sup>1</sup>

2. Defendants admit that one purpose of medical research is to improve public health and medical treatment. Defendants admit that some medical research is funded by the United States government through a process that is, at times, competitive. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 2 and, therefore, deny those allegations.

3. Defendants admit that Potts-Kant told Duke University's Ad Hoc Investigation Committee ("the Committee") that, while she was employed at Duke University, she "fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications . . . ." Defendants deny the remaining allegations contained in Paragraph 3.

4. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she "fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications by changing or making up data to either reduce variability in experimental results (small error bars or p values), or to enhance or create a 'signal' that indicated a contrast between control and experimental animals or animals under different treatments or conditions." Defendants admit that Duke University made certain certifications, including certifications of accuracy and completeness of the grant documents and

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<sup>1</sup> Defendants have included the headings from Relator's Amended Complaint in their Answer for the Court's reference. Defendants have not provided a response to these headings.

certifications of compliance with its policies and federal regulations governing research misconduct, in connection with federal grant awards. Defendants deny any remaining allegations contained in Paragraph 4.

5. Defendants admit that Foster ran a lab that conducted research for certain individuals at Duke University and at other institutions. Defendants admit that Foster was a supervisor of Potts-Kant. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications . . . .” Defendants deny any remaining allegations contained in Paragraph 5.

6. Defendants admit that Foster and Potts-Kant authored scientific publications. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications . . . .” Defendants deny any remaining allegations contained in Paragraph 6.

7. Defendants lack sufficient information to form a belief as to the truth of the allegation regarding whether Foster received warnings and allegations regarding Potts-Kant’s research results and, therefore, deny this allegation. Defendants admit that Potts-Kant’s embezzlement of Duke University dollars resulted in an internal review of Potts-Kant’s reported research results. Defendants deny any remaining allegations contained in Paragraph 7.

8. Defendants deny the allegations contained in Sentence 1 and Sentence 2 of Paragraph 8. Defendants admit that the Committee determined that, after March 2013, certain researchers at Duke University submitted a grant application (P01A1081672-06) that contained two flexiVent figures (Figure 11 and Figure 9) that were potentially affected by Potts-Kant's research misconduct. Defendants further admit that certain researchers at Duke University disclosed in the Final Progress Report for grant P0A1081672 that the progress report submitted in June of 2013 for this grant contained three figures (Figure 2, Figure 3, and Figure 4) that were potentially affected by Potts-Kant's research misconduct. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 8 and, therefore, deny those allegations.

9. Defendants deny the allegations contained in Paragraph 9.

10. Defendants admit that, under the FCA, a defendant may be liable to the United States for treble damages and civil penalties. Defendants deny any remaining allegations contained in Paragraph 10.

## **II. Jurisdiction and Venue**

11. Defendants admit that subject matter jurisdiction is proper under 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732 and 3730(b).

12. As a result of the Western District of Virginia's decision to transfer this matter to the Middle District of North Carolina, this allegation is moot. Defendants admit that the Middle District of North Carolina has personal jurisdiction of Defendants under

31 U.S.C. § 3732(a).

13. As a result of the Western District of Virginia's decision to transfer this matter to the Middle District of North Carolina, this allegation is moot. Defendants admit that venue is proper in the Middle District of North Carolina under 31 U.S.C. § 3732(a).

14. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 14 and, therefore, deny the allegations.

15. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 15 and, therefore, deny the allegations.

### **III. Parties and Other Key Players**

#### **A. Joseph M. Thomas.**

16. Defendants admit that Thomas was an employee of Duke University from September 9, 2008 through October 31, 2014. Defendants admit that, during his employment at Duke University, Thomas was a resident of North Carolina. Defendants deny any remaining allegations contained in Paragraph 16.

17. Defendants admit that Thomas worked in the Cell Biology Department of the Duke University Medical Center from September 9, 2008 until March 31, 2012. Defendants deny any remaining allegations contained in Paragraph 17.

18. Defendants admit that Thomas moved to the laboratory of Dr. Monica Kraft in the Pulmonary, Asthma and Critical Care Division in March 2012. Defendants admit that Thomas was employed as a Laboratory Research Associate at that time. Defendants lack sufficient information to form a belief as to the truth of whether Thomas developed,

designed, and conducted experiments for the Pulmonary Division and therefore, deny that allegation. Defendants deny any remaining allegations contained in Paragraph 18.

**B. Duke University**

19. Defendants admit the allegations contained in Paragraph 19.

**C. DUHS**

20. Defendants admit that DUHS is a health-care-services company located in Durham, North Carolina. Defendants deny that DUHS is a subsidiary of Duke. Defendants admit that DUHS operates the Duke University Medical Center. Defendants deny any remaining allegations contained in Paragraph 20.

21. Defendants admit that certain employees of Duke University share cross-appointments with DUHS. Defendants deny the remaining allegations contained in Paragraph 21.

**D. Erin N. Potts-Kant**

22. Defendants admit that Potts-Kant was an employee of Duke University from January 18, 2005 through March 29, 2013 and worked in the Airway Physiology Laboratory. Defendants deny that Potts-Kant was an employee of DUHS. Defendants admit that Potts-Kant was 24 years old when she began working at Duke University. Defendants deny any remaining allegations contained in Paragraph 22.

23. Defendants admit that Potts-Kant had the title “Clinical Research Coordinator” within the Pulmonary Division from December 1, 2008 to the end of her employment at Duke. Defendants admit that Exhibit A accurately represents the job

description for the position of Clinical Research Coordinator II. Defendants lack sufficient information to form a belief as to the authenticity of the document attached as Exhibit A in Paragraph 23 and, therefore, deny any remaining allegations that relate to that Exhibit. Defendants deny any remaining allegations contained in Paragraph 23.

**E. William Michael Foster, Ph.D.**

24. Defendants admit that Foster was a Research Professor of Medicine in the Pulmonary Division from July 1, 2002 through July 30, 2006 and that he was a Professor (Track V) in the Pulmonary Division from July 1, 2006 through March 31, 2015. Defendants further admit that Foster was a supervisor of Potts-Kant. Defendants deny that Foster had a cross-appointment with DUHS. Defendants deny any remaining allegations contained in Paragraph 24.

25. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 25 and, therefore, deny those allegations.

**F. Other Key Players**

**(i) The Foster Lab**

26. Defendants admit that the Foster Lab studied the effects of environmental factors on the airways of laboratory mice. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 26 and, therefore, deny those allegations. Defendants deny any remaining allegations contained in Paragraph 26.

27. Defendants admit the allegations contained in Paragraph 27.

28. Defendants lack sufficient information to form a belief as to the truth of the

allegations contained in Paragraph 28 and, therefore, deny those allegations.

**(ii) The Pulmonary Division**

29. Defendants admit that the Pulmonary Division is within the Department of Medicine and is made up of several researchers who possess degrees including but not limited to a Ph.D., an M.D., or both. Because Relator has not identified certain researchers who are “Principal Investigators,” Defendants lack sufficient information regarding whether such individuals direct, manage, and supervise the research performed in the laboratories at Duke University as alleged in Paragraph 29 and, therefore, deny that allegation. Defendants admit that Principal Investigators apply for federal grant funding. Defendants deny the remaining allegations contained in Paragraph 29.

30. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications . . .” and her research misconduct directly affected certain research for Principal Investigators within the Pulmonary Division. Defendants deny that Exhibit A-1 pertains to or supports the allegations contained in Paragraph 30. Defendants lack sufficient information to form a belief as to the authenticity of the document attached as Exhibit A-1 in Paragraph 30 and, therefore, deny the allegations that relate to that Exhibit. Defendants deny the remaining allegations contained in Paragraph 30.

31. Defendants admit that, during his employment at Duke, Foster was a Principal Investigator for some research projects conducted within the Pulmonary



Division.

32. Defendants admit that, during her employment at Duke, Dr. Monica Kraft was a Principal Investigator for some research projects conducted within the Pulmonary Division and was Division Chief from January 1, 2013 through September 30, 2014.

33. Defendants admit that, during his employment at Duke, Dr. Paul W. Noble was a Principal Investigator for some research projects conducted within the Pulmonary Division and was Division Chief from July 1, 2006 through December 31, 2012.

34. Defendants admit that, during his employment at Duke, Dr. John W. Hollingsworth was a Principal Investigator for some research projects conducted within the Pulmonary Division, and that he worked with Foster and Potts-Kant on certain research projects. Defendants admit that Dr. Hollingsworth was a supervisor for Potts-Kant on certain projects. Defendants deny any remaining allegations contained in Paragraph 34.

35. Defendants admit that Dr. Loretta G. Que is a Principal Investigator for some research projects conducted within the Pulmonary Division and worked with Foster and Potts-Kant on certain research projects. Defendants deny any remaining allegations contained in Paragraph 35.

36. Defendants admit that, during his employment at Duke, Dr. Jerry Eu was a Principal Investigator for some research projects conducted within the Pulmonary Division.

37. Defendants admit that Dr. Julia K. Walker is a Principal Investigator for

some research projects conducted within the Pulmonary Division.

38. Defendants admit that Dr. Julie G. Ledford was an Assistant Professor at Duke University from July 1, 2011 through February 13, 2015. Defendants admit that Dr. Ledford worked with Dr. Kraft. Defendants deny any remaining allegations contained in Paragraph 38.

39. Defendants admit that Dr. Jennifer Ingram is an Assistant Professor at Duke University who worked with Dr. Kraft on certain research projects. Defendants deny any remaining allegations contained in Paragraph 39.

40. Defendants admit that, during his employment at Duke, Dr. David M. Brass was a Principal Investigator for some research projects conducted within in the Pediatric Department who worked on certain research projects with Dr. Hollingsworth. Defendants deny any remaining allegations contained in Paragraph 40.

41. Defendants admit that Barbara S. Theriot worked in the laboratory of Dr. Walker. Defendants deny any remaining allegations contained in Paragraph 41.

42. Defendants admit that Dave Francisco was a Laboratory Research Analyst at Duke University from July 6, 2008 through March 31, 2015. Defendants admit that Francisco worked in Dr. Kraft's lab. Defendants deny any remaining allegations contained in Paragraph 42.

43. Defendants admit that Charles Giamberardino<sup>2</sup> was a Laboratory Research Analyst at Duke University from July 1, 2009 through July 29, 2016. Defendants deny

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<sup>2</sup> Relator's Amended Complaint misspells Charles Giamberardino's last name.

any remaining allegations contained in Paragraph 43.

(iii) Other Researchers

44. Defendants admit the allegations contained in Paragraph 44.

45. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications . . .” and her research misconduct directly affected certain research for Principal Investigators outside of the Pulmonary Division. Defendants deny any remaining allegations contained in Paragraph 45.

46. Defendants admit that Dr. Soman Abraham (Department of Immunology, Pathology, and Molecular Genetics and Microbiology); Dr. Jo Rae Wright (Department of Cell Biology);<sup>3</sup> Dr. Mary Sunday (Department of Pathology); Dr. Michael “Dee” Gunn (Department of Medicine, Cardiology). Dr. Richard L. Auten (Department of Pediatrics); Njira L. Lugogo (Assistant Professor of Medicine; and Amy M. Pastva (Assistant Professor of Orthopaedic Surgery) were Principal Investigators for certain research projects in their departments. Defendants lack sufficient information to form a belief as to the truth of whether Donald N. Cook (Department of Immunology) was a Principal Investigator for any certain projects in his department, and therefore deny that allegation. Defendants deny any remaining allegations contained in Paragraph 46.

#### **IV. Legal Framework**

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<sup>3</sup> Defendants admit that Dr. Wright passed away in 2012.

## **A. The FCA**

47. Defendants admit that Relator has accurately quoted portions of the current version of 31 U.S.C. § 3729.<sup>4</sup>

48. Defendants admit that Relator has accurately quoted portions of the current version of 31 U.S.C. § 3729(b)(1)(A). Defendants admit that Relator has accurately paraphrased portions of the current version of 31 U.S.C. § 3729(b)(1)(B).<sup>5</sup>

49. Defendants admit that Relator has accurately quoted portions of the current version of 31 U.S.C. § 3729(b)(2).

50. Defendants admit that Relator has accurately quoted portions of the current version of 31 U.S.C. § 3729(b)(4).

51. Defendants admit that Relator has accurately quoted portions of the current version of 31 U.S.C. § 3729(b)(3).

## **B. NIH Grants**

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

52. Defendants admit the allegations contained in Paragraph 52.

53. Defendants admit the allegations contained in Paragraph 53.

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<sup>4</sup> Relator's Amended Complaint notes in footnote 5: "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."

<sup>5</sup> Relator's Amended Complaint notes in footnote 7: "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."

54. Defendants admit the allegations contained in Paragraph 54.

**(ii) The purpose of NIH grants.**

55. Defendants admit that the NIH had a \$29.15 billion budget for FY 2013.

56. Defendants admit that the NIH awards grants to research institutions, including Duke University, through a process that is, at times, competitive. Defendants deny any remaining allegations contained in Paragraph 56.

57. Defendants admit that certain NIH grants include allocations for “indirect costs.” Because Relator has not provided support for his allegation in Sentence 2 of Paragraph 57, Defendants lack sufficient information to form a belief as to the truth of this allegation and, therefore, deny this allegation.

58. Defendants admit that Relator has accurately quoted portions of the NIH Grants Policy Statement (2013). Defendants deny the remaining allegations contained in Paragraph 58.

59. Defendants admit that Relator has accurately quoted portions of the NIH Grants Policy Statement (2013). Defendants deny any remaining allegations contained in Paragraph 59.

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

60. Defendants admit that Relator has accurately quoted portions of the NIH Grants Policy Statement (2013). Defendants deny any remaining allegations contained in Paragraph 60.

61. Defendants admit that Relator has accurately paraphrased portions of the

NIH Grants Policy Statement (2013). Defendants deny any remaining allegations contained in Paragraph 61.

62. Defendants admit that Relator has accurately quoted portions of the NIH Grants Policy Statement (2013).

63. Defendants admit that Relator has accurately paraphrased portions of the NIH Grants Policy Statement (2013).

64. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.103.

65. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.100(a). Defendants deny any remaining allegations contained in Paragraph 65.

66. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.100(b).

67. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.412(a)). Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.300(c) and 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). Defendants deny any remaining allegations contained in Paragraph 67.

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

68. Defendants admit that Relator has accurately paraphrased portions of the

NIH Policy Statement (2013). Defendants admit that Relator has accurately quoted portions of the current versions of 42 C.F.R. § 93.101(d) and 42 C.F.R. § 93.301(a).

69. Defendants admit that Relator has accurately paraphrased portions of the NIH Grant Policy Statement (2013).

70. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.300.

71. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.301(b).

72. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.302(a). Defendants deny any remaining allegations contained in Paragraph 72.

73. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.302(b).

74. Defendants admit that Relator has accurately paraphrased some of the ways that a grantee institution maintains its assurance status.

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

75. Defendants admit that the regulations found in 42 C.F.R. § 93 impose certain obligations on grantee institutions to investigate allegations of research misconduct and to make certain disclosures to ORI under certain circumstances.

76. Defendants admit that Relator has accurately paraphrased portions of the current version of Form PHS 6349. Defendants deny any remaining allegations contained

in Paragraph 76.

77. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.307.

78. Defendants admit that Relator has accurately paraphrased portions of the current versions of 42 C.F.R. §§ 93.307 and 93.309.

79. Defendants admit that Relator has accurately paraphrased portions of the current versions of 42 C.F.R. §§ 93.309 and 93.310.

80. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.313.

81. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.313.

82. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.318.

83. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.400(a). Defendants admit that the current version of 42 C.F.R. § 93.402 states that, “[w]hen ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.” Defendants deny any remaining allegations contained in Paragraph 83.

84. Defendants admit that Relator has accurately paraphrased portions of the



current versions of 42 C.F.R. §§ 93.402, 93.400(a), and 93.402. Defendants deny the remaining allegations contained in Paragraph 84.

85. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.400.

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

86. Defendants admit that Relator has accurately paraphrased portions of the NIH Grants Policy Statement (2013). Defendants deny any remaining allegations contained in Paragraph 86.

87. Defendants admit that acceptance of a grant award “including the ‘Terms and Conditions’ is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.” Defendants deny the remaining allegations contained in Paragraph 87.

**(vii) Institutional certifications relating to grant awards.**

88. Defendants admit to the allegations contained in Paragraph 88.

89. Defendants admit that Relator has accurately quoted portions of the NIH Grant Policy Statements (2013). Defendants deny any remaining allegations contained in Paragraph 89.

90. Defendants admit that Relator has accurately quoted portions of the NIH Grant Policy Statements (2013). Defendants deny any remaining allegations contained in Paragraph 90.

91. Defendants admit that Relator has accurately quoted portions of the current

version of Form PHS 398.

92. Because Relator fails to define “the time period at issue,” Defendants lack sufficient knowledge to form a belief as to the truth of the first sentence of Paragraph 92. Defendants admit that Relator has accurately quoted portions of the current version of Form SF 424 (R&R).

93. Defendants admit that 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”). Defendants admit that Relator has accurately quoted portions of the current version of Section 2.7 of the U.S. Department of Health and Human Services, Public Health Service, Supplemental Grant Instructions For All Competing Applications and Progress Reports.

94. Defendants admit that Relator has accurately quoted portions of the NIH Grant Policy Statements (2013). Defendants deny any remaining allegations contained in Paragraph 94.

95. Defendants admit that Relator has accurately quoted and paraphrased portions of the NIH Grant Policy Statements (2013). Defendants deny any remaining allegations contained in Paragraph 95.

96. Defendants admit that Relator has accurately paraphrased portions of the NIH Grant Policy Statements (2013).

97. Defendants admit that Relator has accurately quoted portions of the NIH Grant Policy Statements (2013). Defendants admit that, when submitting a Final Progress Report through eRa Commons, the grantee institution makes the following certification statement as part of the current closeout progress: “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.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 97 and, therefore, deny those allegations.

98. Defendants admit the “Instructions for All Final Progress Reports (exclusive of SBIR/STTR Phase II Final Progress Reports)” state that “[t]he final progress report should include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications.” Defendants admit that, when submitting a Final Progress Report through eRa Commons, the grantee institution makes the following certification statement as part of the current closeout progress: “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.” Defendants lack sufficient

information to form a belief as to the truth of the remaining allegations contained in Paragraph 98 and, therefore, deny those allegations.

99. Defendants admit that Relator has accurately quoted portions of the current version of PHS 2590.

100. Defendants admit that Section V of the Institutional Assurance and Annual Report contains a certification. Defendants admit that 42 C.F.R. § 93.302(b) states that “[a]n institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part.” Defendants deny any remaining allegations contained in Paragraph 100.

101. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 101 and, therefore, deny those allegations.

**(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. Defendants admit that Relator has accurately paraphrased portions of the current versions of Form PHS 398, Form SF 424 (R&R), and the Application Guide for NIH and Other PHS Agencies.

103. Defendants admit that Relator has accurately paraphrased portions of the current versions of Form PHS 398, Form SF 424, and the Application Guide for NIH and Other PHS Agencies.

104. Defendants admit that Relator has accurately paraphrased portions of the current versions of Form PHS 2590.

105. Defendants admit the “Instructions for All Final Progress Reports (exclusive of SBIR/STTR Phase II Final Progress Reports)” state that “[t]he final progress report should include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications.” Defendants deny any remaining allegations contained in Paragraph 105.

106. Defendants admit that, currently, research results 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. Defendants admit that Relator has accurately paraphrased portions of the current version of NIH Public Access Policy Details. Defendants deny any remaining allegations contained in Paragraph 106.

**(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. Defendants admit that Relator has accurately quoted portions of the NIH Grants Policy Statement (2013).

108. Defendants admit that Relator has accurately paraphrased portions of the NIH Grants Policy Statement (2013).

109. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.407(b).

110. Defendants admit that Relator has accurately paraphrased and quoted portions of the current version of 42 C.F.R. § 93.412(a).

111. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.412(b).

112. Defendants admit that Relator has accurately paraphrased portions of the current version of 42 C.F.R. § 93.413(c).

113. Defendants admit that Relator has accurately quoted portions of the current version of 42 C.F.R. § 93.413(d).

### **C. EPA Grants**

114. Defendants admit the allegations contained in Paragraph 114.

#### **(i) Certifications Relating to EPA Grant Awards**

115. Defendants admit that, in connection with EPA grant funding, an institution makes certifications related to its request for, and proposed use of, federal funds. Defendants deny the remaining allegations contained in Paragraph 115.

116. Defendants admit that Relator has accurately quoted portions of the current version of Form SF 424.

117. Defendants admit the allegations contained in Paragraph 117.

118. Defendants admit the allegations contained in Paragraph 118.

119. Defendants admit that Relator has accurately paraphrased portions of the current version of 40 C.F.R. § 40.160-1.

120. Defendants admit that Relator has accurately paraphrased portions of the current version of 40 C.F.R. § 40.160 in Sentence 1 of Paragraph 120. Defendants admit that the EPA Research and Related Agency Specific Requirements (July 2008) state that “the recipient agrees to submit an Executive Summary with the final report for posting on the Internet. This will be placed on EPA/ORD web site(s) along with a list of

publications.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 120 and, therefore, deny those allegations.

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

121. Defendants admit that the Relator has accurately paraphrased portions of the current version of the EPA Research and Related Terms and Conditions. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 121 and, therefore, deny those allegations.

122. Defendants admit the allegation contained in Sentence 1 of Paragraph 122. Defendants further admit that the EPA Research and Related Agency Specific Requirements (July 2008) state that “the recipient agrees to submit an Executive Summary with the final report for posting on the Internet. This will be placed on EPA/ORD web site(s) along with a list of publications.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 122 and, therefore, deny those allegations.

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

123. Defendants admit that the EPA approved its current Policy and Procedures for Addressing Research Misconduct (“EPA Research Misconduct Policy”) in 2003.

124. Defendants admit that Relator has accurately quoted portions of the current version of the EPA Research Misconduct Policy.

125. Defendants admit that Relator has accurately quoted portions of the current version of the EPA Research Misconduct Policy.

126. Defendants admit that Relator has accurately quoted portions of the current version of the EPA Research Misconduct Policy.

127. Defendants admit that Relator has accurately quoted portions of the current version of the EPA Research Misconduct Policy.

128. Defendants admit that Relator has accurately quoted portions of the current version of the EPA Research Misconduct Policy. Defendants deny any remaining allegations contained in Paragraph 128.

129. Defendants admit that Relator has accurately paraphrased and quoted portions of the current version of the EPA Research Misconduct Policy. Defendants deny any remaining allegations contained in Paragraph 129.

130. Defendants admit that Relator has accurately quoted portions of the current version of 65 Fed. Reg. 76263 (III).

## **V. Factual Allegations**

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

131. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 131 and, therefore, deny those allegations.

132. Defendants deny the allegations contained in Paragraph 132.

133. Defendants admit that medical research can serve the public interest and can also advance and benefit the researchers and institutions that conduct it. Defendants



deny any remaining allegations contained in Paragraph 133.

134. Defendants admit that this advancement and benefit can take many forms. Defendants admit that researchers and institutions can receive direct and indirect benefits from research efforts. Defendants admit that, for example, grants can fund certain costs of research, including salaries and institutional support and infrastructure. Defendants admit that medical research can lead to the development of lucrative patents for researchers and institutions. Defendants deny any remaining allegations contained in Paragraph 134.

135. Defendants admit that medical research can have certain intangible benefits. Defendants admit that, for researchers, medical research can lead to promotion and advancement. Defendants admit that, for researchers and institutions, medical research can increase professional esteem, prestige and reputations. Defendants deny any remaining allegations contained in Paragraph 135.

136. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 136 and, therefore, deny those allegations.

137. Defendants admit that there can be a risk of research fraud and misconduct in connection with grant funding for medical research. Defendants deny the remaining allegations contained in Paragraph 137.

138. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 138 and, therefore, deny those allegations.

## **B. Duke University's Policy**

139. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 139 with respect to other research institutions and, therefore, deny those allegations. Defendants admit that Duke University has a policy or procedure directed towards research misconduct. Defendants deny any remaining allegations contained in Paragraph 139.

140. Defendants admit the allegations contained in Paragraph 140.

141. Defendants admit that Relator has accurately quoted portions of the Duke University Faculty Handbook.

142. Defendants admit that Relator has accurately quoted portions of the Duke University Faculty Handbook.

143. Defendants admit that Relator has accurately quoted portions of the Duke University Faculty Handbook. Defendants deny any remaining allegations contained in Paragraph 143.

144. Defendants admit that Relator has accurately paraphrased portions of the Duke University Faculty Handbook. Defendants deny any remaining allegations contained in Paragraph 144.

145. Defendants admit that Relator has accurately paraphrased portions of the Duke University Faculty Handbook. Defendants deny any remaining allegations contained in Paragraph 145.

146. Defendants admit that Duke University adopted this policy for numerous reasons, including, in part, to comply with certain regulations. Defendants deny the

remaining allegations contained in Paragraph 146.

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

147. Defendants admit the allegations contained in Paragraph 147.

148. Defendants admit the allegations contained in Paragraph 148.

149. Defendants admit the allegations contained in Paragraph 149.

150. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 150 and, therefore, deny those allegations.

151. Defendants admit the allegations contained in Paragraph 151.

152. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 152 and, therefore, deny those allegations.

153. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 153 and, therefore, deny those allegations.

154. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants deny the remaining allegations contained in Paragraph 154.

155. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 155 and, therefore, deny those allegations.

156. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and

multiplex (cytokine) data that were included in various publications and grant applications by changing or making up data to either reduce variability in experimental results (small error bars or p values), or to enhance or create a ‘signal’ that indicated a contrast between control and experimental animals or animals under different treatments or conditions.” Defendants lack sufficient information as to the truth of the remaining allegations contained in Paragraph 156 and, therefore, deny those allegations.

157. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications by changing or making up data to either reduce variability in experimental results (small error bars or p values), or to enhance or create a ‘signal’ that indicated a contrast between control and experimental animals or animals under different treatments or conditions.” Defendants lack sufficient information as to the truth of the remaining allegations contained in Paragraph 157 and, therefore, deny those allegations.

158. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications by changing or making up data to either reduce variability in experimental results (small error bars or p values), or to enhance or create a ‘signal’ that indicated a contrast between control and experimental animals or animals under different treatments or conditions.” Defendants lack sufficient information as to the truth of the remaining

allegations contained in Paragraph 158 and, therefore, deny those allegations.

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

159. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants admit that Potts-Kant co-authored over 38 scientific papers and journal articles during her employment at Duke. Defendants admit that Potts-Kant was 32 years old in 2013. Defendants deny that Exhibit B pertains to or supports the allegations contained in Paragraph 159. Defendants lack sufficient information to form a belief as to the authenticity of the documents attached as Exhibit B to Paragraph 159 and, therefore, deny the allegations that relate to that Exhibit. Defendants deny any remaining allegations contained in Paragraph 159.

160. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants admit that Foster co-authored over 38 scientific papers and journal articles during his employment at Duke. Defendants deny any remaining allegations contained in Paragraph 160.

161. Defendants admit that publications are discussed in detail below. Defendants deny any remaining allegations contained in Paragraph 161.

**(i) PMID 17993584—*Airway Smooth Muscle Relaxation is Impaired in Mice Lacking***

*the p47 Subunit of NAD(P)H Oxidase*

162. Defendants admit that Potts-Kant contributed data to the paper entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47<sup>phox</sup> Subunit of NAD(P)H Oxidase*. Defendants lack sufficient information to form a belief as to the truth of whether such experiments were performed in 2007 or by Foster and, therefore, deny those allegations. Defendants deny that this publication can be found in Exhibit B. Defendants deny any remaining allegations contained in Paragraph 162.

163. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 9a by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors of the publication.” Defendants admit that the Committee determined that “[t]he epk and source data for Figure 9b matched (PV loops)” and, therefore, deny the allegations pertaining to Figure 9b. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 163 and, therefore, deny those allegations.

164. Defendants admit that the paper entitled *Airway Smooth Muscle Relaxation is Impaired in Mice Lacking the p47<sup>phox</sup> Subunit of NAD(P)H Oxidase* was published in the American Journal of Physiology - Lung Cellular and Molecular Physiology in 2008. Defendants lack sufficient information to form a belief as to the truth of the remainder of Paragraph 164 and therefore, deny those allegations.

165. Defendants admit that the article entitled *Airway Smooth Muscle Relaxation*

*is Impaired in Mice Lacking the p47<sup>phox</sup> Subunit of NAD(P)H Oxidase* cites financial support from NIH grants HL067021, HL075307 and HL67281. Defendants deny any remaining allegations contained in Paragraph 165.

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

166. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury*. Defendants deny that Exhibit B, at Relator\_000447, pertains to or supports the allegations contained in Paragraph 166. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

167. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1 and Figure 4 of this paper. Defendants admit that Potts-Kant was involved in producing Multiplex data for Figure 3 and Figure 6 of this paper. Defendants admit that the journal, *Environmental Health Perspectives*, stated that the authors of the paper informed the Journal that they “had an independent laboratory replicate experiments to analyze the original role of cytokines reported in Figure 3 and Figure 6” and that they “did not observe the same results and could not definitively determine whether or not the findings were valid.” Defendants admit that *Environmental Health Perspectives* stated that the authors of the paper informed the Journal that they “requested that an independent laboratory replicate the experiments of animal airway physiology presented in Figure 1 and Figure 4. The results of the replicated experiments validated the

originally reported central role of mindin in airway hyper-responsiveness after exposure to either lipopolysaccharide (LPS) or ozone.” Thus, Defendants deny that researchers were unable to repeat the experiments published in Figure 1 and Figure 4 and deny that they observed results that were contrary to the findings published in Figures 1 and 4. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 167 and, therefore, deny these allegations.

168. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in figures 1 and 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 168 and, therefore, deny those allegations.

169. Defendants admit the allegations contained in Paragraph 169.

170. Defendants admit that the paper entitled *The Role of the Extracellular Matrix Protein Mindin in Airway Response to Environmental Airways Injury* cites financial support from NIH grants ES016126, ES020446, ES016347, and HL081825. Defendants deny the remaining allegations in Paragraph 170.

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

171. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide*. Defendants deny that Exhibit B, at Relator\_000169, pertains to or



supports the allegations contained in Paragraph 171. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

172. Defendants admit that Potts-Kant was involved in producing the data published in Figure 1C, Figure 2C, Figure 4C and Figure 5C (*flexiVent*) of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 172 and, therefore, deny these allegations.

173. Defendants admit that the Committee determined that Potts-Kant “falsified *flexiVent* data in Figures 2c, 4c, and 5c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 173 and, therefore, deny those allegations.

174. Defendants admit that the *Journal of Immunology* stated that the authors of the paper informed the Journal that they “repeated the experiments described in Fig. 5C of the published article and were unable to replicate the airway hyperresponsiveness findings.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 174 and, therefore, deny those allegations.

175. Defendants admit the allegations contained in Paragraph 175.

176. Defendants admit that the article entitled *Hyaluronan Fragments Contribute to the Ozone Primed Immune Response to Lipopolysaccharide* cites financial

support from NIH grants ES016126, ES016659, ES016347, AI064789 and AI081672.

Defendants deny the remaining allegations contained in Paragraph 176.

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

177. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice*. Defendants deny that Exhibit B, at Relator\_000437, pertains to or supports the allegations contained in Paragraph 177. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

178. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figures 1a, 1b, 5a, and 5b this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 178 and, therefore, deny those allegations.

179. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 1a, 1b, 5a, and 5b changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 179 and, therefore, deny those allegations.

180. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 180 and, therefore, deny those allegations.

181. Defendants admit the allegations contained in Paragraph 181.

182. Defendants admit that the article entitled *SP-A Preserves Airway Homeostasis During Mycoplasma pneumoniae Infection in Mice* cites financial support from NIH grants F32HL091642, ESO1 1961, PHL073907 and HL084917. Defendants deny the remaining allegations contained in Paragraph 182.

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

183. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace*. Defendants deny that Exhibit B, at Relator\_000120, pertains to or supports the allegations contained in Paragraph 183. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

184. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1b and Figure 1c of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 184 and, therefore, deny those allegations.

185. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 1b and 1c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 185 and, therefore, deny those

allegations.

186. Defendants admit the allegations contained in Paragraph 186.

187. Defendants admit that the article entitled *The extracellular matrix protein mindin regulates trafficking of murine eosinophils into the airspace* cites financial support from ES 11961, ES 12496, ES 16126 and National Heart, Lung and Blood Institute grant HL91335. Defendants deny the remaining allegations contained in Paragraph 187.

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

188. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Ambient Ozone Primes Pulmonary Innate Immunity in Mice*. Defendants deny that Exhibit B, at Relator\_000052, pertains to or supports the allegations contained in Paragraph 188. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

189. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 189 and, therefore, deny these allegations.

190. Defendants admit that the *Journal of Immunology* stated that the authors of the paper informed the Journal that they “repeated the experiments described in Fig. 1 of the published article and were unable to replicate the airway hyperresponsiveness

findings.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 190 and, therefore, deny those allegations.

191. Defendants admit that the Committee found that Potts-Kant “fabricated flexiVent data in Figures 1a, b, and c.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 191 and, therefore, deny those allegations.

192. Defendants admit the allegations contained in Paragraph 192.

193. Defendants admit that the article entitled *Ambient Ozone Primes Pulmonary Innate Immunity in Mice* cites financial support from ES 12717, ES 11961, National Institute of Allergy and Infectious Disease grant AI58161 and National Heart, Lung and Blood Institute grant HL91335. Defendants deny the remaining allegations in Paragraph 193.

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

194. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP*. Defendants deny that Exhibit B, at Relator\_000177, pertains to or supports the allegations contained in Paragraph 194. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

195. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figures 1b, 1c, 6a, 6b, and 6c of this paper. Defendants lack sufficient information to

form a belief as to the truth of the remaining allegations contained in Paragraph 195 and, therefore, deny those allegations.

196. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 196 and, therefore, deny those allegations.

197. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 1b, 1c, 6a, 6b, and 6c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figures 1a” of the paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 197 and, therefore, deny those allegations.

198. Defendants admit that the article entitled *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP* was accepted for publication on October 11, 2011 by the scientific journal PLoS ONE. Defendants deny the remaining allegations contained in Paragraph 198.

199. Defendants admit that the article entitled *Hyaluronan Signaling during Ozone-Induced Lung Injury Requires TLR4, MyD88, and TIRAP* cites financial support from NIH grants ES016126 and ES020426. Defendants deny the remaining allegations in Paragraph 199.

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

200. Defendants admit that Potts-Kant and others co-authored an article entitled

*Alveolar Macrophages from Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype.* Defendants deny that Exhibit B, at Relator\_0000523, pertains to or supports the allegations contained in Paragraph 200. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

201. Defendants admit that Potts-Kant was involved in producing Multiplex data for Table 3 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 201 and, therefore, deny those allegations.

202. Defendants admit that the *American Journal of Respiratory and Critical Care Medicine* stated that the authors “have decided to retract the article because of problems with the reliability of its data.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 202, and therefore deny those allegations.”

203. Defendants admit that the Committee determined that Potts-Kant “falsified multiplex (cytokine) data in Table 3 and Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 203 and, therefore, deny those allegations.

204. Defendants admit the allegations contained in Paragraph 204.

205. Defendants admit that the article entitled *Alveolar Macrophages from*

*Overweight/Obese Subjects with Asthma Demonstrate a Proinflammatory Phenotype* cites financial support from American Thoracic Society Grant 07 012, and NIH grants P50-HL-084917, HL-05-009, HL086887, ES016126, and AI081672. Defendants deny the remaining allegations contained in Paragraph 205.

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

206. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice*. Defendants deny that Exhibit B, at Relator\_000202, pertains to or supports the allegations contained in Paragraph 206. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

207. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 3B, Figure 4C, and Figure 6A. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 207 and, therefore, deny those allegations.

208. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 208 and, therefore, deny those allegations.

209. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 3b and 4c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that Potts-



Kant “fabricated flexiVent data in Figure 6a” of this publication. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 209 and, therefore, deny those allegations.

210. Defendants admit that the article entitled *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice* was accepted for publication on March 1, 2012 by the scientific Journal of Allergy and Clinical Immunology. Defendants deny the remaining allegations in Paragraph 210.

211. Defendants admit that the article entitled *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A)-/- mice* cites financial support from NIH grants F32-HL091642 and P01-AI81672. Defendants deny any remaining allegations contained in Paragraph 211.

**(x) Additional Publications**

212. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants deny that Exhibit E pertains to or supports the allegations contained in Paragraph 212. Defendants incorporate their answers to individual paragraphs contained in Exhibit E to their answer of Paragraph 212. Defendants deny any remaining allegations contained in Paragraph 212.

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

213. Defendants admit that Potts-Kant told the Committee that, while she was

employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants admit that Potts-Kant and Foster co-authored the publications referenced in Exhibit E, ¶¶ 1-5 and 70-74 and that these publications cited financial support from an EPA grant. Defendants deny the remaining allegations in Paragraph 213.

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

214. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants deny the remaining allegations contained in Paragraph 214.

215. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 215 and, therefore, deny those allegations.

216. Defendants admit that, since April 2008, all publications that included funded research must be made available to the public. Defendants admit that publications must cite any grants that provided financial support to the publication. Defendants admit that grant progress reports must cite any publications that have been published or accepted for publication since the last reporting period. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 216 and, therefore, deny those allegations.

217. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 217 and, therefore, deny those allegations.

218. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 218 and, therefore, deny those allegations.

219. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants deny that Exhibits E, C, and C-1 pertain to or support the allegations contained in Paragraph 219. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 219 and, therefore, deny those allegations.

220. Defendants admit that PMID 22502799 titled *Mast cell TNF receptors regulate responses to Mycoplasma pneumoniae in surfactant protein A (SP-A) -/- mice* was co-authored by Foster, Potts-Kant, and others, and was accepted for publication on March 1, 2012. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 3b and 4c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating

investigators/co-authors for publication.” Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 6a” of this publication. Defendants admit that this publication cites financial support from NIH Grant P01-AI081672. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 220 and, therefore, deny those allegations.

221. Defendants admit that Potts-Kant, Foster, and others co-authored PMID 19762564 titled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice* in 2009. Defendants admit that the Committee determined that Potts-Kant “falsified multiplex data in Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that this publication cites financial support from EPA Grant RD83329301. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 221 and, therefore, deny those allegations.

222. Defendants deny that Exhibit C pertains to or supports the allegations contained in Paragraph 222. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit C and therefore, deny those allegations. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 222 and, therefore, deny those allegations.

223. Defendants deny that Exhibits C-1, B, and E pertain to or support the allegations contained in Paragraph 223. Defendants lack sufficient information to form a

belief as to the authenticity of the documents referenced in Exhibit C-1, B, and E and therefore, deny those allegations. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 223 and, therefore, deny those allegations.

**F. Duke University made false certifications.**

224. Defendants deny the allegations contained in Paragraph 224.

225. Defendants deny the allegations contained in Paragraph 225.

226. Defendants deny the allegations contained in Paragraph 226.

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

227. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . [and] acknowledge[d] that this conduct constitute[d] ‘research misconduct’ under Public Health Service regulations.” Defendants admit that Potts-Kant embezzled funds from Duke University to make personal purchases during her employment at Duke University. Defendants admit that Potts-Kant’s embezzlement involved the production of false invoices for scientific equipment and supplies for reimbursement. Defendants admit that Potts-Kant embezzled more than \$14,000. Defendants deny any remaining allegations contained in Paragraph 227.

228. Defendants admit the allegations contained in Paragraph 228.

229. Defendants admit that Duke University placed Potts-Kant on leave on

March 12, 2013. Defendants admit that the Durham Police Department arrested Potts-Kant on an embezzlement charge on March 29, 2013. Defendants deny any remaining allegations contained in Paragraph 229.

230. Defendants admit that, after Duke University placed Potts-Kant on leave, individual researchers began reviewing certain data Potts-Kant had produced in connection with certain grant applications, grant progress reports, and publications. Defendants admit that this review included analyzing the raw data, trying to recalculate Potts-Kant's results using the raw data, and repeating experiments. Defendants deny any remaining allegations contained in Paragraph 230.

231. Defendants admit that senior administrators within Duke University were aware that a review of data produced by Potts-Kant was occurring. Defendants deny the remaining allegations contained in Paragraph 231.

232. Defendants admit that Foster, Dr. Que, Dr. Ledford, Dr. Brass, Ms. Theriot, and others participated in this review effort. Defendants lack sufficient information as to the truth of whether Mr. Francisco or Relator participated in this review effort alleged in Paragraph 232 and, therefore, deny those allegations.

233. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 233 and, therefore, deny those allegations.

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

234. Defendants admit that the raw data for some experiments performed by Potts-Kant could not be located. Defendants deny any remaining allegations contained in

Paragraph 234.

235. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 235 and, therefore, deny those allegations.

236. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 236 and, therefore, deny those allegations.

237. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 237 and, therefore, deny those allegations.

238. Defendants admit that the Committee determined that, in connection with Figure 1 of PMID 22073274, Potts-Kant “provided a dataset to the co-authors under the premise that it represented information obtained from a flexiVent procedure she conducted when, in fact, no corresponding data appears to have been generated on that date.” Defendants admit that the Committee determined that, in connection with PMID 21037098, “[n]o epk or source data were found for flexivent data in Figure 1c.” Defendants admit that the Committee determined that, in connection with Figure 1 of PMID 17878331, “[t]here was no source data found among the flexiVent machine files corresponding to the data sent to the co-authors by the [Potts-Kant.]” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 238 and, therefore, deny these allegations.

239. Defendants deny that PMID 21930959, PMID 22073274, PMID 22773729, PMID 21684833, PMID 21037098, PMID 17993584, and PMID 17878331 all 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. Defendants admit that in some cases, researchers in the Pulmonary Division concluded that Potts-Kant may not have run experiments for which she had provided data. Defendants lack sufficient information as to the truth of whether Potts-Kant simply made up the results of experiments and, therefore, deny that allegation.

241. Defendants admit that Duke University researchers withdrew a pending grant application because of questions regarding data included in the application that had been produced by Potts-Kant. Defendants admit that Dr. Que believed that Potts-Kant had never run certain experiments for which she had provided data. Defendants lack sufficient information as to the truth of whether Dr. Ledford observed regarding the data reported for Dr. Hollingsworth's epigenetic work. Defendants deny any remaining allegations contained in Paragraph 241.

242. Defendants admit that the Committee determined that, in connection with PMID 22773729, Potts-Kant "falsified multiplex (cytokine) data in Figures 3b and 3b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication." Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 242 and, therefore, deny those allegations.



243. Defendants admit that the Committee determined that, in connection with PMID 20543006, Potts-Kant “falsified multiplex data in Figure 2 . . . by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 243 and, therefore, deny those allegations.

244. Defendants admit that the Committee determined that, in connection with PMID 22773729, Potts-Kant “falsified multiplex (cytokine) data in Figures 3b and 3b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 20543006, Potts-Kant “falsified multiplex data in Figure 2 and flexiVent data in Figure 6 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 244 and, therefore, deny those allegations.

245. Defendants admit that the publications designated PMID 22773729 and PMID 20543006 cite financial support from NIH Grants HL82504, HL81763, HL36982, ES16347, AI81672, HL05009, HL086887, ES016126, P50-HL08491, and American Thoracic Society grant 07-012. Defendants deny any remaining allegations contained in Paragraph 245.

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

246. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 246 and, therefore, deny those allegations.

247. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 247 and, therefore, deny those allegations.

248. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 248 and, therefore, deny those allegations.

249. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 249 and, therefore, deny those allegations.

250. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 250 and, therefore, deny those allegations.

251. Defendants admit that the Committee determined that, in connection with PMID 22073274, Potts-Kant “falsified flexiVent data in Figures 1b, 1c, 6a, 6b, and 6c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants further admit that the Committee determined, in connection with PMID 22073274, that Potts-Kant “fabricated flexiVent data in Figures 1a” of the publication. Defendants admit

that the Committee determined that, in connection with PMID 21684833, Potts-Kant “falsified flexiVent data in Figures 1 and 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 21037098, Potts-Kant “falsified flexiVent data in Figures 2c, 4c and 5c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 17878331, Potts-Kant “fabricated flexiVent data in Figure 1a, b, and c” of the publication. Defendants admit that the Committee determined that, in connection with PMID 19494306, Potts-Kant “falsified flexiVent data in Figures 1a, 1b, 5a, and 5b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 251 and, therefore, deny those allegations.

252. Defendants deny that publications PMID 22073274, PMID 21930959, PMID 21684833, PMID 21037098, PMID 17878331, and PMID 19494306 all state that the reported research was funded by NIH Grants ES016126, ES02046 (PMID 21684833), ES016347, HL081825, AI081672 (PMID 21037098), ES016659, AI064789, AI58161, ESI 1961, ES12717, HL91335, F32-HL091642 (PMID 19494306), PHL073907, and HL084917, and HL077291 (PMID 21930959).

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

253. Defendants admit that the Committee determined that Potts-Kant had altered or manipulated the results of certain experiments. Defendants deny any remaining allegations contained in Paragraph 253.

254. Because Relator has not identified particular Multiplex experiments, Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 254 and, therefore, deny those allegations.

255. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 255 and, therefore, deny those allegations.

256. Defendants admit that, in connection with PMID 22773729, the Committee determined that Potts-Kant “falsified multiplex (cytokine) data in Table 3 and Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 256 and, therefore, deny those allegations.

257. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 257 and, therefore, deny those allegations.

258. Defendants admit that the Committee determined that, in connection with PMID 20348208, Potts-Kant “falsified flexiVent data in Table 1, Figure 1, and Figure 7 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants

lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 258 and, therefore, deny those allegations.

259. Defendants admit that the Committee determined that, in connection with PMID 19762564, Potts-Kant “falsified multiplex data in Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 22052876, Potts-Kant “falsified multiplex data in Figures 1 and 3 and flexiVent data in Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 22773729, Potts-Kant “falsified multiplex (cytokine) data in Table 3 and Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 20543006, Potts-Kant “falsified multiplex data in Figure 2 and flexiVent data in Figure 6 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 20348208, Potts-Kant “falsified flexiVent data in Table 1, Figure 1, and Figure 7 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-

authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 259 and, therefore, deny those allegations.

260. Defendants deny that these publications all state that the reported research was funded by Grants 1-K08-AI068822, AI81672 (PMID 20543006), 1-P30-ES011961, ES016347, ES016126, HL05009, 5-R01-HL086887-03 (PMID 20348208), HL82504, HL81763, HL36982, 5-P50-HL084917 (PMID 22773729), 5-R01-HL068072, 5-R01-HL058795, 5-R01-HL084123, 5-R01-HL081285, HL079915, ATS 07-012, and EPA RD 83329301.

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

261. Defendants admit that Duke University researchers re-ran experiments in an attempt to replicate the results of experiments Potts-Kant had performed. Defendants admit that Dr. Ledford and Ms. Theriot participated in this effort. Defendants lack sufficient knowledge that Thomas and Mr. Francisco participated in this effort. Defendants deny that DUHS researchers re-ran experiments in an attempt to replicate the results of experiments Potts-Kant had performed. Defendants deny any remaining allegations contained in Paragraph 261.

262. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 262 and, therefore, deny those allegations.

263. Defendants admit that Ms. Theriot re-ran certain experiments related to Dr. Hollingsworth’s work as published in PMID 17878331. Defendants admit that

researchers were unable to replicate the results described in Figure 1 of the published article. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 263 and, therefore, deny those allegations.

264. Because Relator has failed to identify the “HA experiments” to which he is referring, Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 264 and, therefore, deny those allegations.

265. Because Relator has failed to identify the “HA experiments” to which he is referring, Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 265 and, therefore, deny those allegations.

266. Defendants admit that Ms. Theriot was involved, in addition to other reviewers, in re-running the flexiVent experiments reported in PMID 20007931. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 266 and, therefore, deny those allegations.

267. Because Relator has failed to identify the “‘mindin’ gene project” to which he is referring, Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 267 and, therefore, deny those allegations.

268. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 268 and, therefore, deny those allegations.

269. Defendants admit that the Committee determined that, in connection with PMID 22773729, Potts-Kant “falsified multiplex (cytokine) data in Table 3 and Figure 4 by changing certain numerical values in the dataset generated by the experiment before

providing it to the collaborating investigators/co-authors for publication.” Defendants admit that, in connection with PMID 17878331, the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 1a, b, and c” of the publication. Defendants admit that the Committee determined that, in connection with PMID 20007931, Potts-Kant “falsified flexiVent data in Figure 3a by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 20348208, Potts-Kant “falsified flexiVent data in Table 1, Figure 1, and Figure 7 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 23560245, Potts-Kant “falsified flexiVent data in Figure 1 and cytokine data in Figure 3 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 21684833, Potts-Kant “falsified flexiVent data in Figures 1 and 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 18818374, Potts-Kant “falsified flexiVent data in Figures 1b and 1c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-



authors for publication.” Defendants admit that the Committee determined that, in connection with PMID 23010656, Potts-Kant “falsified flexiVent data in Figure 2a, 5a, and 5b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants deny any remaining allegations contained in Paragraph 269.

270. Defendants deny that these publications all state that the reported research was funded by NIH Grants AI081672, AI58161, 1-K08-AI068822, AI089756, ESI 1961, ES12717, ES16347, ES16659, ES12496, ES020350, HL05009, 5-R01-HL086887-03 (PMID 20348208), HL91335, 5-P50-HL084917, 5-R01-HL068072, 5-R01-HL058795, 5-R01-HL084123, HL079915, HL77291, HL91335, P50-HL084917, 1-P30-ES011961 (PMID 20348208), ES16126 (PMID 20007931, PMID 18818374), ES02046, and 5-R01-HL081825 (PMID 21684833).

**(vi) Dr. Ledford identifies specific “manipulated” data.**

271. Defendants deny that Exhibit D pertains to or supports the allegations contained in Paragraph 271. Defendants lack sufficient information to form a belief as to the authenticity of Relator\_000116 through Relator\_000119 attached as Exhibit D in Paragraph 271 and, therefore, deny the allegations that relate to that Exhibit. Defendants deny any remaining allegations contained in Paragraph 271.

272. Defendants admit that the documents attached as Relator\_000114 and Relator\_000115 in Exhibit D were created by Dr. Ledford. Defendants deny that Exhibit D pertains to or supports the allegations contained in Paragraph 272. Defendants lack

sufficient information to form a belief as to the authenticity of Relator\_000116 through Relator\_000119 attached as Exhibit D in Paragraph 272 and, therefore, deny the allegations that relate to that Exhibit. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 272 and, therefore, deny those allegations.

273. Defendants deny that Exhibit D pertains to or supports the allegations contained in Paragraph 273. Defendants lack sufficient information to form a belief as to the authenticity of pages Relator\_000116 through Relator\_000119 attached as Exhibit D in Paragraph 273 and, therefore, deny the allegations that relate to that Exhibit. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 273 and, therefore, deny those allegations.

274. Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 6a” of PMID 22502799. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 274 and, therefore, deny those allegations.

275. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 275 and, therefore, deny those allegations.

276. Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 6a” of PMID 22502799. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 276 and, therefore, deny those allegations.

277. Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 6a” of PMID 22502799. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 277 and, therefore, deny those allegations.

278. Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 6a” of PMID 22502799. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 278 and, therefore, deny those allegations.

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

279. Defendants lack sufficient information as to the truth of the allegation regarding Foster’s priority during the review of data produced by Potts-Kant. Defendants deny the remaining allegations contained in Paragraph 279.

280. Defendants deny the allegations contained in Paragraph 280.

281. Defendants admit that Foster was involved in the review of experimental data produced by Potts-Kant. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 281 and, therefore, deny those allegations.

282. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 282 and, therefore, deny those allegations.

283. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 283 and, therefore, deny those allegations.

284. Defendants admit that Duke University researchers repeated experiments and reanalyzed experimental data that Potts-Kant had produced in an attempt to replicate Potts-Kant's results. Defendants deny the remaining allegations contained in Paragraph 284.

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

285. Defendants admit that, in April and May 2013, talking points were distributed to researchers with information regarding how to communicate information about the Potts-Kant data review to individuals outside of Duke. The talking points stated “there was an employment issue within the lab” and that Duke was “continuing to review data generated to identify any corrections that may be needed.” Defendants deny the remaining allegations contained in Paragraph 285.

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

286. Defendants admit that Duke University researchers acknowledged that certain publications may have required retractions after reviewing data that Potts-Kant had produced. Defendants deny the remaining allegations contained in Paragraph 286.

287. Defendants deny the allegations contained in Paragraph 287.

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

288. Defendants admit that, in 2009, 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. Defendants deny any remaining allegations contained in Paragraph 288.

289. Defendants admit the allegations contained in Paragraph 289.

290. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 290 and, therefore, deny those allegations.

291. Defendants admit that 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 acknowledge the financial support of the SPA-Grant (P01AI081672). Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 291 and, therefore, deny those allegations.

292. Defendants admit that Duke University submitted a grant progress report on the SP-A Grant in June 2013 that included research reports based in part on certain data provided by Potts-Kant and the Foster Lab. Defendants deny the remaining allegations contained in Paragraph 292.

293. Defendants admit that Duke University sought renewal of the SP-A project in order to obtain an additional five years of grant funding. Defendants deny the remaining allegations contained in Paragraph 293.

294. Defendants admit that Duke University submitted a renewal grant application for the SP-A grant on September 24, 2013.

295. Because Relator has not defined “recalculation,” Defendant lack sufficient to form a sufficient belief as to the true of the allegations contained in Paragraph 295.

296. Defendants lack sufficient information to form a belief as to the truth of the

allegations contained in Paragraph 296 and, therefore, deny those allegations.

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

297. Defendants lack sufficient knowledge as to the truth of the allegation regarding the statement Dr. Kraft made and whether Foster sought to protect his personal interests. Defendants deny the remaining allegations contained in Paragraph 297.

298. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 298 and, therefore, deny those allegations.

299. Defendants admit that since March 2013, Dr. Kraft, Dr. Hollingsworth, Dr. Ledford, and Mr. Francisco have left the Pulmonary Division, resigning their employment with Duke University. Defendants deny the remaining allegations contained in Paragraph 299 as to DUHS.

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

300. Defendants admit that there were other instances of research misconduct allegations that occurred at Duke University during Potts-Kant's employment. Defendants deny the remaining allegations contained in Paragraph 300.

301. Defendants admit that Dr. Anil Potti was formerly a Duke University medical researcher, focusing on Oncology. Defendants admit that Dr. Potti officially resigned from Duke University on February 1, 2011. Defendants deny any remaining allegations contained in Paragraph 301.

302. Defendants admit the allegations contained in Paragraph 302.

303. Defendants admit that the Potti matter received widespread attention in the

scientific community and in the media. Defendants deny the remaining allegations contained in Paragraph 303.

304. Defendants admit that the events surrounding Dr. Potti's work, in part, prompted the Institute of Medicine to form a committee, which then published a 300 page report titled *Evolution of Translational Omics: Lessons Learned and the Path Forward*. Defendants deny the remaining allegations contained in Paragraph 304.

305. Defendants admit that, on September 10, 2011, The Economist published an article about the Potti matter titled *Misconduct in science: An array of errors*. Defendants admit that, on February 12, 2012, 60 Minutes ran a story on the Potti matter titled "Deception at Duke." Defendants deny any remaining allegations contained in Paragraph 305.

306. Defendants admit that Relator has accurately quoted The Economist article.

307. Defendants admit that on January 26, 2015, Dr. Califf was quoted in the Triangle Business Journal on the Potti matter. 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." Defendants admit that, at the time the Amended Complaint was filed, Dr. Califf had 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. Defendants deny any remaining allegations contained in Paragraph 307.

308. Defendants admit the allegations contained in Paragraph 308.

309. Defendants admit the allegations contained in Paragraph 309 to the extent they relate to the finding of research misconduct against Dr. Shamarendra Sanyal discussed in Paragraph 309. To the extent that it refers to a different separate instance of research misconduct, Defendants lack sufficient information to form a belief as to the truth of the allegation and, therefore, deny that allegation.

310. Defendants admit that on October 11, 2011, HHS published notice in the Federal Register regarding a finding of research misconduct against Dr. Shamarendra Sanyal, a former postdoctoral scholar within the Pulmonary Division. Defendants admit that Dr. Sanyal worked under the supervision of Dr. Eu. Defendants deny any remaining allegations contained in Paragraph 310.

311. Defendants admit that the Office of Research Integrity found that Dr. Sanyal engaged in research misconduct by falsifying data in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI), a sub-agency of NIH. Defendants deny any remaining allegations contained in Paragraph 311.

312. Defendants deny the allegations contained in Paragraph 312.

**J. The Defendants' acts and omissions occurred knowingly.**

313. Defendants admit that Potts-Kant was an employee of Duke University from January 18, 2005 through March 29, 2013. Defendants admit that Foster was an employee of Duke University from July 1, 2002 through March 31, 2015. Defendants deny that Potts-Kant and Foster were employees of DUHS at any time. Defendants deny the remaining allegations contained in Paragraph 313 and, therefore, deny those



allegations.

314. Defendants admit that some Principal Investigators were employees of Duke University. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations.

315. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 315 and, therefore, deny those allegations.

316. Defendants admit that Potts-Kant told the Committee that, while she was employed at Duke University, she “fabricated and/or falsified Flexivent (sic) and multiplex (cytokine) data that were included in various publications and grant applications. . . .” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 316 and, therefore, deny those allegations.

317. Defendants lack sufficient information to form a belief as to the truth of what Foster knew regarding the reported research results contained in Paragraph 317 and, therefore, deny those allegations. Defendants deny the remaining allegations contained in Paragraph 317.

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

318. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 318 and, therefore, deny those allegations.

319. Defendants admit that, at some point in time, Dr. Jaime Cyphert requested a copy of Potts-Kant’s script for the flexiVent machine. Defendants lack sufficient

information to form a belief as to the truth of the remaining allegations contained in Paragraph 319 and, therefore, deny those allegations.

320. Defendants admit that the Foster Lab did not share Potts-Kant's flexiVent script with other researchers. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 320 and, therefore, deny those allegations.

321. Defendants lack sufficient information to form a belief as to the truth of the allegation regarding what Dr. Eu told Foster or Hollingsworth contained in Paragraph 321 and, therefore, deny those allegations. Defendants admit that, in 2011, Dr. Eu asked Potts-Kant to perform an experiment to which she was blinded. Defendants deny any remaining allegations contained in Paragraph 321.

322. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 322 and, therefore, deny those allegations.

323. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 323 and, therefore, deny those allegations.

324. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 324 and, therefore, deny those allegations.

325. Defendants deny the allegations contained in Paragraph 325.

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

326. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 326 and, therefore, deny those allegations.

327. Defendants admit that Potts-Kant's method of processing mice through the flexiVent machine deviated from the methods used by other researchers conducting similar experiments. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 327 and, therefore, deny those allegations.

328. Because Relator has not specified a time period for his allegation that there were only two flexiVent machines in the Pulmonary Division alleged in Paragraph 328, Defendants lack sufficient information to form a belief as to the truth of whether there were *only* two flexiVent machines in the Pulmonary Division and, therefore, deny those allegations. Defendants admit that there were at least two flexiVent machines in the Pulmonary Division: one in the Foster Lab and one in the laboratory of Dr. Walker. Defendants admit that Ms. Theriot operated the flexiVent machine in Dr. Walker's lab. Defendants deny any remaining allegations contained in Paragraph 328.

329. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 329 and, therefore, deny those allegations.

330. Defendants admit that it took Potts-Kant and Ms. Theriot different amounts of time to process a mouse through the flexiVent machine. Defendants lack sufficient information to form a belief as to the truth of the time it would take Potts-Kant and Ms. Theriot to process each mouse. Defendants deny any remaining allegations contained in Paragraph 330.

331. Defendants lack sufficient information to form a belief as to the truth of the

allegations contained in Paragraph 331 and, therefore, deny those allegations.

332. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 332 and, therefore, deny those allegations.

333. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 333 and, therefore, deny those allegations.

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

334. Defendants admit that Foster was a supervisor of Potts-Kant's work. Defendants deny Sentence 2 of Paragraph 334. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 334 and, therefore, deny those allegations.

335. Defendants admit that the Committee determined that Foster failed to implement "some type of 'quality' review of the data generated in his laboratory." Defendants admit that the Committee further determined that, "[d]espite not undertaking this direct review of [Potts-Kant's] source data, Dr. Foster did not leave [Potts-Kant] to work in isolation. Dr. Foster involved [Potts-Kant] as an integral member of the laboratory team and involved her in laboratory meetings and other discussions of experimental methods and laboratory operations." Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 335 and, therefore, deny those allegations.

336. Defendants admit that the Committee determined that "there appears to have been no request for periodic review of [Potts-Kant's] source data by the investigators"

working with Potts-Kant. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 336 and, therefore, deny those allegations.

337. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 337 and, therefore, deny those allegations.

338. Defendants deny the allegations contained in Paragraph 338.

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

339. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 339 and, therefore, deny those allegations.

340. Defendants admit that Principal Investigators began questioning Potts-Kant's research results in March 2013. Defendants deny the remaining allegations contained in Paragraph 340.

341. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 341 and, therefore, deny those allegations.

**K. The Defendants' acts and omissions were material.**

342. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 342 and its subparts and, therefore, deny those allegations.

343. Defendants deny the allegations contained in Paragraph 343.

**L. Failure to Disclose and Concealment.**

344. Defendants lack sufficient information to form a belief as to the truth of the

allegations regarding Foster contained in Paragraph 344 and, therefore, deny those allegations. Defendants deny the remaining allegations contained in Paragraph 344.

345. Defendants deny the allegations contained in Paragraph 345.

## **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. Defendants incorporate by reference the preceding Paragraphs of this Answer.

347. Defendants admit that Relator seeks relief against Defendants under the False Claims Act.

348. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 348 and, therefore, deny those allegations.

349. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 349 and, therefore, deny those allegations.

350. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 350 and, therefore, deny those allegations.

351. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 351 and, therefore, deny those allegations.

352. Defendants deny the allegations contained in Paragraph 352.

353. Defendants deny the allegations contained in Paragraph 353.

354. Defendants deny the allegations contained in Paragraph 354.

355. Defendants deny the allegations contained in Paragraph 355.

356. Defendants deny the allegations contained in Paragraph 356.

357. Defendants deny the allegations contained in Paragraph 357.

358. Defendants deny the allegations contained in Paragraph 358.

359. Defendants deny the allegations contained in Paragraph 359.

**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. Defendants incorporate by reference the preceding Paragraphs of this Answer.

361. Defendants admit that Relator seeks relief against Defendants under the False Claims Act.

362. Defendants deny the allegations contained in Paragraph 362.

363. Defendants deny the allegations contained in Paragraph 363.

364. Defendants deny the allegations contained in Paragraph 364.

365. Defendants deny the allegations contained in Paragraph 365.

366. Defendants deny the allegations contained in Paragraph 366.

367. Defendants deny the allegations contained in Paragraph 367.

368. Defendants deny the allegations contained in Paragraph 368.

369. Defendants deny the allegations contained in Paragraph 369.

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

370. Defendants incorporate by reference the preceding Paragraphs of this Answer.

371. Defendants admit that Relator seeks relief against Defendants under the False Claims Act.

372. Defendants deny the allegations contained in Paragraph 372.

373. Defendants deny the allegations contained in Paragraph 373.

374. Defendants deny the allegations contained in Paragraph 374.

375. Defendants deny the allegations contained in Paragraph 375.

376. Defendants deny the allegations contained in Paragraph 376.

377. Defendants deny the allegations contained in Paragraph 377.

378. Defendants deny the allegations contained in Paragraph 378.

379. Defendants deny the allegations contained in Paragraph 379.

**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. Defendants incorporate by reference the preceding Paragraphs of this Answer.

381. Defendants admit that Relator seeks relief against Defendants under the False Claims Act.

382. Defendants deny the allegations contained in Paragraph 382.

383. Defendants deny the allegations contained in Paragraph 383.

384. Defendants deny the allegations contained in Paragraph 384.

385. Defendants deny the allegations contained in Paragraph 385.

386. Defendants deny the allegations contained in Paragraph 386.



387. Defendants deny the allegations contained in Paragraph 387.

388. Defendants deny the allegations contained in Paragraph 388.

389. Defendants deny the allegations contained in Paragraph 389.

390. Defendants deny the allegations contained in Paragraph 390.

391. Defendants deny the allegations contained in Paragraph 391.

**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. Defendants incorporate by reference the preceding Paragraphs of this Answer.

393. Defendants admit that Relator seeks relief against Defendants under the False Claims Act.

394. Defendants deny the allegations contained in Paragraph 394.

395. Defendants deny the allegations contained in Paragraph 395.

396. Defendants deny the allegations contained in Paragraph 396.

397. Defendants deny the allegations contained in Paragraph 397.

398. Defendants deny the allegations contained in Paragraph 398.

399. Defendants deny the allegations contained in Paragraph 399.

400. Defendants deny the allegations contained in Paragraph 400.

401. Defendants deny the allegations contained in Paragraph 401.

402. Defendants deny the allegations contained in Paragraph 402.

**DEFENSES**

### **FIRST DEFENSE**

**Relator's claims are barred, in whole or in part, by the statute of limitations contained in the federal False Claims Act.**

### **SECOND DEFENSE**

**Relator's claims against Defendants are barred in whole or in part by government knowledge.**

### **THIRD DEFENSE**

**Relator's claims are barred under the False Claims Act public disclosure bar because the claims, allegations, and transactions described in the Amended Complaint were "publicly disclosed" prior to the filing or unsealing of the lawsuit; and (2) Plaintiffs are not an "original source" of the information as defined by section 3730(e)(4)(B).**

### **FOURTH DEFENSE**

**The damages and civil fines Relator seeks are grossly disproportionate to Defendants' alleged conduct and, therefore, would violate the Excessive Fines Clause of the Eighth Amendment of the United States Constitution if Defendants were held liable under Plaintiff's theory of the case.**

### **FIFTH DEFENSE**

**The damages and civil fines Relator seeks are grossly disproportionate to Defendants' alleged conduct and, therefore, would violate the Due Process Clause of the Fifth Amendment of the United States Constitution if Defendants were held**

liable under Plaintiff's theory of the case.

### SIXTH DEFENSE

Defendants herein reserve the right to assert additional affirmative defenses that become known to them during the course of this action.

### DEMAND FOR JUDGMENT

WHEREFORE, Defendants respectfully pray for relief against Relator as follows:

- (i) An award dismissing Relator's First Amended Complaint with prejudice
- (ii) Judgment in favor of Defendants;
- (iii) An award of Defendants' attorneys' fees and expenses;
- (iv) An award of all of Defendants' costs and expenses of the suit; and
- (v) Such other relief as the Court may deem just and proper.

Dated: June 19, 2017

Respectfully submitted,

/s/ Carol Poindexter

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*Counsel for Defendants Duke University  
and Duke University Health System, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on June 19, 2017 the foregoing document was filed electronically with the Clerk of the Court using the CM/ECF and served upon counsel of record.

/s/ Carol Poindexter  
Carol Poindexter

## EXHIBIT E<sup>1</sup>

### **PMID 22052876-*Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring***

1. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring*. Defendants deny that Exhibit B, at Relator\_000226, pertains to or supports the allegations contained in Paragraph 1. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

2. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 4 of this paper. Defendants admit that Potts-Kant was involved in producing Multiplex data for Figure 1 and Figure 3. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 2 and, therefore, deny these allegations.

3. Defendants admit that the Committee determined that Potts-Kant “falsified multiplex data in Figures 1 and 3 and flexiVent data in Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in

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<sup>1</sup> Defendants have included the headings from Relator’s Amended Complaint in their Answer for the Court’s reference. Defendants have not provided a response to these headings.

Paragraph 3 and, therefore, deny those allegations.

4. Defendants admit that the paper entitled *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring* was published on April 1, 2012, by the American Journal of Respiratory Cell and Molecular Biology. Defendants deny any remaining allegations contained in Paragraph 4.

5. Defendants admit that the paper entitled *Maternal Diesel Inhalation Increases Airway Hyperreactivity in Ozone-Exposed Offspring* cites financial support from Environmental Protection Agency Children's Environmental Health Center Award RD 83329301 and NIH grant ES-016347. Defendants deny the remaining allegations contained in Paragraph 5.

**PMID21960548 - *Protective Role of T-bet and Th1 Cytokines in Pulmonary Graft-versus-Host Disease and Peribronchiolar Fibrosis.***

6. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Protective Role of T-bet and Th1 Cytokines in Pulmonary Graft-versus-Host Disease and Peribronchiolar Fibrosis.* Defendants deny that Exhibit B, at Relator\_000429, pertains to or supports the allegations contained in Paragraph 6. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

7. Defendants admit that Potts-Kant was involved in producing the data published in Figure 2I and Figure 2J (flexiVent) of the paper. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 7

and, therefore, deny those allegations.

8. Defendants admit that the Committee determined that “flexiVent data in Figures 2I and 2J matched the source data.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 8 and, therefore, deny those allegations.

9. Defendants admit that the article entitled *Protective Role of T-bet and Th1 Cytokines in Pulmonary Graft-versus-Host Disease and Peribronchiolar Fibrosis* was published on February 1, 2012, in the American Journal of Respiratory Cell and Molecular Biology. Defendants deny any remaining allegations contained in Paragraph 9.

10. Defendants admit that the paper entitled *Protective Role of T-bet and Th1 Cytokines in Pulmonary Graft-versus-Host Disease and Peribronchiolar Fibrosis* cites financial support from International Society for Heart and Lung Transplantation Research Award 6860201585, and NIH Grants 1-P50-HL084917-01, 1-F32HL090265-01, RR024 127-03, 1-P30 ES-011961-01A1, 1-K24 HL91140-01A2 and A1081672. Defendants deny the remaining allegations contained in Paragraph 10.

**PMID 21930959 – *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation***

11. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages That Limit Oxidative Stress and Inflammation*. Defendants deny that



Exhibit B, at Relator\_000285, pertains to or supports the allegations contained in Paragraph 11. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

12. Defendants admit that Potts-Kant was involved in producing flexiVent and multiplex data for Figures 5C and 5G of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 12 and, therefore, deny those allegations.

13. Defendants admit that the *Journal of Immunology* stated that the researchers notified the journal that they were able to replicate the study in Figure 5C and that “the new data support the originally published findings.” Defendants admit that the *Journal of Immunology* stated that the researchers notified the journal that they “were unable to repeat the experiments in Fig. 5G[.]” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 13 and, therefore, deny those allegations.

14. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 14 and, therefore, deny those allegations.

15. Defendants admit the allegations contained in Paragraph 15.

16. Defendants admit that the article entitled *Ozone Inhalation Promotes CX3CR1-dependent Maturation of Resident Lung Macrophages which Limit Oxidative Stress and Inflammation* cites financial support from NIH grants ES016126, ES016347,

ES020426, and HL077291. Defendants deny the remaining allegations in Paragraph 16.

**PMID 23560245 – *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase***

17. Defendants admit that Potts-Kant and others co-authored an article entitled *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase*. Defendants deny that Exhibit B, at Relator\_000120, pertains to or supports the allegations contained in Paragraph 17. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

18. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1 of this paper. Defendants admit that Potts-Kant was involved in producing cytokine data for Figure 3 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 18 and, therefore, deny those allegations.

19. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 1 and cytokine data in Figure 3 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 19 and, therefore, deny those allegations.

20. Defendants lack sufficient information to form a belief as to the truth of the

allegations contained in Paragraph 20 and, therefore, deny those allegations.

21. Defendants admit the allegations contained in Paragraph 21.

22. Defendants admit that the article entitled *Extracellular Matrix Protein Mindin is Required for the Complete Allergic Response to Fungal-Associated Proteinase* cites financial support from NIH grants ES016126, ES020426, and HL77291. Defendants deny the remaining allegations in Paragraph 22.

**PMID 21784966-*S-nitrosoglutathione* supplementation to ovalbumin-sensitized and –challenged mice ameliorates methacholine-induced bronchoconstriction**

23. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *S-nitrosoglutathione supplementation to ovalbumin-sensitized and –challenged mice ameliorates methacholine-induced bronchoconstriction*. Defendants deny that Exhibit B, at Relator\_000405, pertains to or supports the allegations contained in Paragraph 23. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

24. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1B, Figure 1C, Figure 2B, and Figure 2C of this paper. Defendants admit that Potts-Kant was involved in producing cytokine data for Figure 4 of this paper. Defendants deny any remaining allegations contained in Paragraph 24.

25. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 2b and cytokine data in Figure 4 by changing certain numerical

values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants further admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figures 1b and 1d. Defendants admit that the *American Journal of Physiology – Lung Cellular and Molecular Physiology* stated that the “authors became aware that the primary data used to calculate the in vivo pulmonary mechanics results were inconsistent with the flexiVent machine-generated raw data, making the data presented in Figs. 1B, 1C, 2B, and 2C unreliable. Moreover, multiplex data presented in Fig. 4 did not match machine-generated raw data, making this data also unreliable.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 25 and, therefore, deny those allegations.

26. Defendants admit the allegations contained in Paragraph 26.

27. Defendants admit that the article entitled *S-nitrosoglutathione supplementation to ovalbumin-sensitized and -challenged mice ameliorates methacholine-induced bronchoconstriction* cites financial support from National Heart Lung and Blood Institute Grant HL086887. Defendants deny the remaining allegations contained in Paragraph 27.

**PMID 21724860 – *NOS2 regulation of LPS-induced airway inflammation via S-Nitrosylation of NF- $\kappa$ B p65***

28. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of*

*NF $\kappa$ B p65*. Defendants deny that Exhibit B, at Relator\_000387, pertains to or supports the allegations contained in Paragraph 28. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

29. Defendants admit that Potts-Kant was involved in producing cytokine data for Figure 3 of this paper. Defendants admit that the Committee determined that Potts-Kant “falsified cytokine data in Figure 3 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained Paragraph 29 and, therefore, deny those allegations.

30. Defendants admit that the article entitled *NOS2 regulation of LPS-induced airway inflammation via S-nitrosylation of NF- $\kappa$ B p65* cites financial support from the March of Dimes, and NIH grants ES016374 and HL092994. Defendants deny the remaining allegations in Paragraph 30.

**PMID 21471107 – *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice***

31. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice*. Defendants deny that Exhibit B, at Relator\_000105, pertains to or supports the allegations contained in Paragraph 31. Defendants lack sufficient

information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

32. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 6 and Figure 8 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 32 and, therefore, deny those allegations.

33. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 5, 6, and 8 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 33 and, therefore, deny those allegations.

34. Defendants admit that the article entitled *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice* was published on June 15, 2011, by the American Journal of Respiratory and Critical Care Medicine. Defendants deny any remaining allegations contained in Paragraph 34.

35. Defendants admit that the article entitled *c-Kit is Essential for Alveolar Maintenance and Protection from Emphysema-like Disease in Mice* cites financial support from NIH grants ES015675, ES016126, ES016659, ES016347, HL077763, HL090146, HL085655, and the German Ministry of Education and Research/National Genome Research Network grant NGFN2:1GR0430. Defendants deny the remaining

allegations in Paragraph 35.

**PMID 21411739 – *β-arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix***

36. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *β-arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix*. Defendants deny that Exhibit B, at Relator\_000076, pertains to or supports the allegations contained in Paragraph 36. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

37. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 37 and, therefore, deny those allegations.

38. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 38 and, therefore, deny those allegations.

39. Defendants admit the allegations contained in Paragraph 39.

40. Defendants admit that the article entitled *β-arrestin Deficiency Protects Against Pulmonary Fibrosis in Mice and Prevents Fibroblast Invasion of Extracellular Matrix* cites financial support from NIH grants HL060539, HL077291, HL16037, HL70631 and HL016347. Defendants deny the remaining allegations in Paragraph 40.

**PMID 21285515 – *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation***

41. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Particulate allergens potentiate allergic asthma in mice through sustained IgE-*

*mediated mast cell activation*. Defendants deny that Exhibit B, at Relator\_000304, pertains to or supports the allegations contained in Paragraph 41. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

42. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1A, Figure 2A, and Figure 7D. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 42 and, therefore, deny those allegations.

43. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 43 and, therefore, deny those allegations.

44. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 1a, 2a (middle panel), and 7d by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 2a (right panel).” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 44 and, therefore, deny those allegations.

45. Defendants admit the allegations contained in Paragraph 45.

46. Defendants admit that the article entitled *Particulate allergens potentiate allergic asthma in mice through sustained IgE-mediated mast cell activation* cites financial support from NIH grants AI081672, ES016347, AI056101, AI150021,



AI074751, DK077307, DK077159, and DK050814. Defendants deny the remaining allegations in Paragraph 46.

**PMID 21252304 – *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma***

47. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma*. Defendants deny that Exhibit B, at Relator\_000143, pertains to or supports the allegations contained in Paragraph 47. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

48. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1A, Figure 1B, Figure 2a, and Figure 2b of the paper. Defendants admit that Potts-Kant was involved in producing cytokine data for Figure 4 and Table 1 of the paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 48, and therefore, deny those allegations.

49. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 1a, 1b, and 2b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication. Defendants further admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figures 1a and 2a” of the paper. Defendants admit that the journal, *Proceedings of the National Academy of Sciences of*

*the United States of America*, stated that the authors reported that the “primary data provided by the pulmonary function laboratory for calculating the in vivo pulmonary mechanics results are inconsistent with the machine-generated raw data, and that most primary data from Multiplex assays of cytokines collected in the bronchoalveolar lavage fluid cannot be located.” Defendants admit that the journal further stated that the authors reported that the above statements applied to Figure 2, part of Figure 4, and Table 1. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 49 and, therefore, deny those allegations.

50. Defendants admit that allegations contained in Paragraph 50.

51. Defendants admit that the article entitled *Gastrin-releasing peptide blockade as a broad-spectrum anti-inflammatory therapy for asthma* cites financial support from the Established Investigator Award from America Asthma Foundation, and NIH grants AI081672 and ES016347. Defendants deny the remaining allegations contained in Paragraph 51.

**PMID 20543006 – *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac***

52. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac*. Defendants deny that Exhibit B, at Relator\_000368, pertains to or supports the allegations contained in Paragraph 52. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny

those allegations.

53. Defendants admit that that Potts-Kant was involved in producing multiplex data in Figure 2 of the paper. Defendants deny any remaining allegations contained in Paragraph 53.

54. Defendants admit that a researcher discovered that data contained in Figure 2 of the paper was not reliable. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 54 and, therefore, deny those allegations.

55. Defendants admit that the Committee determined that Potts-Kant “falsified multiplex data in Figure 2 and flexiVent data in Figure 6 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 55 and, therefore, deny those allegations.

56. Defendants admit the allegations contained in Paragraph 56.

57. Defendants admit that the article entitled *MARCKS-related peptide modulates in vivo the secretion of airway Muc5ac* cites financial support from NIH grants HL82504, HL81763, HL36982, ES16347 and P01-AI81672. Defendants deny the remaining allegations contained in Paragraph 57.

58. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 58 and, therefore, deny those allegations.

**PMID 20386143– Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats**

59. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats*. Defendants deny that Exhibit B, at Relator\_000214, pertains to or supports the allegations contained in Paragraph 59. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

60. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 2A and Figure 2B. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 60 and, therefore, deny those allegations.

61. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 2a and 2b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 61 and, therefore, deny those allegations.

62. Defendants admit the allegations contained in Paragraph 62.

63. Defendants admit that the article entitled *Mast Cells Mediate Hyperoxia-Induced Airway Hyper-reactivity in Newborn Rats* cites financial support from the

Children's Miracle Network, National Institutes of Child Health and Human Development grant HD043728, National Heart, Lung and Blood Institute grant HL067021, and NIH grants ES011961 and ES012496. Defendants deny the remaining allegations contained in Paragraph 63.

**PMID 20348208 – *Nitric Oxide Mediates Relative Airway Hyperresponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice***

64. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Nitric Oxide Mediates Relative Airway Hyporesponsiveness to Lipopolysaccharide in Surfactant Protein A-Deficient Mice*. Defendants deny that Exhibit B, at Relator\_000269, pertains to or supports the allegations contained in Paragraph 64. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

65. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1, Figure 7, and Table 1 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 65 and, therefore, deny those allegations.

66. Defendants admit that the journal, *American Journal of Respiratory Cell and Molecular Biology*, stated that the authors reported that they “could not confirm the major finding of the publication that treatment with the inducible nitric oxide synthase-specific inhibitor 1400W abrogated relative airway hyporesponsiveness in LPS-treated

SP-A<sup>-/-</sup> mice, nor could it confirm that treatment with 1400W further enhanced airway responsiveness in LPS-treated wild-type mice, as reported in Figure 7.” Defendants deny the first sentence as to Table 1 and Figure 1, as the *American Journal of Respiratory Cell and Molecular Biology* stated that the authors reported that they were “able to substantiate the results shown in Table 1 and Figure 1.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 66 and, therefore, deny those allegations.

67. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Table 1, Figure 1 and Figure 7 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 67 and, therefore, deny those allegations.

68. Defendants admit that the article entitled *Nitric Oxide Mediates Relative Airway Hyporesponsiveness to Lipopolysaccharide in Surfactant Protein A- Deficient Mice* was published on February 1, 2011, by the American Journal of Respiratory Cell and Molecular Biology. Defendants deny any remaining allegations contained in Paragraph 68.

69. Defendants admit that the article entitled *Nitric Oxide Mediates Relative Airway Hyporesponsiveness to Lipopolysaccharide in Surfactant Protein A- Deficient Mice* cites financial support from NIH grants 1K08-AI068822, 5P50HL084917,

5R01HL068072, 5R01HL058795, 1P30ES011961, 5R01HL084123, 5R01HL081285, 5R01HL086887-03 and HL079915. Defendants deny the remaining allegations contained in Paragraph 69.

**PMID 19762564 – *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice***

70. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice*. Defendants deny that Exhibit B, at Relator\_000233, pertains to or supports the allegations contained in Paragraph 70. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

71. Defendants admit that Potts-Kant was involved in producing Multiplex data in Figure 2 and Figure 4 of this paper. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 5 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 71 and, therefore, deny those allegations.

72. Defendants admit that the Committee determined that Potts-Kant “falsified multiplex data in Figure 4 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants further admit that the journal, *American Journal of Respiratory and Critical Care Medicine*, stated that the authors reported that they “had reexamined

the raw data used in their article and determined that the results reported in Figures 2, 4, and 5 were unreliable.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 72 and, therefore, deny those allegations.

73. Defendants admit that the article entitled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice* was published on December 15, 2009, in the American Journal of Respiratory and Critical Care Medicine. Defendants deny any remaining allegations contained in Paragraph 73.

74. Defendants admit that the article entitled *Maternal Exposure to Particulate Matter Increases Postnatal Ozone-induced Airway Hyperreactivity in Juvenile Mice* cites financial support from Children's Environmental Health Center Award RD 83329301-0, and NIH grants ES011961 and ES016347. Defendants deny the remaining allegations contained in Paragraph 74.

**PMID 1958159 – NPAS3 is a tracheless homolog critical for lung development and homeostasis**

75. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NPAS3 is a tracheless homolog critical for lung development and homeostasis*. Defendants deny that Exhibit B, at Relator\_000279, pertains to or supports the allegations contained in Paragraph 75. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.



76. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 4D of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 76 and, therefore, deny those allegations.

77. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 4d by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 77 and, therefore, deny those allegations.

78. Defendants admit that the allegations contained in Paragraph 78.

79. Defendants admit that the article entitled *NPAS3 is a trachealess homolog critical for lung development and homeostasis* cites financial support from the Established Investigator Award from the American Asthma Foundation, and NIH grants ES 011961, ES016347, and 2R01 HL44984. Defendants deny the remaining allegations contained in Paragraph 79.

**PMID 19324975 – *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols***

80. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols*. Defendants deny that Exhibit B, at Relator\_000421, pertains to or supports the allegations contained in Paragraph 80. Defendants lack sufficient

information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

81. Defendants admit that Potts-Kant was involved in producing flexiVent data in Figure 5 of the paper. Defendants admit that Potts-Kant was involved in producing multiplex data in Figure 7 of the paper. Defendants lack sufficient information to form a belief as to the remaining allegations in Paragraph 81 and, therefore, deny these allegations.

82. Defendants admit that the Committee determined that Potts-Kant “fabricated PV loop flexiVent data in Figure 5b (ENO and O, LPS data) and multiplex (cytokine) data in Figure 7.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 82 and, therefore, deny those allegations.

83. Defendants admit the allegations contained in Paragraph 83.

84. Defendants admit that the article entitled *Protection from Lipopolysaccharide-induced Lung Injury by Augmentation of Airway S-Nitrosothiols* cites financial support from NIH grants U19-ES12496, ES11961, American Lung Association Grant RG-11485, the March of Dimes, and the Jean and George Brumley, Jr. Neonatal-Prenatal Research Institute. Defendants deny the remaining allegations contained in Paragraph 84.

***PMID 19204996 – A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized 3He MRI***

85. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized 3He MRI*. Defendants deny that the article can be found in Exhibit B.

86. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 3B and Figure 3C of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 86 and, therefore, deny those allegations.

87. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 3b and 3c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 87 and, therefore, deny those allegations.

88. Defendants admit the allegations contained in Paragraph 88.

89. Defendants admit that an article entitled *A Robust Protocol for Regional Evaluation of Methacholine Challenge in Mouse Models of Allergic Asthma Using Hyperpolarized 3He MRI* cites financial support from Merck & Co, Inc., and NIH Grants ES 11961, ES 16347, P41 RR005959, 5R21HL87094-2, 1-P30ES0111961, 5-R01HL084123, 5-R01HL081285, 5-R01HL086887-03, and HL079915. Defendants deny the remaining allegations contained in Paragraph 89.

**PMID 19059883 – *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans***

90. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans*. Defendants deny that the article entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans* is found in Exhibit B, at Relator\_000249.

91. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 91 and, therefore, deny those allegations.

92. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 1 by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 92 and, therefore, deny those allegations.

93. Defendants admit that an article entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans* was published on July 1, 2009, by the American Journal of Respiratory Cell and Molecular Biology. Defendants deny any remaining allegations contained in Paragraph 93.

94. Defendants admit that the article entitled *NAD(P)H Quinone Oxidoreductase 1 Is Essential for Ozone-Induced Oxidative Stress in Mice and Humans* cites financial support from NIH grants HL082504, HL081763, ES07943, ES011961, and ES012496. Defendants deny the remaining allegations contained in Paragraph 94.

**PMID 18802477- *In utero supplementation with methyl donors enhances allergic airway disease in mice***

95. Defendants admit that Potts-Kant and others co-authored an article entitled *In utero supplementation with methyl donors enhances allergic airway disease in mice*. Defendants deny that Exhibit B, at Relator\_000185, pertains to or supports the allegations contained in Paragraph 95. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

96. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 1A of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 96 and, therefore, deny those allegations.

97. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 1A by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 97 and, therefore, deny those

allegations.

98. Defendants admit the allegations contained in Paragraph 98.

99. Defendants admit that the article entitled *In utero supplementation with methyl donors enhances allergic airway disease in mice* cite financial support from the Intramural Research Program of the NIH, National Heart, Lung and Blood Institute, and National Heart, Lung and Blood Institute grant HL91335. Defendants deny the remaining allegations contained in Paragraph 99.

**PMID 18566189 – *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury***

100. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury*. Defendants deny that Exhibit B, at Relator\_000319, pertains to or supports the allegations contained in Paragraph 100. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

101. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 6 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 101 and, therefore, deny those allegations.

102. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 102 and, therefore, deny those allegations.

103. Defendants admit the allegations contained in Paragraph 103.

104. Defendants admit that the article entitled *A micro-CT analysis of murine lung recruitment in bleomycin-induced lung injury* cites financial support from the National Center for Research Resources, National Cancer Institute National Biomedical Technology Resource Award P41 RR-005959, 024-CA-092656, and NIH grant ES011961. Defendants deny the remaining allegations contained in Paragraph 104.

***PMID 18539952 – Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis***

105. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis*. Defendants deny that Exhibit B, at Relator\_000098, pertains to or supports the allegations contained in Paragraph 105. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

106. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 106 and, therefore, deny those allegations.

107. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 107 and, therefore, deny those allegations.

108. Defendants admit that an article entitled *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis* was published on November 1, 2008, by the American Journal of Respiratory Cell and

Molecular Biology. Defendants deny the remaining allegations contained in Paragraph 108.

109. Defendants admit that the article entitled *Chronic LPS Inhalation Causes Emphysema-Like Changes in Mouse Lung that Are Associated with Apoptosis* cites financial support from the Intramural Research Programs at the National Institute of Environmental Health Sciences and the National Heart, Lung, and Blood Institute, the Department of Veterans Affairs (Merit Review), and NIH grants ES11375, ES7498, ES9607, ES11961, AI58161 and HL91335. Defendants deny the remaining allegations contained in Paragraph 109.

**PMID 23010656 – *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness***

110. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness*. Defendants deny that Exhibit B, at Relator\_000162, pertains to or supports the allegations contained in Paragraph 110. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

111. Defendants admit that Potts-Kant was involved in producing flexiVent data in Figure 2A, Figure 5A, and Figure 5C of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 111 and, therefore, deny those allegations.



112. Defendants admit that the journal, *Environmental Health Perspectives*, stated that the authors reported that they “proceeded to replicate experiments of animal airway physiology presented in Figure 2A. These replicate experiments failed to validate the originally reported role of Nlrp3, ASC, and caspase 1 in airway hyperresponsiveness after exposure to ozone.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 112 and, therefore, deny those allegations.

113. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figure 2a, 5a, and 5b by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 113 and, therefore, deny those allegations.

114. Defendants admit the allegations contained in Paragraph 114.

115. Defendants admit that the article entitled *Hyaluronan Activation of the Nlrp3 Inflammasome Contributes to the Development of Airway Hyperresponsiveness* cites financial support from NIH grants ES016126, AI081672, ES020350, ES020426, AI089756, and an unrestricted educational grant from China Scholarship Counsel. Defendants deny the remaining allegations contained in Paragraph 115.

**PMID 22815821 – *Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice***

116. Defendants admit that Potts-Kant and others co-authored an article entitled *Innate Immune Activation by Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice*. Defendants deny that Exhibit B, at Relator\_000193, pertains to or supports the allegations contained in Paragraph 116. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

117. Defendants admit that Potts-Kant was involved in producing cytokine data for Figure 9 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 117 and, therefore, deny those allegations.

118. Defendants admit that the journal, *PLOS One*, stated that the authors reported “concerns about the reliability of a subset of the reported data, specifically the data underlying Figures 7–9 and the observation that NAC alters the response to silica and LPS in mouse lung. The authors have discovered discrepancies between the raw data from the pulmonary function laboratory and the data it provided for publication[.]” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 118 and, therefore, deny those allegations.

119. Defendants admit the allegations contained in Paragraph 119.

120. Defendants admit that the article entitled *Innate Immune Activation by*

*Inhaled Lipopolysaccharide, Independent of Oxidative Stress, Exacerbates Silica-Induced Pulmonary Fibrosis in Mice* cites financial support from the March of Dimes, and NIH grants ES016126, ES016000, and AI081672. Defendants deny the remaining allegations contained in Paragraph 120.

**PMID 22659878-*NAD(P)H:Quinone Oxidoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice***

121. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NAD(P)H:Quinone Oxidoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice*. Defendants deny that Exhibit B, at Relator\_000242, pertains to or supports the allegations contained in Paragraph 121. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

122. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 3d of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 122 and, therefore, deny those allegations.

123. Defendants admit that the Committee determined that Potts-Kant “falsified flexiVent data in Figures 2 and 3d by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figures 2 and 3d.” Defendants lack sufficient information to

form a belief as to the truth of the remaining allegations contained in Paragraph 123 and, therefore, deny those allegations.

124. This scientific paper was accepted for publication on February 2, 2012 by the scientific journal *Free Radical Biology & Medicine*.

124. Defendants admit that an article entitled *NAD(P)H:Quinone Oxidoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice* was accepted for publication on November 22, 2011, by the scientific journal *Free Radical Biology & Medicine*. Defendants deny the remaining allegations contained in Paragraph 124.

125. Defendants admit that the article entitled *NAD(P)H:Quinone Oxidoreductase 1 Protects Lungs From Oxidant-Induced Emphysema in Mice* cites financial support from NIH grants ES016126, ES020426, and ES016347. Defendants deny the remaining allegations contained in Paragraph 125.

**PMID 23275341 – *NADPH:Quinone Oxidoreductase 1 Regulates Host Susceptibility to Ozone via Isoprostane Generation***

126. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NADPH:Quinone Oxidoreductase 1 Regulates Host Susceptibility to Ozone via Isoprostane Generation*. Defendants deny that Exhibit B, at Relator\_000574, pertains to or supports the allegations contained in Paragraph 126. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

127. Defendants lack sufficient information to form a belief as to the truth of the

allegations contained in Paragraph 127 and, therefore, deny those allegations.

128. Defendants lack sufficient information to form a belief as to the truth of the allegations contained in Paragraph 128 and, therefore, deny those allegations.

129. Defendants admit the allegations contained in Paragraph 129.

130. Defendants admit that the article entitled *NADPH:Quinone Oxidoreductas1 Regulates Host Susceptibility to Ozone via Isoprostane Generation cites financial support from NIH grant R01-ES016836*. Defendants deny the remaining allegations contained in Paragraph 130.

**PMID 22659878-*NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia***

131. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia*. Defendants deny that Exhibit B, at Relator\_000565, pertains to or supports the allegations contained in Paragraph 131. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

132. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 3b and 3c of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 132 and, therefore, deny those allegations.

133. Defendants admit that the Committee determined that Potts-Kant “falsified

multiplex (cytokine) data in Figures 3b and 3c by changing certain numerical values in the dataset generated by the experiment before providing it to the collaborating investigators/co-authors for publication.” Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 133 and, therefore, deny those allegations.

134. Defendants admit that an article entitled *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia* was published on August 1, 2012 by the American Journal of Physiology-Lung Cellular and Molecular Physiology. Defendants deny the remaining allegations contained in Paragraph 134.

135. Defendants admit that the article entitled *NAD(P)H quinone oxidoreductase 1 regulates neutrophil elastase-induced mucous cell metaplasia* cites financial support from the Duke Children's Miracle Network grant, and NIH grants T32-HL098099, R01-HL082504, and R01-ES016347. Defendants deny the remaining allegations contained in Paragraph 135.

***PMID 22241062-Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized <sup>3</sup>He magnetic resonance imaging in an allergic mouse model***

136. Defendants admit that Potts-Kant, Foster, and others co-authored an article entitled *Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized <sup>3</sup>He magnetic resonance imaging in an allergic mouse model*. Defendants deny that Exhibit B pertains to or supports the allegations contained in

Paragraph 136. Defendants lack sufficient information to form a belief as to the authenticity of the document referenced in Exhibit B and therefore, deny those allegations.

137. Defendants admit that Potts-Kant was involved in producing flexiVent data for Figure 8 of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 137 and, therefore, deny those allegations.

138. Defendants admit that the Committee determined that Potts-Kant “fabricated flexiVent data in Figure 8 and Bronchoalveolar lavage (BAL) data in Figure 7” of this paper. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations contained in Paragraph 138 and, therefore, deny those allegations.

139. Defendants admit the allegations contained in Paragraph 139.

140. Defendants admit that the article entitled *Effects of corticosteroid treatment on airway inflammation, mechanics, and hyperpolarized <sup>3</sup>He magnetic resonance imaging in an allergic mouse model* cites financial support from Merck Research, and NIH grants AI081672 and NCI 1R01-CA-142842. Defendants deny the remaining allegations contained in Paragraph 140.